



American College of Cardiology

Scientific Session News



56th Annual Scientific Session



INNOVATION IN INTERVENTION
American College of Cardiology in co-sponsorship with SCAI

Sunday

March 25, 2007
New Orleans

Inside

- Meeting reminders 2
- Dack Lecture 3
- Drug-Eluting Stent Safety 4
- Live Case Transmission 5
- Campaign for the Future 7
- Closing session redesigned 8
- ACC to launch new journals 12

Don't Forget

Lessons Learned From Katrina and Medical Aspects of Disaster Planning, Monday, 11 a.m. to 12:30 p.m., Hall A

38th Annual Louis F. Bishop Lecture, Monday, 11 a.m. to 12 p.m., Room 265

Exposition hours are: Sunday and Monday, 9 a.m. to 5 p.m.; Tuesday, 9 a.m. to 1:30 p.m.

Expo Lunch and Learn program, 12 to 1:30 p.m. Sunday, Monday, Tuesday

Today...

i2 Summit Emerging Technology I

8 to 10 a.m., Room 245

ACC.07 Late-Breaking Clinical Trials

8:30 to 10:30 a.m. Hall A

Annual Business Meeting

11 to 11:15 a.m. Rooms 228-230

i2 Summit Late-Breaking Clinical Trials

11 a.m. to 12 p.m., La Nouvelle Orleans C

ACC.07 Smaller Late-Breaking Clinical Trials

1:30 to 3 p.m., Hall A

All Chapter Reception

5:30 to 7:30 p.m. Marriott Convention Center, Arcadia

ACC makes commitment to New Orleans

Opening Session includes remarks from Mayor, ACC President

With vibrant Dixieland sounds from the Storyville Stompers Jazz Band providing the backdrop, the ACC kicked off ACC.07 and i2 Summit with a Grand Opening Celebration Saturday afternoon.

A grateful city

Given that this meeting is the largest to convene in New Orleans since Hurricane Katrina, New Orleans Mayor Ray Nagin made a special visit to the Opening Session to present a proclamation honoring ACC for returning to the city.

The meeting is particularly special to ACC President Steven E. Nissen, M.D., F.A.C.C.

"This year we return to one of our most cherished destinations. In the wake of Hurricane Katrina, many thought New Orleans wouldn't ever recover," Dr. Nissen said. "Today, as this extraordinary city plays host to many thousands of us, I believe we can safely say that New Orleans is back and as welcoming as ever."

He encouraged participants to visit Booth #2461 to donate to the Association of Black Cardiologists' Health Outreach Prevention and



ACC President Steven E. Nissen, M.D. welcomes ACC members to New Orleans Saturday.

Empowerment Project (HOPE) and the Greater New Orleans Medical Foundation of the New Orleans Parish Medical Society.

The organizations will split funds collected during ACC.07 and i2 Summit to help rebuild the medical infrastructure of New Orleans. For those who want to physically help, visit Hands-on New Orleans, Booth #2459, to learn about opportunities for volunteers.

A combined effort

The afternoon included a moving presentation

of the colors from the Marine Force Reserve Color Guard of New Orleans; a musical interlude with the Greater Antioch Choir; a video presentation from CNN's Larry King; and the musical stylings of the St. Augustine Marching Band, the Purple Knights.

Dr. Nissen recognized a distinguished group of dignitaries and supporters, including the Simon Dack Lecturer (*see related story on page 3*); President-elect James Dove, M.D., F.A.C.C.; the Board of Trustees; the co-chairs

SEE GRAND OPENING, PAGE 10

Field's forefather set stage for bright future

After a young German physician, Andreas Gruentzig, M.D., brought the world coronary angioplasty 30 years ago, he tirelessly promoted the technique.

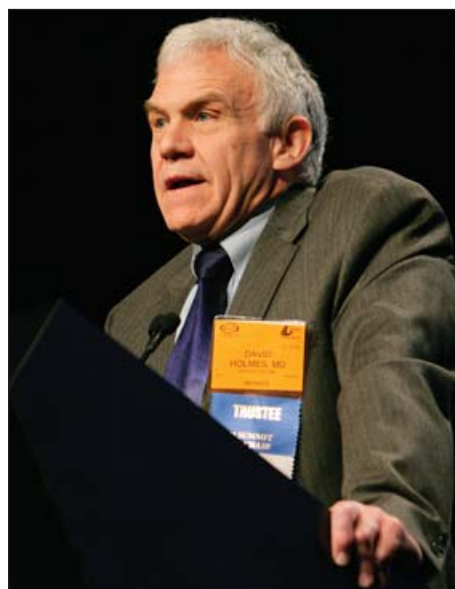
Given the success rate of his initial study, it is conceivable that similar results today would not garner the support that Dr. Gruentzig received, said David Holmes Jr., M.D., F.A.C.C., F.S.C.A.I., i2 Summit co-chair.

Of the 76 patients with known double- or triple-vessel disease, the success rate was 72 percent. Of the 21 unsuccessful cases, eight required urgent surgery.

It would be hard to go to your Institutional Review Board today with results like that for a new procedure, noted Dr. Holmes, who spoke at the Opening Session of the i2 Summit Saturday, giving attendees a 30-year look back on the field's progress, his insights on where it's headed and how i2 fits into this journey.

Eight years after introducing coronary angioplasty, Dr. Gruentzig died in a plane crash, but he left a legacy that forever set the stage for the field of interventional cardiology.

The crudely fashioned instruments that Dr. Gruentzig and his earlier predecessors brought



David Holmes, M.D.: 'What about i2? It's a place for you to start your journey — this year, next year and forever and a day.'

to cardiology were what Dr. Holmes referred to as disruptive technologies that changed the

SEE I2 SUMMIT, PAGE 11

LBCTs include bioabsorbable stent trial

Late-breaking clinical trials presented yesterday at an i2 Summit special session and a news conference following the session included the 6-month results of the ABSORB trial, the first clinical trial assessing the safety and overall performance of a fully bioabsorbable drug-eluting stent.

In the ABSORB trial, researchers from the Thoraxcentre at the Erasmus University Hospital, Rotterdam, the Netherlands, evaluated the Bioabsorbable Everolimus-Eluting Coronary Stent System, which has a bioabsorbable stent made of polylactic acid (a polymer derived from lactic acid) coated with everolimus, an immunosuppressant used to prevent rejection, said Patrick W. Serruys, M.D., F.A.C.C., who presented the study.

Dr. Serruys and his colleagues treated

SEE LBCT, PAGE 10

Meeting reminders for ACC.07 and i2 Summit

Registration

ACC.07 registration is in Hall F of the Ernest N. Morial Convention Center and is open during the following hours:

Sunday7 a.m. - 7 p.m.
Monday7 a.m. - 5:30 p.m.
Tuesday7 a.m. - 3 p.m.

The i2 Summit registration is in Hall F of the convention center and is open during the following hours:

Sunday7 a.m. - 7 p.m.
Monday7 a.m. - 5:30 p.m.
Tuesday7 a.m. - 3 p.m.

ACC Office

The ACC Office is in Room 204 of the convention center, (504) 670-6704; fax: (504) 670-6705. ACC staff are available during the following hours:

Sunday.....7:30 a.m. - 6 p.m.
Monday7 a.m. - 6 p.m.
Tuesday7 a.m. - 5 p.m.

ACC Central

ACC Central, Booth #2267, is the place to visit for news on educational programs, products, advocacy developments and new College ventures designed to improve clinical

practice and management. Attendees may also update their memberships and pick up copies of the latest College publications.

ACC Exposition

The ACC Exposition, which is held in Halls B-G of the convention center, features nearly 400 exhibitors displaying a variety of equipment, pharmaceuticals, devices and services. The expansive Exposition, a must-see for all cardiovascular professionals, is open to ACC.07 and Innovation in Intervention: i2 Summit 2007 attendees. Visit the Expo floor during the mid-day break, from 12 to 1:30 p.m. Sunday, Monday and Tuesday, and for

the Expo Lunch and Learn program, where exhibitors will be offering complimentary lunches.

Sunday9 a.m. - 5 p.m.
Monday.....9 a.m. - 5 p.m.
Tuesday9 a.m. - 1:30 p.m.

Shuttle Service

Complimentary shuttle service will operate daily from the convention center and the official hotels. Check the shuttle signs posted in the lobby of each hotel for additional information, changes, frequency of service and specific departure times for the designated route. General hours of operation are:

Sunday.....6:30 a.m. - 8 p.m.
Monday6 a.m. - 6:30 p.m.
Tuesday6 a.m. - 4:30 p.m.

The scheduled end times are when the last shuttles will depart from the convention center. The last shuttles will depart from hotels approximately 90 minutes before this time.

Information Stations

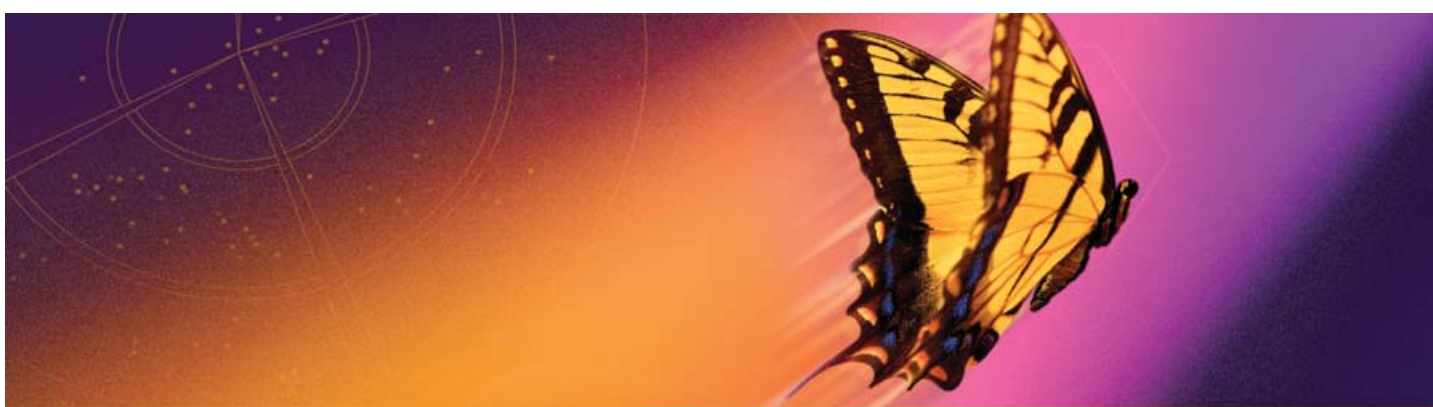
Attendees will find Information Stations located in lobbies of the convention center. At the Information Stations, attendees may access the Internet, browse the education sessions, plan, save and print on-site itineraries, access ACCustom, exhibitors and products, and view the Exposition floor plan.

Information Station 1.....Lobby B1
Information Station 2Lobby D
Information Station 3.....Lobby E
Information Station 4Lobby H
Information Station 5Level 2, outside Room 238

Restaurant Reservations

The Annual Scientific Session Restaurant Reservation Service is located in Lobby F of the convention center during the following hours:

Sunday9 a.m. - 6 p.m.
Monday.....9 a.m. - 6 p.m.
Tuesday.....9 a.m. - 3 p.m.



ENVISION THE FUTURE ...

Please join us for...

The Awards Ceremony to Announce the 2007 International Competitive Grants Awards for Young Investigators

Hosted by Dr Valentin Fuster, Committee Chairman

A wine reception featuring the "Flavors and Sounds of New Orleans"
Sunday, March 25, 2007
5:30 PM-7:30 PM

Louisiana Ballroom I/Parish Hall
Loews New Orleans Hotel
300 Poydras Street
New Orleans, LA

This event is not part of the official ACC Annual Scientific Session and/or i2 Summit 2007 as planned by the Annual Scientific Session Program Committee (ASSPC) and/or the i2 Summit Program Committee.



GlaxoSmithKline
RESEARCH &
EDUCATION
FOUNDATION
for
DISEASE

Living Science.
It's more than our job...it's our mission.

