



Embargo: March 31, 2008 at 5:40 PM (Brussels Time)

## PHASE III STUDIES OF INVESTIGATIONAL TRILIPIX™ (SLV348/ABT-335), IN COMBINATION WITH STATINS, MEETS PRIMARY ENDPOINTS ON IMPROVING LDL, TRIGLYCERIDES AND HDL

*TriLipix™ in combination with statins improved all three key lipids and had reported safety consistent with TriLipix™ or statin monotherapies*

New data from two Phase III studies show that in patients with multiple lipid problems, SLV348/ABT-335 combined with two commonly prescribed statins (atorvastatin and simvastatin), significantly improved three key lipids – LDL "bad" cholesterol, triglycerides and HDL "good" cholesterol – compared to the corresponding monotherapies. Results were presented today at the American College of Cardiology (ACC) 57<sup>th</sup> Annual Scientific Sessions in Chicago. SLV348/ABT-335, an investigational new fenofibric acid molecule, co-developed by Solvay Pharmaceuticals and Abbott, will be known as TriLipix™.

Both TriLipix™ studies are part of the largest clinical program to date designed to evaluate the efficacy and safety of a fibrate in combination with statins. These studies using fenofibric acid in combination with atorvastatin and simvastatin met their primary endpoints. Combination therapy significantly improved HDL and triglycerides compared to statin therapy alone, and significantly improved LDL compared to TriLipix™ alone. Both the combinations and the two statins had clinically meaningful reductions in LDL. In the clinical trials, combination therapy was generally well tolerated, with reported safety similar to the monotherapies. No rhabdomyolysis or unexpected liver, kidney or muscle safety signals were identified.

"With more than 30 million Americans taking lipid-altering therapies and only one quarter of them reaching treatment goals, there is a clear need for more data to support combination treatment options," said Christie Ballantyne, M.D., the Methodist DeBakey Heart and Vascular Center, Houston, and investigator in the TriLipix™ studies. "Data from these two studies show that TriLipix™ in combination with atorvastatin or simvastatin improved all three key lipids – LDL, HDL and triglycerides – in patients with multiple lipid problems."

Treatment guidelines endorsed by the National Cholesterol Education Panel (NCEP), the ACC and the American Heart Association 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.

### **About the TriLipix™ Clinical Program**

The two studies being presented at the ACC conference are part of a broad clinical program to evaluate the efficacy and safety of TriLipix™ combined with statins. The efficacy and safety of TriLipix™ in combination with the three most commonly prescribed statins – rosuvastatin, atorvastatin and simvastatin – were evaluated in three, randomized, multi-center, double-blind, controlled, 12-week, Phase III studies, totaling 2,698 patients with mixed dyslipidemia. Patients included in the studies had multiple lipid problems, with an LDL greater than 130mg/dL, triglycerides greater than 150mg/dL and HDL less than 40mg/dL for men and less than 50mg/dL for women.

These studies, along with a 52-week long-term efficacy and safety open-label extension study of 1,911 patients, represent the largest program to date examining the efficacy and safety of a fibrate in combination with statins. More than 2,200 patients were treated with TriLipix™ in combination with statins across the four studies.

In the atorvastatin and simvastatin studies, presented at the ACC conference, 613 and 657 patients, respectively, were randomized to receive either TriLipix™ (135mg) combined with either 20mg or 40mg of the corresponding statin, TriLipix™ monotherapy (135mg) or statin monotherapy (20mg, 40mg or 80mg). The 80mg statin 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 pertained, firstly, to mean percent changes in HDL and triglycerides for the combination therapy versus a statin alone and, secondly, to mean percent change in LDL for the combination therapy versus TriLipix™ alone. Both studies met all of their primary endpoints, with the combinations resulting in significant improvements over the pre-specified monotherapies for all three key lipids – LDL, triglycerides and HDL.

Additional data supporting TriLipix™, including data from the Phase III trial evaluating TriLipix™ in combination with rosuvastatin in over 1,400 patients with mixed dyslipidemia, are planned for presentation at scientific forums throughout the year.

“This large clinical program for TriLipix™ shows Solvay’s commitment, together with Abbott, to provide physicians with clinical data to help support a potential new option for the treatment of dyslipidemia,” 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 for treating unhealthy lipid levels, including LDL cholesterol, triglycerides and HDL cholesterol. A New Drug Application for TriLipix™ for use as monotherapy or in combination with statins has been submitted by Abbott to the U.S. Food and Drug Administration in Q4 of 2007. Upon FDA approval, Solvay Pharmaceuticals will co-promote TriLipix™ with Abbott in the U.S.

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