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**SOLVAY WELCOMES FDA APPROVAL FOR TRILIPIX™ (FENOFIBRIC ACID),  
FIRST AND ONLY FIBRATE INDICATED FOR USE IN COMBINATION WITH A STATIN  
FOR CHOLESTEROL MANAGEMENT**

*New therapy in combination with a statin helped patients  
improve HDL and LDL cholesterol and triglycerides in clinical studies*

Solvay's and Abbott's TriLipix™ (fenofibric acid delayed-release capsules) was approved by the U.S. Food and Drug Administration (FDA) for use along with diet to help lower triglycerides and LDL cholesterol, and to raise HDL cholesterol in patients with lipid problems. TriLipix™ is the first and only fibrate to be approved for use in combination with a statin. In certain patients, treatment guidelines recommend the combination of a fibrate with a statin to further improve lipid levels. TriLipix has not been shown to prevent heart disease or heart attack.

"Only 35 percent of patients with lipid problems are currently being treated with lipid therapies and many are not reaching treatment targets for all three key lipids," said Michael Davidson, M.D., clinical professor and director of Preventive Cardiology, University of Chicago Pritzker School of Medicine. "The approval of TriLipix™ is good news for patients because now there is a new treatment option that can be used alone or in combination with a statin to help address lipid problems."

TriLipix™ was studied in 2,698 patients with mixed dyslipidemia, a disorder of all three key lipids affecting millions of American adults. In the TriLipix™ studies, mixed dyslipidemia was characterized by elevated LDL (bad cholesterol) and triglycerides (a type of fat found in the blood) and low HDL (good cholesterol). These studies demonstrated that TriLipix™ used in combination with the most commonly prescribed statins helped patients manage all three key lipids better than the corresponding therapies alone..

Treatment guidelines endorsed by the National Cholesterol Education Panel (NCEP), the American College of Cardiology 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.

TriLipix™ will be copromoted in the U.S. by Solvay Pharmaceuticals Inc and Abbott.

**About the TRILIPIX™ Clinical Trial Program**

The FDA's approval of TriLipix™ was based on the largest clinical trial program to date designed to evaluate the efficacy and safety of a fibrate in combination with various statins. The efficacy and safety of TriLipix™ in combination with the three most commonly prescribed statins – rosuvastatin, atorvastatin and simvastatin – was 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  $\geq$  130 mg/dL, triglycerides  $\geq$  150 mg/dL and HDL less than 40 mg/dL for men and less than 50 mg/dL for women. A total of 1,911 patients who completed one of the 12-weeks studies subsequently enrolled in a 52-week long-term, open-label extension study.

The Phase III combination studies all met their primary endpoints. Combination therapy significantly improved HDL and triglycerides compared to statin therapy alone, and significantly improved LDL compared to TRILIPIX™ alone. All of the combinations and the statins had clinically meaningful reductions in LDL.

"With TriLipix™ we continue to offer physicians solutions to help them manage their patients' lipid problems", said Claus Steinborn, M.D., Senior Executive Vice President, Global R&D. "The robust clinical program to support the use of TriLipix™ also shows Solvay's continuing commitment, together with Abbott, in the area of dyslipidemia treatments."

### **TRILIPIX™ Indications**

TriLipix is a prescription medication used along with diet in adults to lower triglycerides and LDL (bad) cholesterol, and increase HDL (good) cholesterol. TRILIPIX can be used alone or with another cholesterol-lowering medicine called a statin. TRILIPIX has not been shown to prevent heart disease or heart attack.

### **Important Safety Information About TRILIPIX™**

TriLipix should not be taken by people with liver, gallbladder, or severe kidney disease, nursing mothers, or those allergic to any product ingredient. Unexplained muscle pain, tenderness, or weakness may be a sign of a serious side effect and should be reported to a healthcare provider right away. Rarely, muscle-related problems can cause kidney damage. These side effects may be increased when TRILIPIX is used with a statin. Patients should tell their healthcare provider about all the medicines they take to help avoid serious side effects. Blood tests may be performed before and during treatment with TRILIPIX. Patients should contact their healthcare provider if they experience abdominal pain, nausea or vomiting while taking TRILIPIX. These may be signs of inflammation of the gallbladder or pancreas. Women who are pregnant should not take statins and should talk with their healthcare provider about TRILIPIX if they are pregnant or may become pregnant. The most common side effects with TRILIPIX include headache, heartburn, nausea, muscle aches and increases in muscle or liver enzymes that are measured by blood tests.

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*For further information please contact :*

**ERIK DE LEYE**  
Corporate Press Officer  
SOLVAY S.A.  
Tel: 32 2 509 7230  
[erik.deleye@solvay.com](mailto:erik.deleye@solvay.com)  
[www.solvaypress.com](http://www.solvaypress.com)

**Dr WERNER VAN DEN EYNDE**  
Pharmaceutical Communications  
SOLVAY PHARMACEUTICALS S.A.  
Tel: 32 2 509 6227  
[werner.vandeneynde@solvay.com](mailto:werner.vandeneynde@solvay.com)  
[www.solvaypharmaceuticals.com](http://www.solvaypharmaceuticals.com)

**PATRICK VERELST**  
Investor Relations  
SOLVAY S.A.  
Tel. 32 2 509 7243  
[patrick.verelst@solvay.com](mailto:patrick.verelst@solvay.com)  
[www.solvay-investors.com](http://www.solvay-investors.com)

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