Butterfly photography by William T. Hart, MD
© 2007 The GlaxoSmithKline Group of Companies
All rights reserved. Printed in USA - March 2007



Scientific Session News

Registration Issue Vol. 25, No. 5

The Scientific Session News is the official publication of ACC's 56th Annual Scientific Sessions. The Scientific Session News is published by the American College of Cardiology Foundation.

American College of Cardiology Foundation
Division of Communications
2400 N St. NW
Washington, D.C. 20037

Editor: Anne Dees
Production: Ascend Media Inc.

©2007 American College of Cardiology Foundation

Dack Lecture focuses on need to link data, education

Randomized controlled clinical trials are designed to discover treatment strategies that will enhance patient care, but this goal is achieved only when trials are in balance with both physician and patient education.

This balance was the focus of Saturday's Simon Dack Lecture, "Seeking Balance: Research and Education," delivered by Marc A. Pfeffer, M.D., Ph.D., F.A.C.C., at the Grand Opening session.

"The randomized controlled trial is the pump that energizes the cycle of clinical therapeutics," said Dr. Pfeffer. "We continually need new discoveries to advance medical care. However, new evidence without implementation would be a hollow victory."

To illustrate the importance of randomized trials, Dr. Pfeffer led attendees through a brief history of clinical trial research in cardiovascular medicine, beginning with the framework established by the Framingham study. That study, a "truly classic citation of factors of risk," said Dr. Pfeffer, provided the first information for researchers seeking targets to develop risk reduction therapies.

The first two major randomized placebo-controlled clinical trials designed to examine risk factors were the Veterans Administration Cooperative Study Group on Antihypertensive Agents I and II, led by Edward Freis, M.D. These trials demonstrated significant reduction in morbidity and mortality for men with diastolic blood pressure of more than 115 mmHg and of 90-114 mmHg, respectively.

"These two groundbreaking trials conclu-



Marc A. Pfeffer, M.D.: 'The randomized controlled trial is the pump that energizes the cycle of clinical therapeutics.'

sively proved that elevated blood pressure was a modifiable risk factor and that rates of stroke, myocardial infarction, heart failure, and cardiovascular death could be effectively reduced by pharmacologically lowering arterial pressure," Dr. Pfeffer said.

He explained that the findings of these two pivotal trials were released at a time when the prevailing thought was that elevated blood pressure was 'essential' to perfuse vital organs. Thus, the results were not immediately embraced by the medical community. It was not until Mary Lasker helped to establish the National Blood Pressure Education Program in 1972 that the importance of treatment for

hypertension was emphasized. Millions of individuals with hypertension would not have received adequate care had the research findings not been coupled with education.

Dr. Pfeffer also discussed clinical trial research on pathophysiologic processes to test novel hypotheses. He noted the valuable benefit derived from the results of studies in Eugene Braunwald's laboratory, which demonstrated that myocardial infarct size could be reduced with immediate treatment. This finding was translated into survival benefits in several trials, including the International Study of Infarct Survival Collaborative Group, which showed advantage of aspirin and streptokinase. These early trials have formed the basis for more recent trials in which angioplasty and pre-hospital fibrinolysis plus adjunctive therapies have led to further reductions in morbidity and mortality from acute myocardial infarction.

"These developments, accompanied by government and privately sponsored educational programs, have greatly improved response times of the general public and emergency medical and hospital triage personnel to promptly diagnose myocardial infarction and initiate life-saving therapy, with the concept that time equals myocytes," Dr. Pfeffer said.

Randomized trials provide not only a list of "to dos" but also a list of "not to dos," or "undos," he said. The balance of research and education is shifted when practice precedes randomized trials, and patient care can suffer as a result. As an example, he pointed to the past use of antiarrhythmic agents to suppress premature ventricular contraction (PVCs),

agents that were subsequently found — in a randomized clinical trial — to heighten the risk of death.

Cardiovascular medicine includes multiple other "humility-building examples," such as inotropic agents for heart failure, calcium-channel blockers in high-risk myocardial infarction, and, more recently, hormone replacement therapy.

"Under the rigors of randomized controlled trials, these solidly entrenched therapies were found not effective and actually harmful. These 'undos' also require an educational effort to change practice patterns and get us out of our false comfort zones," Dr. Pfeffer said.

The most recent example of an "undo" is the U.S. Food and Drug Administration's warning of the potential for increased risk of cardiovascular complications if the dosing recommendations for erythropoietic agents are exceeded.

"We must use this as a case study to learn how the market so expanded despite a paucity of rigorous outcomes data," Dr. Pfeffer said.

In closing, Dr. Pfeffer noted, "Just as randomized controlled trials in cardiovascular medicine have improved and matured, so too must the process of guideline development. By extending the guideline development process to include more societies, regulators, payers and practitioners, the risks that the use of a therapy or device will outstrip the objective data will be minimized. Linking payers in this process may raise the incentives to get critical risk benefit data earlier. We need to strive for balance or the word education will be replaced by marketing." ■

State-of-the-art lectures look at three issues

In an i2 Summit special session Saturday morning, three experts, including ACC President Steven E. Nissen, M.D., F.A.C.C., explored the state-of-the-art in statin therapy for coronary atherosclerosis, carotid stenting and percutaneous aortic valve replacement.

Dr. Nissen described the groundbreaking work he and his colleagues are doing at the Cleveland Clinic's Heart and Vascular Institute on plaque regression to reduce coronary atherosclerosis.

"We've learned that with the appearance of the first stenosis, 100 percent of the coronary tree is atherosclerotic," said Dr. Nissen, chairman of the department of cardiovascular medicine at the Cleveland Clinic. His research has focused on ways to reduce plaque in the vessel wall of the coronary arteries.

"Cardiovascular disease hides from us. As plaque forms, the size of the lumen is maintained without change," he said. "For every one lesion we see, there are 50 to 100 we don't see."

Dr. Nissen and his colleagues have found that aggressive statin therapy can cause regression of plaque and reduce patients' burden of atherosclerotic disease. In his research, he used 40 mg rosuvastatin to reduce low-density lipoprotein (LDL) cholesterol below 70 mg/dL. He achieved an average LDL of 60.8 mg/dL. Two-thirds of the patients he treated had plaque regression at 24 months.

Furthermore, he found that aggressive therapy not only reduces LDL cholesterol but also increases high-density lipoprotein (HDL) cholesterol and that the combination of effects helps reduce the burden of atherosclerotic disease.

Carotid stenting

Gary S. Roubin, M.D., Ph.D., F.A.C.C., chairman of the department of interventional cardiology at Lenox Hill Hospital in New York, described the latest developments in carotid stenting, saying the good news is that stents and embolic protection devices continue to improve and receive FDA approval.

"There is no doubt that over the last few years, the technology has improved significantly, and this improvement has manifest itself in better outcomes," Dr. Roubin said.

In addition, the post-marketing approval registries have expanded clinical experience and are providing accumulating knowledge about the best techniques and optimal patient selection. "And there is some credible rigorous clinical trial data, but still not much," he added.

The bad news in carotid stenting is that some poorly designed and executed clinical trials continue to be published, it is difficult to transfer evidence-based practice standards to clinical practice and the reimbursement policies of the Centers for Medicare and Medicaid Services remain restrictive, he said.

Dr. Roubin is a principal investigator for the NIH-funded Carotid Revascularization versus Stenting Trial (CREST), comparing the outcomes of carotid artery stenting and carotid endarterectomy surgery.

Based on the results of this trial, he said that the outcomes from carotid artery stenting depend on two things: operator experience and patient selection. Operators need to be experienced in performing the procedures and have a history with a large number of cases as well as

experience working as part of a team. As to patient selection, older patients, those over age 70, tend to have greater complications from the procedure, he said.

Aortic valve therapy

Finally, John G. Webb, M.D., F.A.C.C., director of the cardiac catheterization laboratory at St. Paul's Hospital, University of British Columbia, Vancouver, described the state-of-the-art in percutaneous valve replacement using artificial valves, including the Cribier-Edwards valve, the Edwards Sapien valve and CoreValue self-expanding valve.

Dr. Webb described his experience with the Cribier-Edwards valve using a transarterial retrograde approach in more than 100 elderly patients (most over age 80) who were not eligible for traditional valve-replacement surgery due to mortality risk.

The procedure improved the patients' left-ventricular function, he said, and patients with the poorest LV function initially had the greatest improvement. Mortality rate was reduced to 12 percent versus the predicted risk of death at 30 days. Symptoms of left-ventricular dysfunction were also reduced.

Dr. Webb described a learning curve in performing the procedure, saying that success rates improved with more experience in conducting the procedures.

Percutaneous aortic valve replacement with left-main stenting is still only performed in patients who are at high risk of death from surgery, but in the future, it may be extended to lower risk patients, Dr. Webb concluded. ■

Blood Drive during ACC.07 to help Gulf Coast area

9 a.m. to 5 p.m. Monday at Booth #5621

Allscripts, the American College of Cardiology Foundation and the Louisiana Chapter of ACC are sponsoring a blood drive Monday during ACC.07 in Hall G of the convention center. With every donation, you will save up to three lives. Please join this effort to make a difference while attending ACC.

The blood drive will support the New Orleans community as donated blood will be used for victims of car accidents, burn victims, patients with anemia, bone marrow and stem cell transplants, organ transplants, cancer patients and more. The Blood Center, the primary supplier of blood, blood components and plasma derivatives to local hospitals throughout Southern Louisiana and parts of the Mississippi Gulf Coast, will assist with the blood drive.

Donors must be healthy, 17 years or older and weigh at least 110 pounds to be eligible to donate blood. Donors need to bring a photo I.D.

Please join us in this major effort to give back to the New Orleans and Gulf Coast community. To donate, go to Booth #5621 Monday. If you wish to schedule a specific time, send an e-mail to acc@thebloodcenter.org. ■

Late-Breaking Clinical Trials

ACC.07 Late-Breaking Clinical Trials I, Session 402

Sunday, 8:30 to 10 a.m. in Hall A of the convention center



56th Annual Scientific Session

Co-Chairs: Marc Edward Shelton, M.D., F.A.C.C., and Randall C. Starling, M.D., F.A.C.C.,

- Prognostic Value of T-Wave Alternans in Patients With Heart Failure Due to Nonischemic Cardiomyopathy: Results of the T-Wave Alternans in Patients With Heart Failure (ALPHA) Study
- Effects of Vasopressin Receptor Antagonism With Tolvaptan on Clinical Status, Morbidity and Mortality in Patients

Hospitalized With Acute Decompensated Heart Failure: Results of the EVEREST Trial

- Results of the Follow-up Serial Infusions of Nesiritide for the Management of Patients With Heart Failure (FUSION II) Trial
- The Influence of Angiotensin Receptor Blockers and Blood Pressure Lowering on Diastolic Function in Patients With Hypertension and Diastolic Dysfunction: The VALsartan in Diastolic Dysfunction (VALIDD) Trial

ACC.07 Smaller Late-Breaking Clinical Trials I, Session 404

Sunday, 1:30 to 3 p.m. in Hall A of the convention center

Chair: C. Noel



56th Annual Scientific Session

Bairey Merz, M.D., F.A.C.C.

- Efficacy and Safety of a Potent New PPAR-Alpha Agonist as Monotherapy or in Combination With Statins in Subjects With Dyslipidemia
- Effects of Ramipril and Rosiglitazone on Atherosclerosis: The Study of Atherosclerosis With Ramipril and

Rosiglitazone

- American Heart Association or Mediterranean Diet Improves Cardiovascular Outcomes After Myocardial Infarction
- Effect of Rosuvastatin on Progression of Carotid Intima Media Thickness in Low-risk Individuals: Results of the METEOR Trial
- How Early Should Eplerenone Be Initiated in Acute Myocardial Infarction Complicated by Heart Failure?

Late-Breaking Clinical Trials II, Session 2405



Sunday, 11 a.m. to 12 p.m. in La Nouvelle Orleans C, of the convention center

Co-Chairs: Verghese Mathew, M.D., F.A.C.C., and Carlos E. Ruiz, M.D., F.A.C.C.

