



TRENDS-in-MEDICINE

BULLETIN:

American College of Cardiology (ACC) – PREVIEW

March 15, 2016
by Lynne Peterson

American College of Cardiology (ACC) officials held a teleconference with reporters to review the key late-breaking clinical trials to be presented at the annual meeting April 2-5, 2016, in Chicago, and to answer reporter questions about them. None of the embargoed results were presented.

ACC president Kim Williams, Sr., MD, chief of the division of cardiology at Rush University Medical Center, put his focus on population health and lifestyle/nutrition data that will be presented at the meeting. ACC.16 Scientific Session program chair Athena Poppas, MD, director of cardiovascular imaging at the Cardiovascular Institute in Providence RI, and ACC.16 Scientific Session program vice chair Jeffrey Kuvin, MD, associate chief of cardiology at Tufts Medical Center, highlighted several trials.

The trial that these experts suggested is likely to be the most practice changing is the long, large, 3-arm HOPE-3 trial which compared blood pressure control vs. lipid control with a statin vs. a combination of blood pressure control and a statin for primary prevention. Two other trials expected to have a big impact on practice are: a study on testing for chest pain patients presenting to the emergency room, and a Danish trial of primary angioplasty vs. stenting, looking at distal embolization.

The key trials that were highlighted that involve new drugs or devices were:

- **AMGEN's Repatha (evolocumab)** – The results of the **GAUSS-3** trial comparing this PCSK9 inhibitor to Merck's Zetia (ezetimibe) in statin-intolerant patients. Dr. Kuvin said cardiologists encounter statin-intolerant patients in practice more often than the statin trials would indicate, "This is not a small population that can't tolerate a full or partial statin dose." Given the higher cost of PCSK9 inhibitors, if Repatha beats Zetia, Dr. Kuvin said, "It will add to our ability to think about these."
- **BIOCONTROL MEDICAL's CardioFit** – The results of the >700-patient **INOVATE-HF** trial of this vagal nerve stimulator to treat chronic Class III heart failure will be presented.
- **EDWARDS LIFESCIENCES' Sapien XT and Sapien 3** – The results of a study of each of these transcatheter aortic valve replacement (TAVR) in intermediate-risk patients will be presented on separate days.
- **LILLY's evacetrapib** – Dr. Kuvin said the results of the 12,000-patient Phase III **ACCELERATE** trial of this CETP inhibitor are important even though it failed because it looks at long-term outcomes.
- **EVONEXUS/TOSENSE's CoVa** – The results of the **IMPEDANCE-HF** trial of this non-invasive lung impedance monitoring device in heart failure patients is interesting. Dr. Poppas said, "One of our ongoing conundrums in cardiology is heart failure readmissions...CMS [the Centers for Medicare and Medicaid Services] is very interested in this. Previously, mostly clinical assessments were when patients are starting to collect fluid and need hospitalization. This is a non-invasive monitoring of lung impedance to maybe detect sooner when patients are collecting fluid and hopefully keep them out of the hospital."

Trends-in-Medicine ■ 2731 N.E. Pinecrest Lakes Blvd ■ Jensen Beach FL 34957
772-334-7409 / 800-589-5018 ■ Fax 772-334-0856 ■ www.trends-in-medicine.com

Trends-in-Medicine has no financial connections with any pharmaceutical or medical device company. The information and opinions expressed have been compiled or arrived at from sources believed to be reliable and in good faith, but no liability is assumed for information contained in this newsletter. Copyright ©2016. This document may not be reproduced without written permission of the publisher.

Here is a guide to the late-breaking clinical trials relating to new drugs and devices.

Saturday, April 2

8 am, North Hall B1 (Main Tent)

- **EDWARDS LIFESCIENCES' Sapien XT** – The final results of the **PARTNER-2A** trial of this TAVR in intermediate-risk patients with aortic stenosis (9:05 am).

Sunday, April 3

8 am, North Hall B1 (Main Tent)

- **LILLY's evacetrapib** – The results of the 12,000-patient Phase III **ACCELERATE** trial of this CETP inhibitor.
- **AMGEN's Repatha (evolocumab)** – The results of the **GAUSS-3** trial comparing this PCSK9 inhibitor to Merck's Zetia (ezetimibe) in statin-intolerant patients.

10:45 am, North Hall B1 (Main Tent)

- **EDWARDS LIFESCIENCES' Sapien 3** – The final one-year results of this TAVR in intermediate-risk patients with severe aortic stenosis (11:30 am).
- **TAVR Volume/Outcome: Relationship** – Results from the STS/ACC TVT Registry comparing procedure volume and TAVR outcomes (11:45 am).

12:30 pm, Room S103cd

- **MEDTRONIC's CoreValve** – 3-year results from the pivotal U.S. trial of this TAVR in high-risk patients with aortic stenosis.
- **TAVR** – STS/ACC TVT Registry data on valve deterioration incidence and outcomes.
- **BOSTON SCIENTIFIC's Synergy** – Two-year results from the **EVOLVE-II** trial of this drug-eluting stent (1 pm).

Monday, April 4

8:00 am, North Hall B1 (Main Tent)

- **MEDTRONIC's Arctic Front** – The results of the **FIRE AND ICE** trial of this cryoballoon in atrial fibrillation (8:15 am).
- **GLAXOSMITHKLINE's losmapimod** – The results of Part A of the Phase III **LATITUDE-TIMI-60** trial of this p38 inhibitor in acute coronary syndrome.
- **ISCHEMIX's CMX-2043** – The results of the Phase IIa **CARIN** trial of this small molecule proto-oncogene-protein-c-akt-modulator to prevent contrast-induced acute kidney injury in coronary angiography patients.

10:45 am, North Hall B1 (Main Tent)

- **NOVARTIS' Tekturna (aliskiren)** – The results of the **ATMOSPHERE** trial of this direct renin inhibitor ± enalapril vs. enalapril in heart failure patients.
 - **CARDIORENTIS' ularitide** – The results of the **TRUE-AHF** trial of this natriuretic peptide in acutely decompensated heart failure patients.
 - **VERICEL's ixmyelocel-T** – The results of the **ixCELL-DCM** trial of transendocardial injection of this gene therapy in heart failure patients with ischemic dilated cardiomyopathy.
 - **BIOCONTROL MEDICAL's CardioFit** – The results of the **INOVATE-HF** trial of this vagal nerve stimulator to treat chronic heart failure (11:30 am).
 - **EVONEXUS/TOSENSE's CoVa** – The results of the **IMPEDANCE-HF** trial of this non-invasive lung impedance monitoring device in heart failure patients.
-

2:00 pm, Grand Ballroom S100bc

- **ROCHE's Noxafil (posaconazole)** – The results of the **STOP-CHAGAS** trial in treating asymptomatic Chagas disease.
- **Obesity** – Final 5-year results from the **STAMPEDE** trial comparing bariatric surgery to intensive medical therapy for long-term treatment of diabetes.

