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## **PHASE III STUDY OF INVESTIGATIONAL TRILIPIX™ (SLV348/ABT-335), IN COMBINATION WITH ASTRAZENECA'S CRESTOR® MEETS PRIMARY ENDPOINTS ON KEY LIPIDS**

*TriLipix™ in combination with Crestor® improved LDL, HDL and Triglycerides  
and had reported safety consistent with monotherapies*

New Phase III data showed that in patients with multiple lipid problems, Solvay's & Abbott's investigational TriLipix™ (SLV348/ABT-335) combined with AstraZeneca's CRESTOR® (rosuvastatin calcium) led to greater improvements than the corresponding monotherapy in treating all three key lipids – LDL "bad" cholesterol, HDL "good" cholesterol and triglycerides. Results from this Phase III study were presented at the National Lipid Association's 2008 Scientific Sessions in Seattle.

According to the American Heart Association (AHA), more than 100 million American adults have elevated total cholesterol. Of the 30 million Americans currently on lipid-altering therapies, the majority are not reaching treatment goals. Treatment guidelines endorsed by the National Cholesterol Education Panel, the American College of Cardiology and the AHA have called for more aggressive management of lipids, including a lower LDL goal for many patients, as well as more aggressive management of HDL and triglycerides.

This study of more than 1,400 patients is part of the largest clinical program to date designed to evaluate the efficacy and safety of a fibrate in combination with statins. Data from the study showed that TriLipix in combination with rosuvastatin met its primary endpoints with significantly greater improvements in HDL and triglycerides compared to rosuvastatin alone, and significantly greater improvements in LDL compared to TriLipix alone. Both the combinations and rosuvastatin alone resulted in clinically meaningful reductions in LDL. In the clinical trial, TriLipix in combination with rosuvastatin was generally well tolerated, with reported safety similar to the monotherapies. No rhabdomyolysis (a rare muscle disorder) or unexpected liver, kidney or muscle safety issues were identified in this study.

"Patients with mixed dyslipidemia may need treatment options that address all these three key lipids," said Peter H. Jones, M.D., FACP, Methodist DeBakey Heart and Vascular Center, Houston, and a lead investigator of the trial. "Results from this study showed that TriLipix in combination with rosuvastatin significantly increased HDL, and decreased both LDL and triglycerides."

### **About the Study**

The efficacy and safety of TriLipix in combination with rosuvastatin was evaluated in a randomized, double-blind, controlled, 12-week, Phase III study of 1,445 patients with mixed dyslipidemia. Patients included in the study had multiple lipid problems, with an LDL greater than or equal to 130 mg/dL, triglycerides greater than or equal to 150 mg/dL and HDL less than 40 mg/dL for men and less than 50 mg/dL for women.

Patients were randomized to receive TriLipix (135mg) combined with either 10mg or 20mg of rosuvastatin, TriLipix monotherapy (135mg) or rosuvastatin monotherapy (10mg, 20mg or 40mg). The 40mg rosuvastatin monotherapy arm was included in the study to assess safety and adverse events, but was not included in the statistical analysis.

The primary efficacy comparisons were mean percent change in HDL and triglycerides in the combination compared to rosuvastatin monotherapy, and mean percent change in LDL in the combination compared to TriLipix monotherapy. The study met all of its primary endpoints. Patients treated with the combination of TriLipix 135mg and rosuvastatin 10mg had an increase in HDL of 20.3 percent and decrease in triglycerides of

47.1 percent compared to an HDL increase of 8.5 percent and triglyceride decrease of 24.4 percent with rosuvastatin 10mg alone. LDL decreased 37.2 percent with the combination compared to 6.5 percent with TriLipix 135mg monotherapy.

Patients treated with the combination of TriLipix 135mg and rosuvastatin 20mg had an increase in HDL of 19.0 percent and decrease in triglycerides of 42.9 percent compared to 10.3 percent and 25.6 percent, respectively, with rosuvastatin 20mg monotherapy. LDL decreased 38.8 percent with the combination compared to 6.5 percent with TriLipix 135mg monotherapy.

### **TriLipix Clinical Development Program**

TriLipix was studied alone and in combination with three of the most commonly prescribed statins (atorvastatin, simvastatin and rosuvastatin) in 2,698 patients with mixed dyslipidemia. The clinical program also includes a 52-week, long-term, open-label extension study. More than 2,200 patients were treated with TriLipix in combination with statins across the four studies.

“This large clinical program for TriLipix™ shows Solvay’s commitment, together with Abbott, to provide physicians with a wealth of data supporting a potential new treatment option to help manage lipids”, said Claus Steinborn, Executive Vice President, Global R&D.

### **About TriLipix (SLV348/ABT-335)**

TriLipix is an investigational new fenofibric acid molecule, currently in clinical development by Solvay and Abbott for treating patients with unhealthy lipid levels, including LDL cholesterol, triglycerides and HDL cholesterol. A New Drug Application (NDA) for TriLipix for use as monotherapy and in combination with statins has been submitted to the U.S. Food and Drug Administration (FDA). Abbott and AstraZeneca are working together to co-develop and market a fixed-dose combination of TriLipix and CRESTOR. The companies plan to submit an NDA to the FDA in 2009.

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