- A Double-blind, Randomized, Placebo Controlled Clinical Trial of Allogeneic Mesenchymal Stem Cells for the Treatment of Patients With Acute Myocardial Infarction
- First U.S. Randomized Controlled Trial Utilizing 3-Dimensional Guided, Catheter-based Delivery of Autologous Skeletal Myoblasts for Ischemic Cardiomyopathy:

Feasibility, Safety and Improvement in Cardiac Performance

- Targeted Inhibition of δ -Protein Kinase C to Ameliorate Reperfusion Injury During Primary Percutaneous Coronary Intervention for Acute ST-Elevation Myocardial Infarction: Results from the DELTA MI Trial
- Randomized Comparison of the Effect of Distal Protection and Drug-eluting Stent Versus Bare Metal Stent Implantation During Percutaneous Coronary Intervention for ST-Elevation Myocardial Infarction (DEDICATION)

Late-Breaking Emerging Technologies and Innovations, Session 2406



Sunday, 1:30 to 3:30 p.m. in La Nouvelle Orleans C of the convention center

Co-Chairs, Augusto Pichard, M.D., F.A.C.C., and Samin K. Sharma, M.D., F.A.C.C.

- Chronic Treatment of Resistant Hypertension With Implantable Device: Preliminary Results of European and United States Trials of RheosTM Baroreflex Activation
- Improved Outcomes in Patients Undergoing Coronary Stenting With Use of a Gradual Computerized Angioplasty Protocol: A Prospective, Randomized Trial
- An Emerging Technology for Managing Peripheral Arterial Disease: An X-Ray

Visible Mesenchymal Stem Cell Delivery and Tracking System

- A Percutaneous Approach to Treat Moderate to Severe Mitral Valve Regurgitation Using the Edwards MONARC System: Interim Results of the Feasibility Experience
- A Novel Device for the Enhancement of Percutaneous Coronary Intervention in Bifurcation Lesions: First-In-Man Experience
- Left Ventricular Assist Device (Impella LP 2.5) Versus Intraaortic Balloon Counterpulsation For Patients With Cardiogenic Shock by Myocardial Infarction: A Prospective, Randomized Trial (ISAR-SHOCK)



Expo floor Opening

Thousands gathered on the ACC.07 Expo floor for Saturday's opening reception. This year's Expo features 240,000 square feet of cardiovascular equipment, pharmaceuticals, devices and services being shown by nearly 400 exhibiting companies.

Safety of drug-eluting stents up for debate

The controversy surrounding the safety of drug-eluting stents (DES) remains, and the consensus is that more data are needed before definitive conclusions can be made about the devices. The ACC.07/i2 Summit 2007 Joint Symposium: "Drug-Eluting Stent Safety—Hype or Reality?" focused on reports published since the findings of two studies indicated that the rates of death and nonfatal myocardial infarction were higher for DES than for bare metal stents (BMS). The data suggest that the use of DES for off-label indications and the premature discontinuation of dual antiplatelet therapy are the primary risk factors for late stent thrombosis leading to adverse events. Careful patient selection is also key.

The first of the two studies that raised the controversy was the Basel Stent Cost-effectiveness Trial—Late Thrombotic Events (BASKET-LATE) trial, the findings of which were presented at last year's ACC meeting. A meta-analysis presented at the 2006 European Society of Cardiology Annual Meeting/World Congress of Cardiology meeting echoed these findings. The results of both studies prompted the U.S. Food and Drug Administration (FDA) to convene an expert panel to review the data and make recommendations. Since then, several reports have provided inconsistent results about whether there is a significant difference in mortality between the two types of stents and whether the benefits of DES outweigh the risks.

John McB. Hodgson, M.D., F.A.C.C., a member of the FDA Review Panel, said that the panel evaluated data on comparisons of adverse events associated with DES and BMS, as well as comparisons of the different types of DES (those eluting sirolimus and those eluting paclitaxel). The panel also reviewed the data on the duration of antiplatelet therapy. "By far and away, the greatest risk factor [for adverse events] is the premature discontinuation of dual antiplatelet therapy," said Dr. Hodgson. Stopping treatment with aspirin and clopidogrel before 12 months is considered premature discontinuation. Dr. Hodgson was also the lead author of a Clinical Alert issued by the Society for Cardiovascular Angiography and Interventions (SCAI), which focused on the importance of careful patient selection and meticulous technique in implanting the stent in

addition to strict compliance with antiplatelet therapy.

The FDA panel also found that there was no evidence of an increased rate of all-cause mortality associated with DES when used for on-label indications. However, there is a risk of adverse events when they are used for off-label indications. Approximately 60 percent to 85 percent of DES are used for off-label indications, noted Martin B. Leon, M.D., F.A.C.C., who addressed the differences in outcomes associated with the two types of stents. Dr. Leon noted that efficacy was initially the most important point about DES, and the fact that they reduced the rate of restenosis was clear. "We were overly seduced by the initial angiograms," he said, as well as "thousands" of peer review manuscripts that were published in the four years after the introduction of DES. Safety is now the priority, and Dr. Leon discussed several studies that have shown inconsistent results.

When the two types of stents are compared, atherosclerotic changes occur much earlier with DES than with BMS. In reviewing the histologic findings associated with stents, Renu Vermani, M.D., F.A.C.C., noted that endothelialization is very important in how these changes occur. She pointed out that a comparison of DES with and without thrombosis showed that the rate of endothelialization was significantly lower for DES with thrombosis (40 percent vs. 85 percent); the difference in the number of uncovered struts was also significant (five per section for DES with thrombosis and two per section for DES without thrombosis). Dr. Vermani said that most of the thrombi and the uncovered struts occurred in the middle of the stent.

Craig Smith, M.D., addressed the question of whether more patients should have coronary artery bypass grafting (CABG). Dr. Smith said that there are no data on comparisons of CABG and DES, as these studies are still ongoing. Other studies have shown that there is a favorable trend for CABG compared with medical treatment, percutaneous coronary intervention, and BMS. The results, he said, show that "the more critical the anatomy, the more CABG excels." He explained that patients who gain the most benefit from

SEE STENTS, PAGE 9

Live case studies show real problems in real time

Textbook descriptions of medical procedures are neat, clean and free of unexpected complications.

Not so the live case study, valuable particularly because it shows how the physician performing the procedure handles a sudden problem.

“We see how physicians do a case on the run, how they actually change strategy when they encounter problems,” said Alan Yeung, M.D., F.A.C.C., moderator of a Live Case Transmission Session Saturday featuring stent placements. “It shows how the physician thinks through a procedure rather than showing a set way to a successful case.”

Dr. Yeung’s session featured four live cases, two transmitted from the Erasmus Medical Center in Rotterdam, the Netherlands, involving coronary artery stents; and two from the Ochsner Clinic in New Orleans on peripheral artery stenting.

Dr. Yeung, director of interventional cardiology and division chief at Stanford University Medical Center, noted that in one of the live demonstrations a stent would not go down, and the interventional cardiologists had to decide immediately which technique to use to engage the guiding catheter to force the stent down.

That ad hoc aspect would probably not be mentioned in a publication describing the procedure, Dr. Yeung said.

The two coronary cases from Rotterdam demonstrated new technologies not available yet in the U.S.

In the first, Dr. Georgios Sianos and colleagues placed an investigational dedicated side-branch stent in a 70-year old man for a bifurcation.

Meanwhile, in the next room at the Erasmus Center, Dr. Eric Duckers demonstrated a procedure involving a stent that attracts endothelial progenitor cells (EPC) in a 67-year old man, part of the non-randomized European Healing IIb feasibility study.

Dr. Yeung said the bifurcation case was important because there is no standard yet for technique or technology.

The EPC stent is coated with an antibody that attracts and is adhesive to the surface of circulating endothelial progenitor cells, trapping them against the stent.

Data on the EPC stent will be valuable because the issue of stent thrombosis is still very large, Dr. Yeung said, and researchers are searching for better healing techniques to make stents safer.

Patients in these two cases were selected for this session for their particular anatomy, Dr. Yeung said, but also because Dutch interventionalists do a great deal of pre-procedural imaging and the lesions in these patients had been thoroughly mapped with CT.

A participant in a panel of experts viewing these cases here, George Dangas, M.D., F.A.C.C., associate professor of medicine, Columbia University Medical Center, New York, noted that the CT imaging performed by the Dutch would be considered redundant in the United States

Dr. Yeung agreed that CT imaging is generally not necessary clinically for the procedure, but pointed out that the Rotterdam team is collecting data on the value of CT as well as on the stent.

The first of the two peripheral artery cases transmitted from Ochsner included a very challenging case in which interventionalist Steven Ramee, M.D., F.A.C.C., placed a balloon stent for common iliac stenosis in a 55-year old man.

In the second peripheral artery case, interventionalist Christopher White, M.D., F.A.C.C., placed a stent in a 62-year old man as part of the CORAL Trial of renal artery stenting versus followup without stenting.

A complication in this procedure illustrated the beauty of live case presentations. Despite

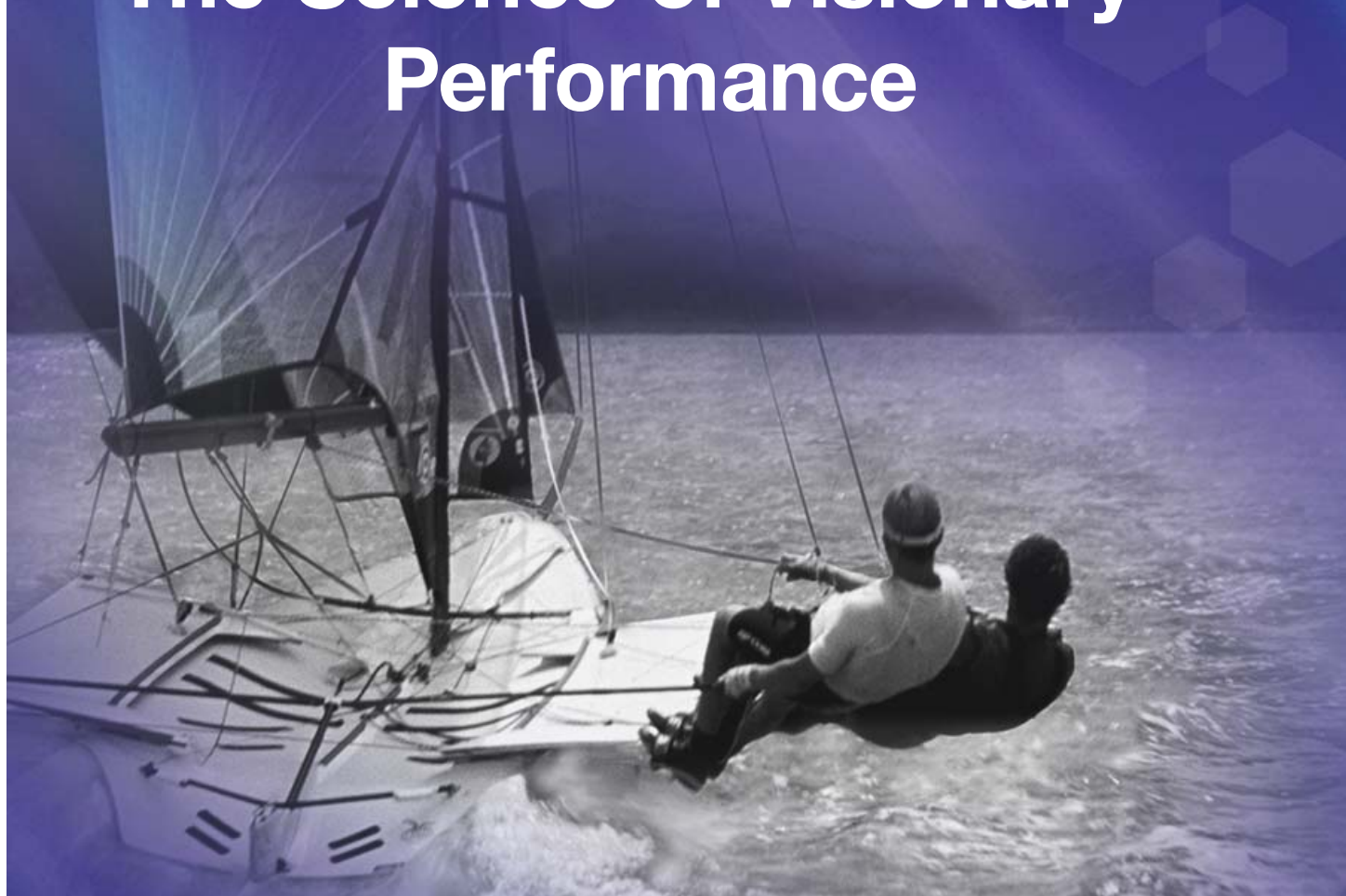
SEE LIVE CASE, PAGE 9



Medical and communication technology was on display at the Live Case Transmission session.



