



57<sup>th</sup> Annual Scientific Session  
MARCH 29 – APRIL 1 • CHICAGO

EMBARGOED FOR RELEASE  
Tuesday, April 1, 2008  
1:00.p.m. CDT

CONTACT: Andrew Crosby  
(901) 575-0010  
[acrosby@crosbyvolmer.com](mailto:acrosby@crosbyvolmer.com)  
Amy Murphy  
(202) 375-6476  
[amurphy@acc.org](mailto:amurphy@acc.org)  
ACC.08 Newsroom  
(312) 949-3450

## **HOSPITALIZED ACUTE HEART FAILURE PATIENTS MAY BENEFIT FROM ROLOFYLLINE**

### *New Agent May Interrupt ‘Vicious Cycle’ of Renal Dysfunction and Heart Failure*

**CHICAGO, IL** – Worsening renal function is a powerful predictor of poor outcomes in patients with acute heart failure. If it occurs during hospital admission, it is often associated with increased mortality, morbidity, increased length of stay, hospital readmission and increased post-discharge death. Chronic renal dysfunction in outpatients can precipitate heart failure, which in turn may worsen kidney dysfunction, thereby creating a true “vicious cycle.”

According to a study presented today at the American College of Cardiology’s 57<sup>th</sup> Annual Scientific Session (ACC.08), rolofylline, a new adenosine A<sub>1</sub>-receptor blocker, offers improved dyspnea and renal function, as well as fewer readmissions due to worsening heart failure. ACC.08 is the premier cardiovascular medical meeting, bringing together cardiologists and cardiovascular specialists to further breakthroughs in cardiovascular medicine.

In this pilot study, 305 patients who were hospitalized for acute decompensated heart failure and associated renal dysfunction were randomized to placebo, or to 10, 20 or 30 mg of intravenous Rolofylline. They were assigned to one of three outcome categories: “Success,” as evidenced by improved dyspnea; “Failure,” as evidenced by worsening heart failure, worsening renal function, heart failure readmission or death; or “Unchanged,” as determined by neither success or failure. The study also looked at change in renal function through day 14 after treatment, 60-day mortality, and hospital readmission for worsening heart failure.

- more -

Rolofylline at a dose of 30 mg was associated with a 44 percent increase in “Success” and a 40 percent decrease in treatment “Failures.” It was also associated with a trend toward reduction in the composite endpoint of 60-day mortality or readmission for cardiovascular or renal cause.

“More studies with Rolofylline are planned,” said lead author Barrie M. Massie, M.D., Professor of Medicine at the University of California, San Francisco, and Chief of the Cardiology Division at the San Francisco Veterans Affairs Medical Center. “This is a pilot study, although it included 305 patients. Our goal was to confirm the optimal dose of Rolofylline and to assess the feasibility and performance of our entry criteria and endpoints in advance of a definitive outcome trial. That trial, PROTECT, is ongoing and should be completed by early 2009. These results show that Rolofylline can improve treatment of acute heart failure, maintain renal function over the near term, and may decrease intermediate mortality and rehospitalizations. PROTECT hopefully will confirm these results.”

*Dr. Massie will present this study, “Effects of Rolofylline, a New Adenosine A1 Receptor Antagonist, on Symptoms, Renal Function and Outcomes in Patients with Acute Heart Failure: Results of the PROTECT Pilot Study” Tuesday, April 1 at 2:00p.m., in North Hall B1.*

###

The American College of Cardiology ([www.acc.org](http://www.acc.org)) represents the majority of board certified cardiovascular physicians in the United States. Its mission is to advocate for quality cardiovascular care through education, research, promotion, development and application of standards and guidelines- and to influence health care policy. ACC.08 is the largest cardiovascular meeting, bringing together cardiologists and cardiovascular specialists to share the newest discoveries in treatment and prevention, while helping the ACC achieve its mission to address and improve issues in cardiovascular medicine.