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## **SOLVAY PHARMACEUTICALS AND WYETH ANNOUNCE SUBMISSION OF NEW DRUG APPLICATION FOR BIFEPRUNOX TO TREAT SCHIZOPHRENIA**

Solvay Pharmaceuticals, Inc. and Wyeth Pharmaceuticals, a division of Wyeth (NYSE:WYE), announce today that a New Drug Application (NDA) was submitted to the U.S. Food and Drug Administration (FDA) for bifeprunox, an investigational, new generation atypical antipsychotic for treatment and maintenance of stability of schizophrenic patients.

The NDA submission is based on safety and efficacy studies that evaluated bifeprunox for the treatment of schizophrenia in approximately 2,550 patients. Patients were evaluated with acute exacerbations for six weeks, and stable patients were evaluated for six months.

“The NDA submission of bifeprunox is an important milestone in our commitment to develop and commercialize compounds that potentially address the long-term treatment outcomes of patients with mental illnesses,” says Laurence Downey, M.D., President and CEO of Solvay Pharmaceuticals, Inc. “In addition to our research in schizophrenia, we’re also exploring treatments for other psychiatric disorders.”

“One recent U.S. government-sponsored study, CATIE (Clinical Antipsychotic Trials of Intervention Effectiveness), showed a significant need for new treatment options, especially over the long-term<sup>1</sup>,” says Joseph Camardo, M.D., Senior Vice President of Global Medical Affairs, Wyeth Pharmaceuticals. “We are pleased that our collaboration with Solvay Pharmaceuticals has resulted in an application with proposed indications for both initial therapy and maintenance, which is an important feature for an atypical antipsychotic.”

In March 2004, Solvay Pharmaceuticals and Wyeth entered into a collaboration agreement exclusively dedicated to neuroscience research and development. Under the terms of the agreement, the partners will codevelop and cocommercialize bifeprunox and two other compounds, currently known as SLV-313 and SLV-314, which are in earlier stages of development as treatments for schizophrenia, bipolar disorder, major depressive disorder with psychotic features and other indications.

### **About Schizophrenia**

Schizophrenia is a chronic form of psychosis that develops in approximately three million North Americans.<sup>2</sup> It is characterized by positive and negative symptoms such as hallucinations, delusions, poverty of speech, disorganized thought and emotional blunting.<sup>3</sup> Severity of the symptoms, and the long-term pattern of schizophrenia, often cause a high degree of disability for patients and place a burden on families, caregivers and communities.<sup>4</sup> Medications for schizophrenia can help reduce and control the distressing symptoms of the illness.<sup>5</sup>

**Solvay Pharmaceuticals, Inc.**, of Marietta, Georgia is the U.S. subsidiary of Solvay Pharmaceuticals. For more information, visit [www.solvaypharmaceuticals-us.com](http://www.solvaypharmaceuticals-us.com).

**Solvay Pharmaceuticals** is a research driven group of companies that constitute the global pharmaceutical business of the Solvay Group. The company seeks to fulfill carefully selected, unmet medical needs in the therapeutic areas of neuroscience, cardio-metabolic, influenza vaccines, gastroenterology, specialized markets and men's and women's health. Its 2005 sales were EUR 2.3 billion and it employs approximately 10,000 people worldwide. For more information, visit [www.solvaypharmaceuticals.com](http://www.solvaypharmaceuticals.com).

**SOLVAY** is an international chemical and pharmaceutical Group with headquarters in Brussels. It employs some 30,000 people in 50 countries. In 2005 its consolidated sales amounted to EUR 8.6 billion generated by its three activity sectors: Chemicals, Plastics and Pharmaceuticals. SOLVAY (Euronext : SOLB.BE - Bloomberg: SOLB.BB - Reuters: SOLBt.BR) is listed on the Euronext stock exchange in Brussels. Details are available at [www.solvay.com](http://www.solvay.com).

*For further information please contact :*

**SOLVAY S.A. Headquarters**

**Martial Tardy**

Corporate Press Officer

Telephone: 32/2/509.72.30

E-mail : [martial.tardy@solvay.com](mailto:martial.tardy@solvay.com)

Internet : [www.solvaypress.com](http://www.solvaypress.com)

**SOLVAY PHARMACEUTICALS**

**Neil Hirsch**

Manager, Public Affairs

Telephone: +1/770/578-2170

E-mail: [neil.hirsch@solvay.com](mailto:neil.hirsch@solvay.com)

[www.solvaypharmaceuticals-us.com](http://www.solvaypharmaceuticals-us.com)

**Puck Bossert**

Director, Pharmaceuticals Communications

Telephone: +31/294-477469

E-mail: [puck.bossert@solvay.com](mailto:puck.bossert@solvay.com)

**Patrick Verelst**

Investor Relations

Telephone: 32/2/509.72.43

E-mail : [patrick.verelst@solvay.com](mailto:patrick.verelst@solvay.com)

Internet: [www.solvay-investors.com](http://www.solvay-investors.com)

Ce communiqué de presse est également disponible en français –Dit persbericht is ook in het Nederlands beschikbaar

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<sup>1</sup> Lieberman J, et al. Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia. *New England Journal of Medicine*. 2005; 1209-1223.

<sup>2</sup> Pan American Health Organization and World Health Organization. *Mental health in the Americas: New challenges in a new millennium*. 35<sup>th</sup> session of the subcommittee on planning and programming. Washington, DC; 2001.

<sup>3</sup> American Psychiatric Association Work Group on Schizophrenia. Practice Guidelines for the Treatment of Patients with Schizophrenia. *Am J Psychiatry*. 1997;154:1-61.

<sup>4</sup> Rosenheck R, Cramer J, Jurgis G, et al. Clinical and psychopharmacologic factors influencing family burden in refractory schizophrenia. *J Clin Psychiatry*. 2000; 61:671-676.

<sup>5</sup> American Psychiatric Association Work Group on Schizophrenia. Practice Guidelines for the Treatment of Patients with Schizophrenia. *Am J Psychiatry*. 1997; 154:1-61.