The Science of Visionary Performance



Discover it at booth #3457 • Hall E

For more information, visit us on the web at abbottvascular.com

©2007 Abbott Laboratories
AP2925447A

Abbott
Vascular

NCDR™ has expanded its focus over last decade

When the ACC established the National Cardiovascular Data Registry (NCDR™) 10 years ago, it had the narrow focus of measuring risk. Today, NCDR has grown to include a suite of registries, and the CathPCI Registry™ is the gold standard for measuring quality in the catheterization lab.

Initially, NCDR's focus was on standardizing how catheterization laboratories reported procedure outcomes so their findings could be used in the continuous quality improvement (CQI) initiatives of hospitals. The primary stakeholders were the cardiologists who performed the catheterizations and the institutions

in which they performed them.

The CathPCI Registry has grown to contain data on more than 4.8 million documented diagnostic catheterization and percutaneous coronary intervention (PCI) procedures. It helps cardiologists and other cardiovascular professionals better understand the risks, benefits and effectiveness of technologies employed in the cardiac catheterization laboratory.

Other NCDR registries have followed CathPCI, including:

- The ICD Registry™, introduced in 2005, which meets a Centers for Medicare and Medicaid Services mandate to track

implantable cardioverter defibrillator activities in more than 1,400 electrophysiology laboratories nationwide.

- The CARE Registry™, launched in 2006, which is designed to help health care providers measure and improve the quality of care they provide to patients who receive carotid artery stents or undergo endarterectomy procedures.
- The NCDR Acute Coronary Treatment and Intervention Outcomes Network (ACTION™) Registry, launched in January, which captures patient data for acute coronary syndrome (ACS). It is the largest, most comprehensive national car-

diovascular database ever developed.

Measuring outcomes of patients with STEMI and/or NSTEMI, ACTION combines the data collection and quality reporting features of two leading national ACS Registries — the National Registry for Myocardial Infarction and CRUSADE. This collaboration merges a history of credible, well-established registry experience to provide new capabilities for broader reporting, benchmarking and quality improvement in a standardized environment. It establishes a national standard for understanding treatment patterns, clinical outcomes, drug safety and the overall quality of care provided for ACS patients. It also provides a streamlined method of collecting, monitoring and reporting clinically relevant cardiovascular data within a framework that ensures both hospital and patient confidentiality.

Enrollment in the ACTION Registry gives participating facilities access to comprehensive information for measuring the quality of care for ACS patients. It also helps to identify gaps in quality of care and to implement effective, CVI processes.

As the NCDR suite of registries has grown, so, too, has the scope of its data in response to the requests of large payers and provider groups, federal agencies and state regulators. NCDR data is now used to measure performance and utilization rates, address certificate-of-need questions, promote CQI, and conduct post-market drug and device surveillance.

As it enters its 10th year, NCDR has emerged as the solution of choice for stakeholders seeking evidence-based benchmarking tools that measure and prove that they provide quality care. As a national, guidelines-based tool "designed by doctors, for doctors," NCDR is poised to take advantage of the health care industry's quest for quality.

Take the NCDR Golf Challenge on Sunday

Join your peers at ACC Central, Booth 2267, to find out more about the NCDR and sign up for the NCDR Golf Challenge to see how you measure up. You'll discover how much you really know about PGA rules and regulations and receive a personalized scorecard and a complimentary, heart-healthy, dark chocolate golf ball. ■

Cardiology Career Center to be open through Tuesday

Planning your career? Don't forget to stop by the ACC Cardiology Career Placement Center at ACC.07/i2 Summit 2007 in Room 224 of the convention center.

The Placement Center will be open throughout the meeting for fellows to search for jobs and meet with employers about potential job openings.

The Placement Center is also hosting an Open House from 9 to 10 a.m. Sunday. Stop in for breakfast and learn how to find the job you want. Hours for the center are:
Sunday8:30 a.m. - 5 p.m.
Monday.....8:30 a.m. - 5 p.m.
Tuesday8:30 a.m. - 1:30 p.m.

HOPE SPRINGS OTSUKA

Cardiovascular disease is a daunting health challenge – for both physicians and patients. Otsuka is hard at work investigating potential new treatments in cardiology. We've funded new research, supported new clinical trials, and pursued the development of new medications...an unfaltering commitment of energy and resources and a clear cause for hope.

1.800.562.3974 • www.otsuka.com

OTSUKA – PEOPLE CREATING NEW PRODUCTS FOR BETTER HEALTH WORLDWIDE

Otsuka America Pharmaceutical, Inc.
Otsuka Pharmaceutical Development & Commercialization, Inc.
Otsuka Maryland Medicinal Laboratories, Inc.

AMERICA PHARMACEUTICALS

© Otsuka 2307/01-07

ACC Foundation to launch Campaign for the Future

A public campaign to address the problems of a lack of funding of cardiovascular training and an inadequate number of cardiologists to treat the growing number of cardiac patients will be launched today.

The ACC Foundation's (ACCF) Campaign for the Future will seek to raise funds for the training of more cardiologists. Working with the ACC will be the Larry King Cardiac Foundation, with King, a renowned talk-show host and victim of heart disease, serving as honorary campaign chair.

If the current trend of cardiology training is not improved, by 2020 there will be only five

cardiologists for every 100,000 patients, according to ACC research.

"The goal of the Campaign for the Future is to raise funds that will be applied to ensuring an adequate workforce of cardiac care professionals, meeting the growing need for professional education, and developing nationwide initiatives related to quality care and healthy lifestyle choices," said the chair of the Campaign, Douglas Zipes, M.D., M.A.C.C. "By addressing issues through the Campaign, we can effectively alleviate growing problems in cardiac care. We're very happy to have the assistance of the Larry King Cardiac Foundation to work with the ACCF."

"The Campaign for the Future has exactly the kind of foresight needed to ensure that there will be quality resources available for everyone," King said. "As one of the more than 60 million people in the U.S. who suffers from heart disease, I am lucky that I have the resources readily available to me. The ACCF's Campaign can make sure that quality care will continue to be available."

The Campaign has exceeded its first milestone of \$10 million, having raised \$11.8 million from the ACC and industry leaders. All members of the ACC Board of Trustees have committed to support the Campaign with personal gifts, including donations from Dr.

Zipes, ACC President Steven E. Nissen, M.D., F.A.C.C., ACC President-Elect James Dove, M.D., F.A.C.C., and Mike Mirro, M.D., F.A.C.C., and Mike Wolk, M.D., M.A.C.C.

Industry support has also been strong, led by donations of \$5 million by Pfizer Inc., \$2.5 million by AstraZeneca LP, and \$1 million each by the Medtronic Foundation and Boston Scientific Corp.

The ACCF's Campaign for the Future kick-off event is sponsored by AstraZeneca Pharmaceuticals, Daiichi-Sankyo Inc., King Pharmaceuticals, Inc., Merck & Co., and Otsuka America Pharmaceutical Inc. ■

Scientific Session News in Brief

Get ready for Convocation Monday

The College's annual Convocation will be held at 6:30 p.m. Monday in the Grand Ballroom at the New Orleans Marriott, 555 Canal Street.

For the Convocation, new Fellows will assemble at the hotel in the Mardi Gras Ballroom D & E at 5:30 p.m.

In preparation, all fellowship candidates must sign the Convocation Register in the Gown and Hood office, adjacent to Registration at the convention center by noon Monday.

The Convocation office will be open from 8:30 a.m. to 5 p.m. Sunday and from 8 to 11 a.m. Monday. Only for those candidates who sign the register by 12 p.m. Monday, certificates will be available immediately following the ceremony.

Be sure to download the e-Program Guide

The ACC.07/i2 Summit e-Program Guide (powered by Skyscape) provides a quick and easy way to browse sessions by topic and date or find exhibitor information and key show information, such as shuttle bus routes.

Attendees may download this essential electronic resource directly to handhelds or Windows Mobile SmartPhones from convenient beaming stations throughout the convention center and or to a memory card. Just look for directional signage along the main show corridor to the e-Program Guide beaming stations.

This year, attendees will be able to save a list of sessions that they plan to attend and use the list as a reference guide for claiming CME credit later. Improved search functionality and the ability to add session information and exhibitors directly to your calendar and contacts are also included.

Support for development and distribution of this application has been provided by GlaxoSmithKline.

CCA event reminders

Cardiac Care Associate Community Room, Room 232 in the convention center, will be open from 8 a.m. to 5 p.m. Sunday and Monday and from 8 a.m. to 4 p.m. Tuesday.

The CCA Reception will be from 5 to 6 p.m. today at the New Orleans Marriott, 555 Canal Street.

Don't miss the boat

**For head-to-head data, set a course for
Booth 757**

VYTORIN[®]
(ezetimibe/simvastatin) tablets

Pick up your complimentary
medical education resource.

MERCK/Schering-Plough Pharmaceuticals

vytorin.com

Copyright © Merck/Schering-Plough Pharmaceuticals, 2007.
VYTORIN is a registered trademark of MSP Singapore Company, LLC.

All rights reserved.

20701634(20)-03/07-VYT

'Experts' session to help attendees dissect information

The wealth of information presented during ACC.07 and the i2 Summit can be overwhelming, but a special session presented Tuesday will feature experts to help attendees edit that information to focus on what might be most useful for them.

The session, "ACC.07 and i2 Summit Highlights: Conversation With the Experts," offers a new format for a panel of experts to go beyond a review of meeting highlights to discuss how new information might be incorporated into practice. The session will be presented from 2 to 3:30 p.m. Tuesday in Hall A.

"In every area there is tremendous depth about what we know in 2007 and what is promised to come. There is no way to absorb even a small portion of this effectively. The

session is aimed to give us insight about what these days are all about," said E. Murat Tuzcu, M.D., F.A.C.C., ACC.07 Program Committee chair and a leader of the Experts session.

"In the past, reviewing presentations in a regimented way didn't always do justice to the audience. We thought we would create an environment with some structure, but also an environment for interaction for people from different disciplines to discuss what is new and what they are going to go home with in their particular medicine," he said.

Dr. Tuzcu will be joined on stage by the two ACC.07 co-chairs, Randall C. Starling, M.D., M.P.H., F.A.C.C., and James D. Thomas, M.D., F.A.C.C., and the i2 Summit program co-chair, William D. Knopf, M.D., F.A.C.C.,

F.S.C.A.I.

Joining them in discussing important presentations from the meetings will be the topic chairs of the physician work groups that helped organize the meetings. Each work group focused on different areas, so the chairs are more familiar with presentations from their areas, Dr. Knopf said. Also participating will be journal editors.

"Each group chair will discuss what was interesting from his or her area, and that will engender some questions and answers from the rest of the people participating," Dr. Knopf said. "This will be set up with the people in comfortable chairs sitting in a semicircle to promote more dialog rather than just rehashing the slides and repeating things that had already

been presented."

- The specific areas to be covered will be:
- Myocardial ischemia and infarction, by Robert A. Harrington, M.D., F.A.C.C.
 - Vascular disease, hypertension and prevention, by James H. Stein, M.D., F.A.C.C.
 - Cardiac function and heart failure, by Lynne E. Wagoner, M.D., F.A.C.C.
 - Cardiac arrhythmias, by Steven M. Markowitz, M.D., F.A.C.C.
 - Imaging and diagnostic testing, by Flordeliza S. Villanueva, M.D., F.A.C.C.
 - Pediatric cardiology and adult congenital heart disease, by John F. Rhodes, Jr. M.D., F.A.C.C.
 - Special topics, by JoAnne M. Foody, M.D., F.A.C.C.

"This allows a climate in which everyone will paint a picture," Dr. Tuzcu said. "There is not time to cover everything in an exhaustive manner, but we will try to give a personal view of what is most exciting, with input from all interested parties."

Dr. Knopf agreed, adding that the late-breaking clinical trials may generate good discussions.

"The idea is to have a chance to talk about the newer information that is being presented and have a pro-and-con discussion of its merits, value and clinical applicability to patient care," he said. "We will not only say, 'This is what was presented,' but discuss what we thought was good about it and what is positive or negative for patients, which should engender some discussion."

The two chairs agreed that the discussions will most likely turn out to be overviews of the topics, but the discussions could have interesting twists because of the people involved.

"Obviously, some of these topics will just have been presented a few hours before, so it will be difficult for people to synthesize that information," Dr. Knopf said. "On the other hand, because there will be a variety of individuals, there will be many different perspectives from people who are looking at a study from a different way."

"This is just another example that the ACC is trying to do innovative education to engender something that is scientific, objective and evidence-based without trying to bias people, and have a healthy discussion of the issues." ■

Uncover the Data.
LEAP to
BOOTH 757

Zetia[®]
(ezetimibe) Tablets

Receive your complimentary medical education resource at **BOOTH 757.**

MERCK / Schering-Plough Pharmaceuticals

Copyright © Merck/Schering-Plough Pharmaceuticals, 2007. All rights reserved. 20701634(1)-03/07-ZET ZETIA is a registered trademark of MSP Singapore Company, LLC. zetia.com

Help heal the heart of the Gulf Coast

Hurricane Katrina broke hearts around the world. You can help to heal the heart of the Gulf Coast — and its cardiovascular patients. Come to Booth #2461 to make a donation to:

- The Association of Black Cardiologists' HOPE Project
- The Greater New Orleans Medical Foundation of the Orleans Parish Medical Society

Your generosity will help both these groups rebuild New Orleans' patient care infrastructure.

Visit Booth #2459 to find out more about Hands-On New Orleans, a volunteer coordinating organization that helps organize rebuilding efforts in New Orleans. ■

Scientific Session News in Brief

ACC Central theater schedule

SUNDAY

11 to 11:30 a.m. and 2 to 2:30 p.m.
ACC Interactive Pocket Guides 101 — PDAs and Beyond

Ashok Mayya, Sr., director of business development, Skyscape

Find and apply patient specific recommendations from the ACC/AHA Guidelines, clinical trial summaries and more on your PDA, SmartPhone and desktop computer

12 to 12:30 p.m.

NCDR CARE Registry™ Presentation: Carotid Artery Stenting and Endarterectomy

Kenneth Rosenfield, M.D., F.A.C.C., F.S.C.A.I., and Ralph G. Brindis, M.D., F.A.C.C., chief medical officer, NCDR

1 to 1:30 p.m. and 3 to 3:30 p.m.

Epocrates® Essentials for Cardiology
Chi-Ming Chow, M.D.C.M., M.Sc., F.R.C.P.C., F.A.C.C.

MONDAY

11 to 11:30 a.m.

NCDR™ CARE Registry™ Presentation: Acute Coronary Syndromes

Christopher P. Cannon, M.D., F.A.C.C., and Ralph G. Brindis, M.D., F.A.C.C., chief medical officer, NCDR™

12 to 12:30 p.m. and 3 to 3:30 p.m.

Epocrates® Essentials for Cardiology

Chi-Ming Chow, M.D.C.M., M.Sc., F.R.C.P.C., F.A.C.C.

1 to 1:30 p.m. and 4 to 4:30 p.m.

ACC Interactive Pocket Guides 101 — PDAs and Beyond

Ashok Mayya, Sr., director of business development, Skyscape

TUESDAY

11 to 11:30 a.m.

ACC Interactive Pocket Guides 101 — PDAs and Beyond

Ashok Mayya, Sr., director of business development, Skyscape

Evaluate and obtain credit certificates

Evaluate your overall ACC Annual Scientific Session experience at individual sessions and of program faculty.

All Annual Scientific Session participants, except those in Nonmedical, Practice Administrator, Family Member, Exhibitor and Exhibits Only categories may print their certificate for Evaluations and Credit Certificates starting March 30.

Certificates can be printed anywhere you have Internet access. Go to www.acc.org and look for the link to the ACC.07 evaluation/credit system. Enter your last name and badge number to access the system. Remember to keep your badge number.

LIVE CASE

CONTINUED FROM PAGE 5

Dr. White's measurements, his balloon catheter did not pass all the way to the end of the guiding catheter. Improvising on the fly, he shortened the guiding catheter, which allowed for successful dilation of the renal artery lesion. Dr. Yeung said the value of stenting in peripheral arteries is not as proven as in the coronary arteries, and that this transmission demonstrated one of

several techniques being tested.

"There is even more work to be done in peripheral artery stenting because there are fewer randomized clinical trials to demonstrate that one device is better than another, so the choice of technique is much more operator dependent," Dr. Yeung said.

He added that patient enrollment is also difficult in peripheral-artery stenting trials because "physicians are biased toward a certain procedure and aren't willing to put their patients into a trial situation." ■

STENTS

CONTINUED FROM PAGE 4

CABG are those who have involvement of the left main coronary artery, multivessel disease, severe symptoms or positive findings on exercise treadmill testing, and reduced left ventricular ejection fraction.

All of the speakers agreed that safer DES are needed. Ronald Waksman, M.D., F.A.C.C., discussed the future direction for DES, noting that new designs should be developed for cases of small vessels, bifurcations, and other off-label indications. Dr. Waksman also explained that new coatings, biologic targets,

drugs, and techniques of elution, as well as prohealing approaches will be the primary mechanisms to improve the safety of DES while maintaining efficacy.

Gregory J. Dehmer, M.D., F.A.C.C., closed the session by summarizing the current recommendations for the use of DES. He emphasized the importance of discussing the need for dual antiplatelet therapy with the patient before the procedure is done. He also encouraged the audience to consider alternatives, such as BMS or balloon angiography and urged them to discuss the importance of complying with antiplatelet therapy with patients as well as other health care professionals. ■

Let Riverwalk enhance your experience

New Orleans' Riverwalk, on Julia Street adjacent to the convention center, is ready to welcome attendees on Sunday and Monday. Join the Riverwalk Jazz band as it strolls through the Food Court from 12 to 2 p.m., enjoy the variety of food selections and visit the unique stores.

Ranexa[®]
ranolazine extended-release tablets

Find out about Ranexa today

Visit us at Booth #1345

CVT CV Therapeutics[®]
The Molecular Cardiology Company™

The safety and efficacy of the TAXUS[®] Stent are clear.¹

Just ask the data.

50% reduction in reintervention, with confirmed patient safety up to 4 years.²

As the leading maker of drug-eluting stents, Boston Scientific is committed to giving you the clinical data you need to make informed decisions about your patients' treatment. The fact is, the safety and efficacy of the TAXUS[®] Express[™] Paclitaxel-Eluting Coronary Stent System are supported by the industry's largest body of independently adjudicated studies – including nearly 3,000 patients in randomized clinical trials with up to four-year follow-up. These randomized trials showed no statistically significant increase in stent thrombosis by any definition compared to the bare-metal stent control, with the same or lower rates of death or myocardial infarction and a nearly 50 percent reduction in the need for repeat revascularization.³ We have enrolled nearly 7,000 patients in real-world registries⁴ with up to two-year follow-up, we are investing in rigorous, post-market studies of even more challenging applications and we will continue to be transparent in the presentation of our clinical data. Because everyone should know the facts.

To get the facts, talk to your local sales representative, call 1-877-TAXUS-411 or visit taxus-stent.com.

Boston Scientific
Delivering what's next.™

Visit us at booth #3733

1. The TAXUS[®] Express[™] Paclitaxel-Eluting Coronary Stent System is indicated for improving luminal diameter for the treatment of de novo lesions ≤28mm in length in native coronary arteries ≥2.5mm to ≤3.75mm in diameter. 2. In patients studied in TAXUS[®] I, II, IV, V Clinical Trials. 3. See "TAXUS[®] Express[™] Paclitaxel-Eluting Coronary Stent System: Clinical Trial and Registry Summary," available at www.bostonscientific.com. 4. Ibid.

GRAND OPENING

CONTINUED FROM PAGE 1

of the combined meetings and Spotlight Sessions; key members of the cardiovascular community, including ACC's partner in i2, the Society for Cardiovascular Angiography and Interventions; industry sponsors; and Jack Lewin, M.D., ACC CEO.

"So many organizations and so many talented individuals deserve to be recognized for bringing this remarkable event to fruition," Dr. Nissen said. "I wish I could thank each and every one of you personally."

A great debate

In his Presidential Address, Dr. Nissen addressed an issue of great concern to the audience — the role of cardiologists in the national debate concerning health care disparities and the uninsured.

"In cardiovascular medicine, we can diagnose and treat heart disease with innovative approaches unimaginable to the previous generation of physicians," he said. "However, as a wealthy nation with a technologically advanced health care system, history will judge us not by our scientific progress, but by how we treat the weakest and most vulnerable among us."

Case in point, he said, is the reality that the field's technological sophistication is irrelevant to the poor and uninsured.

"If you cannot afford \$50 a month in blood pressure medications, it doesn't matter that we can ablate your atrial arrhythmias using advanced magnetically guided robotic catheter placement," he said.

For Dr. Nissen this dire situation cannot be blamed on a lack of financial expenditures, given the country's place in the world in health care spending but ranking 46th in life expectancy and high rates of infant mortality.

"We fail because we provide health care unevenly, offering extraordinary benefits to the most economically privileged and inadequate access to health care for the weakest and poorest among us," he said.

Within the specialty, too, disparities exist, said Dr. Nissen, noting that outcomes for the financially disadvantaged are profound.

"Although we have neglected these problems for decades, the national will to solve the problem of health care disparities and access to care seems to have gained considerable momentum during the past two years," he said. "But we have been there before and have always come away empty-handed. This time, we must not fail."

Admittedly, he said, a principal question for all the stakeholders is the dilemma of where to find the billions of dollars needed to solve the problem.

Cardiologists should realize that they are part of the problem, said Dr. Nissen, pointing to the inappropriate use of costly technologies that do not maximize overall health care benefits.

"The efforts of the College to promote appropriateness criteria for these technologies can play a pivotal role in containing costs, thereby freeing significant resources to provide coverage for the uninsured," Dr. Nissen said. "As an organization, we must support the adoption of these appropriateness guidelines, so that we minimize health care costs, while maximizing quality."

While an "array of proposals" have been made and he argued that cardiologists should not sit on the sidelines of this debate.

"No one better understands the needs of the patients, and we have the creative energy to be a key source of innovation in seeking solutions to these daunting problems he said. "Let's get engaged." ■

LBCT

CONTINUED FROM PAGE 1

30 patients with one coronary artery lesion at four sites in Europe and New Zealand. Key endpoints included ischemia-driven major adverse cardiac events (MACE), in-stent late loss, and in-stent and in-segment angiographic restenosis.

The 6-month results of the trial show a low 11.5 percent restenosis rate and a 0.44 mm in-stent late loss of lumen area. The late loss falls in between the 0.85 mm late loss associated with bare metal stents and 0.10 to 0.20 late loss associated with other types of drug-eluting stents, Dr. Serruys said. No patients experienced late stent thrombosis, and the MACE rate was low at 3.3 percent. The acute procedure success rate was 100 percent.

"Ladies and gentlemen, I think it may be the beginning of a new era," he said. "At 6-months' follow-up, the bioabsorbable everolimus drug-eluting stent is safe and effective. The 0.44 mm late loss is acceptable, with a median of 0.39. It was possibly driven by bioactive remodeling or mechanical late recoil, which is already being addressed by a modification of the stent design," he said.

Stent thrombosis

Another late-breaking clinical trial presented yesterday was a study of Stent Thrombosis After Implantation of Drug-Eluting and Bare Metal Coronary Stents in Western Denmark, presented by Michael Maeng, M.D., from the Aarhus University Hospital, Skejby, Denmark.

Researchers from three university hospitals in Western Denmark studied more than 12,000 stent patients, of whom 11,730 received bare metal stents (BMS) and 5,422 received drug-eluting stents (DES). Both groups also received dual antiplatelet therapy after stent implantation. The investigators followed the patients for 15 months and assessed the rates of stent thrombosis, myocardial infarction, mortality and revascularization.

Overall, the results were similar in the two groups. There was no significant difference in stent thrombosis (1.9 percent for BMS patients versus 2.2 percent for DES patients) or myocardial infarction rates (3.0 percent versus 3.2 percent). Mortality rates were also similar in the two groups. However, there was a 43 percent reduction in target lesion revascularization in the DES group compared with the BMS group.

At follow up between 12 and 15 months, the researchers found a small but significant excess of definite stent thrombosis and myocardial infarction in the DES group.

"While the minor risk of very late stent thrombosis and myocardial infarction after 12 months warrants further research over an extended period of time, these results do not outweigh the benefits of drug-eluting stents at 15-month follow-up," Dr. Maeng said.

SPIRIT III trial

Greg W. Stone, M.D., F.A.C.C., professor of medicine and director of the Cardiovascular Research and Education Center for Interventional Vascular Therapy at Columbia University Medical Center, New York, presented clinical, angiographic

and interventional ultrasound (IVUS) results from the large multicenter, randomized SPIRIT III trial comparing the everolimus-eluting Xience V stent to the paclitaxel-eluting Taxus stent.

The trial was conducted at 65 U.S. sites among 1,002 patients with coronary lesions in up to two coronary arteries. Patients were randomized in a 2:1 ratio to receive either the Xience V stent or the Taxus stent and evaluated by angiography or IVUS.

Nine months after stent implantation, the two patient groups had similar rates of target vessel failure (7.2 percent for Xience patients versus 9.0 percent for Taxus patients), but a strong trend toward fewer ischemic-driven target lesion revascularization procedures (2.6 percent versus 5.0 percent), Dr. Stone said.

The researchers found a significant 44 percent reduction in MACE among patients treated with the Xience stent compared with those treated with Taxus. They also found reduced angiographic diameter stenosis with a strong trend toward lower binary restenosis in the Xience group. The rates of death, myocardial infarction and stent thrombosis were similar in both groups, he said.

Dr. Stone concluded the SPIRIT III trial demonstrates that the Xience stent decreases angiographic restenosis and improves overall freedom from adverse events at nine months after implantation when compared with the Taxus stent.

Thrombin-receptor antagonist

Finally, David Moliterno, M.D., F.A.C.C., from the Gill Heart Institute at the University of Kentucky, Lexington, gave the results of a multinational, randomized, double-blind, placebo-controlled trial of the use of a novel thrombin-receptor antagonist (SCH 530348) in percutaneous coronary intervention (PCI).

Dr. Moliterno and colleagues at sites across North America and Europe randomized 1,030 patients in a 3:1 ratio to receive a 10 mg, 20 mg or 40 mg loading dose of SCH 530348 or placebo. Of these patients, 573 underwent PCI, 75 had coronary artery bypass grafting (CABG) and 382 received medical management. Those who underwent PCI were further randomized to receive a 0.5 mg, 1.0 mg or 2.5 mg daily maintenance dose of the novel agent or placebo for 60 days.

Overall, treatment with the novel thrombin-receptor antagonist improved adverse event rates without increasing the risk of bleeding, Dr. Moliterno said. The researchers found that SCH 530348 was not associated with an increase in TIMI (Thrombolysis in Myocardial Infarction) major or minor bleeding or non-TIMI bleeding.

While not statistically significant, the agent was associated with an overall 32 percent reduction in death or MACE, with a 42 percent reduction at the highest loading dose. The overall rate of myocardial infarction was reduced by 41 percent and by 52 percent with the highest dose, he said.

"Thrombin-receptor antagonist therapy has the potential to be transformational antiplatelet therapy in the treatment of atherothrombosis, and large phase 3 trials are warranted," Dr. Moliterno said. ■

TAXUS® EXPRESS™ PACLITAXEL-ELUTING CORONARY STENT SYSTEM

INDICATIONS: The TAXUS Express² Paclitaxel-Eluting Coronary Stent System is indicated for improving luminal diameter for the treatment of de novo lesions ≤ 28 mm in length in native coronary arteries ≥ 2.5 mm to ≤ 3.75 mm in diameter.

CONTRAINDICATIONS: Use of the TAXUS Express² Paclitaxel-Eluting Coronary Stent System is contraindicated in patients with: Known hypersensitivity to paclitaxel or structurally related compounds. • Known hypersensitivity to the polymer or its individual components. Coronary artery stenting is contraindicated for use in: Patients in whom antiplatelet and/or anticoagulant therapy is contraindicated. • Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or delivery device.

WARNINGS: To maintain sterility, the inner package should not be opened or damaged prior to use. • The use of this product carries the risks associated with coronary artery stenting, including subacute thrombosis, vascular complications, and/or bleeding events. Patients with known hypersensitivity to 316L stainless steel may suffer an allergic reaction to this implant.

Potential adverse events (in alphabetical order) which may be associated with the use of a coronary stent in native coronary arteries include, but are not limited to: Aneurysm • Arrhythmias • Bleeding complications • Death • Distal emboli • Emergent CABG • Myocardial infarction • Myocardial ischemia • Occlusion • Stent delivery failures • Target lesion revascularization • Thrombosis • Vascular complications • Vessel dissection. **Potential adverse events not captured above that may be unique to the paclitaxel drug coating:** Alopecia • Allergic reaction to the drug or the polymer • Anemia • Blood product transfusion • Gastrointestinal symptoms • Hematologic dyscrasia • Hepatic enzyme changes • Histologic changes in vessel wall, including inflammation, cellular damage or necrosis • Myalgia/arthralgia • Peripheral neuropathy. **The safety and effectiveness of the TAXUS Express² Paclitaxel-Eluting Coronary Stent System have not been established in the following patient populations:** Women who are pregnant or lactating. • Men intending to father children. • Pediatric patients. • Patients with unresolved vessel thrombus at the lesion site. • Patients with coronary artery reference vessel diameters < 2.5 mm or > 3.75 mm. • Patients with lesions located in the saphenous vein grafts, in the unprotected left main coronary artery, ostial lesions, or lesions located at a bifurcation. • Patients with diffuse disease or poor flow distal to the identified lesions. • Patients with tortuous vessels (> 60 degrees) in the region of the obstruction or proximal to the lesion. • Patients with a recent acute myocardial infarction where there is evidence of thrombus or poor flow. • Patients with multiple overlapping stents. • Patients with longer than 12-month follow-up.

Prior to use, please see the complete "Directions for Use" at www.taxus-stent.com for more information on indications, contraindications, warnings, precautions, adverse events and operator's instructions.

CAUTION: Federal law restricts this product to sale by or on the order of a physician.

TRADEMARKS: TAXUS, Express² and Delivering What's Next are trademarks of Boston Scientific Corporation or its affiliates.

© 2007 Boston Scientific Corporation or its affiliates. All rights reserved.

The NEW Stent Platform for Controlled Drug Delivery

Visit and view at ACC: Booth #3533

Conor DES Stent Platform Features

- NO drug/polymer surface coating
- NO residual drug/polymer on stent
- Cobalt chromium alloy for enhanced deliverability

www.CONORMED.com

Caution: CoStar[®] is an investigational device not currently available for sale in the United States. Limited by law to investigational use in the US.

© Conor Medsystems, Inc. All rights reserved.



i2 SUMMIT

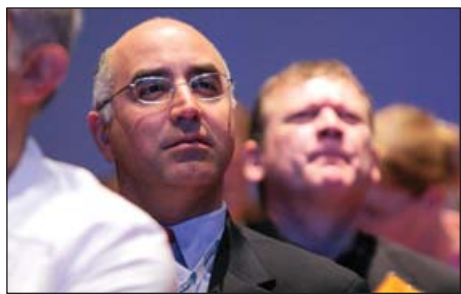
CONTINUED FROM PAGE 1

face of care.

“A disruptive technology is an innovation that eventually overturns the existing dominant technology. This (Dr. Gruentzig’s technology) led to a revolution that forever changed the face of modern cardiovascular care,” said Dr. Holmes, a professor of medicine at the Mayo Clinic College of Medicine, Rochester, Minn.

In addition to establishing a PTCA registry at the NHLBI and providing live demonstrations on its use, Dr. Gruentzig further pushed the balloon procedure by calling for follow-up data and cooperation with cardiac surgery to treat complications.

Now, the characteristics of interventional cardiology are vast, said Dr. Holmes, who pointed to the domination of stents in coronary



Attendees listen to the remarks of David Holmes, Jr., M.D., during Saturday’s i2 Summit Opening Session.

intervention strategies, migration to other vascular beds, reperfusion therapy for AMI and new strokes, cell replacement therapy and evaluation of patients with vulnerable plaques.

With all roads seemingly leading to intervention, more than 3,000 attendees have gathered for 789 sessions during this year’s i2 Summit, Dr. Holmes said.

A year after the first i2 Summit in Atlanta, the 2007 meeting accepted 225 of 760 submitted abstracts and 17 of 29 submitted late-breaking clinical trials.

“We have more live cases, with five U.S. sites and others from Montreal, the Netherlands and Japan,” he said. “We have new technologies, simulations and taped sessions. We’ll also have a nurses/technology program, the Fellows Boot Camp, Laptop Learning and a joint ACC 2007/i2 Symposium on Drug-Eluting Stent Safety.”

He called on participants to look ahead, pointing to advances in noninvasive coronary imaging, new approaches for adverse lesions, the role of stroke centers, expanded targeted regeneration therapy, early detection of patients at risk for subsequent events, new approaches for structural heart disease, and benchmarking and quality improvement.

Still, the issues facing interventional cardiologists must be addressed, said Dr. Holmes, pointing to stent thrombosis, different anatomy, reimbursement and device removal concerns.

However, by expanding the “tent,” the most vexing of issues has become the parameters of turf, which he said must be resolved.

“We are on our journey, and you are part of that journey,” Dr. Holmes said. “What about i2? It’s a place for you to start your journey — this year, next year and forever and a day. The College determined that this is a tremendously important group to address — for our patients and for our professional lives.

“The sun is rising on interventional cardiology. The future is incredibly bright for our field. We just have to imagine because the sky is the limit for our field, for you and for our patients.” ■

Congenital cardiology program to expand in 2008

This year ACC.07 features numerous sessions on adult congenital heart disease and pediatric cardiology; however, 2008 promises to be a groundbreaking year for congenital heart disease education, according to Gerard Martin, M.D., F.A.C.C., F.A.A.P., chair of ACC’s Adult Congenital Heart Disease/Pediatric Cardiology Committee/Section.

“The College, recognizing the increased

education needs of pediatric cardiologists and the growing population of adults with congenital heart disease, has begun a process to address our members’ education needs,” Dr. Martin said. “The end result will be Congenital Cardiology Solutions 2008, a ‘meeting within a meeting’ with content that actually connects ACC.08 and i2 Summit 2008.”

The development of Congenital

Cardiology Solutions 2008 has already begun with the formation of a special committee comprising pediatric interventional cardiologists and planning committee representatives from the other two meetings.

Congenital Cardiology Solutions 2008 will take place on Tuesday of next year’s Annual Scientific Session in Chicago, and the program will include live case demonstrations from hospitals around the country. ■

LIPITOR® (Atorvastatin Calcium) Tablets
Brief Summary of Prescribing Information

CONTRAINDICATIONS: Active liver disease or unexplained persistent elevations of serum transaminases. Hypersensitivity to any component of this medication. **Pregnancy and Lactation** — Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **ATORVASTATIN SHOULD BE ADMINISTERED TO WOMEN OF CHILDBEARING AGE ONLY WHEN SUCH PATIENTS ARE HIGHLY UNLIKELY TO CONCEIVE AND HAVE BEEN INFORMED OF THE POTENTIAL HAZARDS.** If the patient becomes pregnant while taking this drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS: Liver Dysfunction — HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. **Persistent elevations (3 times the upper limit of normal [ULN] occurring on 2 or more occasions) in serum transaminases occurred in 0.7% of patients who received atorvastatin in clinical trials. The incidence of these abnormalities was 0.2%, 0.2%, 0.6%, and 2.3% for 10, 20, 40, and 80 mg, respectively.** One patient in clinical trials developed jaundice. Increases in liver function tests (LFT) in other patients were not associated with jaundice or other clinical signs or symptoms. Upon dose reduction, drug interruption, or discontinuation, transaminase levels returned to or near pretreatment levels without sequelae. Eighteen of 30 patients with persistent LFT elevations continued treatment with a reduced dose of atorvastatin. **It is recommended that liver function tests be performed prior to and at 12 weeks following both the initiation of therapy and any elevation of dose, and periodically (eg, semiannually) thereafter.** Liver enzyme changes generally occur in the first 3 months of treatment with atorvastatin. Patients who develop increased transaminase levels should be monitored until the abnormalities resolve. Should an increase in ALT or AST of >3 times ULN persist, reduction of dose or withdrawal of atorvastatin is recommended. Atorvastatin should be used with caution in patients who consume substantial quantities of alcohol and/or have a history of liver disease. Active liver disease or unexplained persistent transaminase elevations are contraindications to the use of atorvastatin (see CONTRAINDICATIONS). **Skeletal Muscle** — **Rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with atorvastatin and with other drugs in this class.** Uncomplicated myalgia has been reported in atorvastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aches or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values >10 times ULN, should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. Atorvastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. The risk of myopathy during treatment with drugs in this class is increased with concurrent administration of cyclosporine, fibric acid derivatives, erythromycin, niacin, or azole antifungals. Physicians considering combined therapy with atorvastatin and fibric acid derivatives, erythromycin, immunosuppressive drugs, azole antifungals, or lipid-lowering doses of niacin should carefully weigh the potential benefits and risks and should carefully monitor patients for any signs or symptoms of muscle pain, tenderness, or weakness, particularly during the initial months of therapy and during any periods of upward dosage titration of either drug. Periodic creatine phosphokinase (CPK) determinations may be considered in such situations, but there is no assurance that such monitoring will prevent the occurrence of severe myopathy. **Atorvastatin therapy should be temporarily withheld or discontinued in any patient with an acute, serious condition suggestive of a myopathy or having a risk factor predisposing to the development of renal failure secondary to rhabdomyolysis (eg, severe acute infection, hypotension, major surgery, trauma, severe metabolic, endocrine and electrolyte disorders, and uncontrolled seizures).**

PRECAUTIONS: General — Before instituting therapy with atorvastatin, an attempt should be made to control hypercholesterolemia with appropriate diet, exercise, and weight reduction in obese patients, and to treat other underlying medical problems (see INDICATIONS AND USAGE in full prescribing information). **Information for Patients** — Patients should be advised to report promptly unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever. **Drug Interactions** — The risk of myopathy during treatment with drugs of this class is increased with concurrent administration of cyclosporine, fibric acid derivatives, niacin (nicotinic acid), erythromycin, azole antifungals (see WARNINGS, *Skeletal Muscle*). **Antacid:** When atorvastatin and Maalox® TC suspension were coadministered, plasma concentrations of atorvastatin decreased approximately 35%. However, LDL-C reduction was not altered. **Antipyrine:** Because atorvastatin does not affect the pharmacokinetics of antipyrine, interactions with other drugs metabolized via the same cytochrome isozymes are not expected. **Colestipol:** Plasma concentrations of atorvastatin decreased approximately 25% when colestipol and atorvastatin were coadministered. However, LDL-C reduction was greater when atorvastatin and colestipol were coadministered than when either drug was given alone. **Cimetidine:** Atorvastatin plasma concentrations and LDL-C reduction were not altered by coadministration of cimetidine. **Digoxin:** When multiple doses of atorvastatin and digoxin were coadministered, steady-state plasma digoxin concentrations increased by approximately 20%. Patients taking digoxin should be monitored appropriately. **Erythromycin:** In healthy individuals, plasma concentrations of atorvastatin increased approximately 40% with coadministration of atorvastatin and erythromycin, a known inhibitor of cytochrome P450 3A4 (see WARNINGS, *Skeletal Muscle*). **Oral Contraceptives:** Coadministration of atorvastatin and an oral contraceptive increased AUC values for norethindrone and ethinyl estradiol by approximately 30% and 20%. These increases should be considered when selecting an oral contraceptive for a woman taking atorvastatin. **Warfarin:** Atorvastatin had no clinically significant effect on prothrombin time when administered to patients receiving chronic warfarin treatment. **Endocrine Function** — HMG-CoA reductase inhibitors interfere with cholesterol synthesis and theoretically might blunt adrenal and/or gonadal steroid production. Clinical studies have shown that atorvastatin does not reduce basal plasma cortisol concentration or impair adrenal reserve. The effects of HMG-CoA reductase inhibitors on male fertility have not been studied in adequate numbers of patients. The effects, if any, on the pituitary-gonadal axis in premenopausal women are unknown. Caution should be exercised if an HMG-CoA reductase inhibitor is administered concomitantly with drugs that may decrease the levels or activity of endogenous steroid hormones, such as ketoconazole, spironolactone, and cimetidine. **CNS Toxicity** — Brain hemorrhage was seen in a female dog treated for 3 months at 120 mg/kg/day. Brain hemorrhage and optic nerve vacuolation were seen in another female dog that was sacrificed in moribund condition after 11 weeks of escalating doses up to 280 mg/kg/day. The 120 mg/kg dose resulted in a systemic exposure approximately 16 times the human plasma area-under-the-curve (AUC, 0-24 hours) based on the maximum human dose of 80 mg/day. A single tonic convulsion was seen in each of 2 male dogs (one treated at 10 mg/kg/day and one at 120 mg/kg/day) in a 2-year study. No CNS lesions have been observed in mice after chronic treatment for up to 2 years at doses up to 400 mg/kg/day or in rats at doses up to 100 mg/kg/day. These doses were 6 to 11 times (mice) and 8 to 16 times (rats) the human AUC (0-24) based on the maximum recommended human dose of 80 mg/day. CNS vascular lesions, characterized by perivascular hemorrhages, edema, and mononuclear cell infiltration of perivascular spaces, have been observed in dogs treated with other members of this class. A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion at a dose that produced plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose. **Carcinogenesis, Mutagenesis, Impairment of Fertility** — In a 2-year carcinogenicity study in rats at dose levels of 10, 30, and 100 mg/kg/day, 2 rare tumors were found in muscle in high-dose females: in one, there was a rhabdomyosarcoma and, in another, there was a fibrosarcoma. This dose represents a plasma AUC (0-24) value of approximately 16 times the mean human plasma drug exposure after an 80 mg oral dose. A 2-year carcinogenicity study in mice given 100, 200, or 400 mg/kg/day resulted in a significant increase in liver adenomas in high-dose males and liver carcinomas in high-dose females. These findings occurred at plasma AUC (0-24) values of approximately 6 times the mean human plasma drug exposure after an 80 mg oral dose. **In vitro**, atorvastatin was not mutagenic or clastogenic in the following tests with and without metabolic activation: the Ames test with *Salmonella typhimurium* and *Escherichia coli*, the HGPRT forward mutation assay in Chinese hamster lung cells, and the chromosomal aberration assay in Chinese hamster lung cells. Atorvastatin was negative in the *in vivo* mouse micronucleus test. Studies in rats performed at doses up to 175 mg/kg (15 times the human exposure) produced no changes in fertility. There was aplasia and aspermia in the epididymus of 2 of 10 rats treated with 100 mg/kg/day of atorvastatin for 3 months (16 times the human AUC at the 80 mg dose); testis weights were significantly lower at 30 and 100 mg/kg and epididymal weight was lower at 100 mg/kg. Male rats given 100 mg/kg/day for 11 weeks prior to mating had decreased sperm motility, sperm head concentration, and increased abnormal sperm. Atorvastatin caused no adverse effects on semen parameters, or reproductive organ histopathology in dogs given doses of 10, 40, or 120 mg/kg for two years. **Pregnancy Category X: See CONTRAINDICATIONS.** Safety in pregnant women has not been established. Atorvastatin crosses the rat placenta and reaches a level in fetal liver equivalent to that of maternal plasma. Atorvastatin was not teratogenic in rats at doses up to 300 mg/kg/day or in rabbits at doses up to 100 mg/kg/day. These doses resulted in multiples of about 30 times (rat) or 20 times (rabbit) the human exposure based on surface area (mg/m²). In a study in rats given 20, 100, or 225 mg/kg/day, from gestation day 7 through to lactation day 21 (weaning), there was decreased pup survival at birth, neonate, weaning, and maturity in pups of mothers dosed with 225 mg/kg/day. Body weight was decreased on days 4 and 21 in pups of mothers dosed at 100 mg/kg/day; pup body weight was decreased at birth and on days 4, 21, and 91 at 225 mg/kg/day. Pup development was delayed (rotorod performance at 100 mg/kg/day and acoustic startle at 225 mg/kg/day;

pinnae detachment and eye opening at 225 mg/kg/day). These doses correspond to 6 times (100 mg/kg) and 22 times (225 mg/kg) the human AUC at 80 mg/day. Rare reports of congenital anomalies have been received following intrauterine exposure to HMG-CoA reductase inhibitors. There has been one report of severe congenital bony deformity, tracheo-esophageal fistula, and anal atresia (VATER association) in a baby born to a woman who took lovastatin with dextroamphetamine sulfate during the first trimester of pregnancy. LIPITOR should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking LIPITOR, it should be discontinued and the patient advised again as to the potential hazards to the fetus. **Nursing Mothers** — Nursing rat pups had plasma and liver drug levels of 50% and 40%, respectively, of that in their mother’s milk. Because of the potential for adverse reactions in nursing infants, women taking LIPITOR should not breast-feed (see CONTRAINDICATIONS). **Pediatric Use** — Safety and effectiveness in patients 10-17 years of age with heterozygous familial hypercholesterolemia have been evaluated in a controlled clinical trial of 6 months duration in adolescent boys and postmenarchal girls. Patients treated with LIPITOR had an adverse experience profile generally similar to that of patients treated with placebo, the most common adverse experiences observed in both groups, regardless of causality assessment, were infections. **Doses greater than 20 mg have not been studied in this patient population.** In this limited controlled study, there was no detectable effect on growth or sexual maturation in boys or on menstrual cycle length in girls (see CLINICAL PHARMACOLOGY, *Clinical Studies* section in full prescribing information). **ADVERSE REACTIONS, Pediatric Patients (ages 10-17 years):** and **DOSAGE AND ADMINISTRATION, Heterozygous Familial Hypercholesterolemia in Pediatric Patients (10-17 years of age)** in full prescribing information. Adolescent females should be counseled on appropriate contraceptive methods while on LIPITOR therapy (see CONTRAINDICATIONS and PRECAUTIONS, *Pregnancy*). **LIPITOR has not been studied in controlled clinical trials involving pre-pubertal patients or patients younger than 10 years of age.** Clinical efficacy with doses up to 80 mg/day for 1 year have been evaluated in an uncontrolled study of patients with homozygous FH including 8 pediatric patients (see CLINICAL PHARMACOLOGY, *Clinical Studies: Homozygous Familial Hypercholesterolemia* in full prescribing information). **Geriatric Use** — The safety and efficacy of atorvastatin (10-80 mg) in the geriatric population (≥65 years of age) was evaluated in the ACCESS study. In this 54-week open-label trial 1,958 patients initiated therapy with atorvastatin 10 mg. Of these, 835 were elderly (≥65 years) and 1,123 were non-elderly. The mean change in LDL-C from baseline after 6 weeks of treatment with atorvastatin 10 mg was -38.2% in the elderly patients versus -34.6% in the non-elderly group. The rates of discontinuation due to adverse events were similar between the two age groups. There were no differences in clinically relevant laboratory abnormalities between the age groups. **Use in Patients with Recent Stroke or TIA** — In a post-hoc analysis of the Stroke Prevention by Aggressive Reduction in Cholesterol Levels (SPARCL) study where LIPITOR 80 mg vs placebo was administered in 4,731 subjects without CHD who had a stroke or TIA within the preceding 6 months, a higher incidence of hemorrhagic stroke was seen in the LIPITOR 80 mg group compared to placebo. Subjects with hemorrhagic stroke on study entry appeared to be at increased risk for hemorrhagic stroke.

ADVERSE REACTIONS: LIPITOR is generally well-tolerated. Adverse reactions have usually been mild and transient. In controlled clinical studies of 2502 patients, <2% of patients were discontinued due to adverse experiences attributable to atorvastatin. The most frequent adverse events thought to be related to atorvastatin were constipation, flatulence, dyspepsia, and abdominal pain. **Clinical Adverse Experiences** — Adverse experiences reported in ≥2% of patients in placebo-controlled clinical studies of atorvastatin, regardless of causality assessment, are shown in the following table.

BODY SYSTEM Adverse Event	Adverse Events in Placebo-Controlled Studies (% of Patients)				
	Placebo N = 270	Atorvastatin 10 mg N = 863	Atorvastatin 20 mg N = 36	Atorvastatin 40 mg N = 79	Atorvastatin 80 mg N = 94
BODY AS A WHOLE					
Infection	10.0	10.3	2.8	10.1	7.4
Headache	7.0	5.4	16.7	2.5	6.4
Accidental Injury	3.7	4.2	0.0	1.3	3.2
Flu Syndrome	1.9	2.2	0.0	2.5	3.2
Abdominal Pain	0.7	2.8	0.0	3.8	2.1
Back Pain	3.0	2.8	0.0	3.8	1.1
Allergic Reaction	2.6	0.9	2.8	1.3	0.0
Asthenia	1.9	2.2	0.0	3.8	0.0
DIGESTIVE SYSTEM					
Constipation	1.8	2.1	0.0	2.5	1.1
Diarrhea	1.5	2.7	0.0	3.8	5.3
Dyspepsia	4.1	2.3	2.8	1.3	2.1
Flatulence	3.3	2.1	2.8	1.3	1.1
RESPIRATORY SYSTEM					
Sinusitis	2.6	2.8	0.0	2.5	6.4
Pharyngitis	1.5	2.5	0.0	1.3	2.1
SKIN AND APPENDAGES					
Rash	0.7	3.9	2.8	3.8	1.1
MUSCULOSKELETAL SYSTEM					
Arthralgia	1.5	2.0	0.0	5.1	0.0
Myalgia	1.1	3.2	5.6	1.3	0.0

Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT) — In ASCOT (see CLINICAL PHARMACOLOGY, *Clinical Studies* in full prescribing information) involving 10,305 participants treated with LIPITOR 10 mg daily (n=5,188) or placebo (n=5,117), the safety and tolerability profile of the group treated with LIPITOR was comparable to that of the group treated with placebo during a median of 3.3 years of follow-up.

Collaborative Atorvastatin Diabetes Study (CARDS) — In CARDS (see CLINICAL PHARMACOLOGY, *Clinical Studies* in full prescribing information) involving 2838 subjects with type 2 diabetes treated with LIPITOR 10 mg daily (n=1428) or placebo (n=1410), there was no difference in the overall frequency of adverse events or serious adverse events between the treatment groups during a median follow-up of 3.9 years. No cases of rhabdomyolysis were reported.

The following adverse events were reported, regardless of causality assessment in patients treated with atorvastatin in clinical trials. The events in italics occurred in ≥2% of patients and the events in plain type occurred in <2% of patients.

Body as a Whole: Chest pain, face edema, fever, neck rigidity, malaise, photosensitivity reaction, generalized edema. **Digestive System:** Nausea, gastroenteritis, liver function tests abnormal, colitis, vomiting, gastritis, dry mouth, rectal hemorrhage, esophagitis, eructation, glossitis, mouth ulceration, anorexia, increased appetite, stomatitis, biliary pain, cheilitis, duodenal ulcer, dysphagia, enteritis, melena, gum hemorrhage, stomach ulcer, tenesmus, ulcerative stomatitis, hepatitis, pancreatitis, cholestatic jaundice. **Respiratory System:** Bronchitis, rhinitis, pneumonia, dyspnea, asthma, epistaxis. **Nervous System:** Insomnia, dizziness, paresthesia, somnolence, amnesia, abnormal dreams, libido decreased, emotional lability, incoordination, peripheral neuropathy, torticollis, focal paralysis, hyperkinesia, depression, hypesthesia, hypertonia. **Musculoskeletal System:** Arthritis, leg cramps, bursitis, tenosynovitis, myasthenia, tendinous contracture, myositis. **Skin and Appendages:** Pruritus, contact dermatitis, alopecia, dry skin, sweating, acne, urticaria, eczema, seborrhea, skin ulcer. **Urogenital System:** Urinary tract infection, hematuria, albuminuria, urinary frequency, cystitis, impotence, dysuria, kidney calculus, nocturia, epididymitis, fibrocystic breast, vaginal hemorrhage, breast enlargement, metrorrhagia, nephritis, urinary incontinence, urinary retention, urinary urgency, abnormal ejaculation, uterine hemorrhage. **Special Senses:** Amblyopia, tinnitus, dry eyes, refractive disorder, eye hemorrhage, deafness, glaucoma, parosmia, taste loss, taste perversion. **Cardiovascular System:** Palpitation, vasodilatation, syncope, migraine, postural hypotension, phlebitis, arrhythmia, angina pectoris, hypertension. **Metabolic and Nutritional Disorders:** Peripheral edema, hyperglycemia, creatine phosphokinase increased, gout, weight gain, hypoglycemia. **Hemic and Lymphatic System:** Echinymosis, anemia, lymphadenopathy, thrombocytopenia, petechia. **Postintroduction Reports** — Adverse events associated with LIPITOR therapy reported since market introduction, that are not listed above, regardless of causality assessment, include the following: anaphylaxis, angioneurotic edema, bullous rashes (including erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis), rhabdomyolysis, fatigue, and tendon rupture. **Pediatric Patients (ages 10-17 years)** In a 26-week controlled study in boys and postmenarchal girls (n=140), the safety and tolerability profile of LIPITOR 10 to 20 mg daily was generally similar to that of placebo (see CLINICAL PHARMACOLOGY, *Clinical Studies* section in full prescribing information and PRECAUTIONS, *Pediatric Use*).

OVERDOSAGE: There is no specific treatment for atorvastatin overdose. In the event of an overdose, the patient should be treated symptomatically, and supportive measures instituted as required. Due to extensive drug binding to plasma proteins, hemodialysis is not expected to significantly enhance atorvastatin clearance.

Please see full prescribing information for additional information about LIPITOR.

Only Distributed by: **Parke-Davis** ©2005 Pfizer Ireland Pharmaceuticals
Manufactured by: **Pfizer Ireland Pharmaceuticals**
Dublin, Ireland
Rev. 13, December 2006

LPU00067A

© 2007 Pfizer Inc.

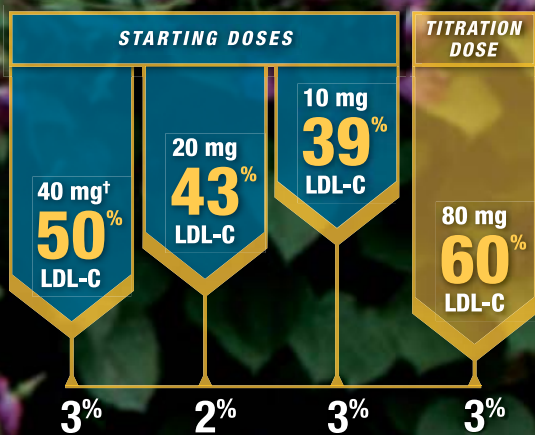
All rights reserved.

February 2007

Pfizer U.S. Pharmaceuticals



Start with LIPITOR: see up to a 50% reduction in LDL-C with a starting dose*†



RATES OF MYALGIA¹
As seen in an analysis of pooled results of 44 clinical trials including more than 9000 patients

Stay with LIPITOR: proven safety profile at every dose

Succeed with LIPITOR: LIPITOR is indicated to reduce the risk of stroke, MI, and revascularization in patients with multiple risk factors but without CHD

*Pooled average results from 2 multicenter, placebo-controlled, dose-response studies in patients with primary hypercholesterolemia. LDL-C values are mean percent reductions compared with baseline. P<.05 vs placebo.

†LIPITOR 40 mg may be a starting dose for patients who require an LDL-C reduction >45%.

I  family visits

BECAUSE THERE'S A LOT TO LOVE
PRESCRIBE THE STATIN YOU LOVE



LIPITOR is indicated to reduce the risk of myocardial infarction, revascularization procedures, angina, and stroke in adult patients with multiple risk factors but without clinically evident CHD; to reduce the risk of myocardial infarction and stroke in patients with type 2 diabetes and without clinically evident CHD, but with multiple risk factors; as an adjunct to diet to reduce elevated total-C, LDL-C, apo B, and TG levels; and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia.

LIPITOR is contraindicated in patients with active liver disease or unexplained persistent elevations of serum transaminases; in women who are or may become pregnant or who are nursing; in patients with hypersensitivity to any component of this medication.

Rare cases of rhabdomyolysis have been reported with LIPITOR and other statins. With any statin, tell patients to promptly report muscle pain, tenderness, or weakness. Discontinue drug if myopathy is suspected, if creatine phosphokinase (CPK) levels rise markedly, or if the patient has risk factors for rhabdomyolysis.

Due to increased risk of myopathy seen with LIPITOR and other statins, physicians should carefully consider combined therapy with fibric acid derivatives, erythromycin, immunosuppressive drugs, azole antifungals, or niacin and carefully monitor patients for signs or symptoms of myopathy early during therapy and when titrating dose of either drug.

It is recommended that liver function tests be performed prior to and 12 weeks following both the initiation of therapy and any elevation of dose, and periodically thereafter. If ALT or AST values >3 x ULN persist, dose reduction or withdrawal is recommended.

In clinical trials, the most common adverse events were constipation, flatulence, dyspepsia, and abdominal pain.

Reference: 1. Newman CB, Palmer G, Silbershatz H, Szarek M. Safety of atorvastatin derived from analysis of 44 completed trials in 9,416 patients. *Am J Cardiol.* 2003;92:670-676.

Please see brief summary of prescribing information on adjacent page.

www.LIPITORhcp.com

ACC to introduce two new journals

The ACC will begin publishing two new journals in January 2008 to supplement the *Journal of the American College of Cardiology* (JACC). Stop by ACC Central, Booth #2267, during ACC.07 and the i2 Summit to sign up to receive the new journals, which will be mailed free to ACC members.

The new journals are *JACC: Cardiovascular Imaging* and *JACC: Cardiovascular Interventions*. Editors will begin accepting manuscript submissions after July 1 for the journals, which initially will be published bimonthly, with a goal of both eventually becoming monthly publications.

The editor-in-chief of *JACC: Cardiovascular Imaging* will be Jagat M. Narula, M.D., Ph.D., F.A.C.C. It will take a broad, balanced view of all aspects of cardiovascular imaging.

The journal will publish original clinical research articles employing non-invasive and invasive imaging techniques, including echocardiography, CT, CMR, nuclear, optical imaging and cine-angiography. Advances in basic science and molecular imaging will be especially welcomed.

Other content will emphasize imaging for the practicing cardiologist, advocacy and practice management, and state-of-the-art reviews.

Full information about the journal and manuscript submissions may be found at jacc-imaging.org.

Spencer B. King, III, M.D., M.A.C.C., has been named editor-in-chief of *JACC: Cardiovascular Interventions*, which will publish studies that will impact the practice of interventional cardiovascular medicine.

Among the studies the journal aims to publish are clinical trials that provide evidence to inform and alter practice guidelines, experimental studies that point to improved technologies, and mechanistic understanding and in-depth discussions of topics of interest by experts in the field.

Because interventional cardiovascular medicine is a highly visual specialty, the print journal will be augmented by electronic publication, allowing the latest technologies to be employed.

Full information about the journal and manuscript submissions may be found at www.jacc-interventions.org.

ACC members can also sign up to receive both publications at ACC Central or the Elsevier Booth, #4451. Non-members can order subscriptions at the Elsevier booth. ■

FIT event reminders for today

The FIT Community Room, Room 231 in the convention center, will be open from 8 a.m. to 4 p.m. Sunday through Tuesday.

Sunday Sessions in Community Room:

- 1 to 2:30 p.m., Welcome to ACC.07 and Roundtable Discussions
- 2 to 4 p.m., FITs: What You Need to Know in Starting a Cardiology Career