U.S. **FDA** Approves **Labopharm** (DDS.TO)'s Antidepressant Trazodone
2/3/2010

LAVAL, QC and PRINCETON, NJ, Feb. 3 /PRNewswire-FirstCall/ - Labopharm Inc. (TSX: DDS; NASDAQ: DDSS) today announced the U.S. Food and Drug Administration (FDA) has approved OLEPTRO(TM) (trazodone hydrochloride) Extended Release Tablets, a novel once-daily formulation of the antidepressant trazodone, for the treatment of major depressive disorder (MDD) in adults. OLEPTRO(TM) utilizes CONTRAMID(R), Labopharm's clinically validated technology that controls the release of active substances within oral medications.

"OLEPTRO(TM) represents Labopharm's second CONTRAMID(R) technology-based product to receive FDA approval in just over a year," said James R. Howard-Tripp, President and Chief Executive Officer, Labopharm Inc. "We are excited about the opportunity for OLEPTRO(TM) and are preparing the product for launch into the $11 billion-plus U.S. antidepressant market. We are working towards finalizing a commercialization path for OLEPTRO(TM) that will maximize the value of our product in this market."

MDD is a common mental illness often characterized by a combination of social and somatic symptoms. It affects more than 14 million adults in the U.S. and is the leading cause of disability globally. OLEPTRO(TM) will offer physicians another therapeutic alternative for their MDD patients.

"There's a large body of evidence demonstrating the efficacy of trazodone in the treatment of MDD," said Dr. Stephen Stahl, Adjunct Professor of Psychiatry, University of California, San Diego School of Medicine. "Labopharm has developed a novel formulation of trazodone that effectively treats depression and provides a tolerable adverse event profile."

Labopharm is actively exploring several alternatives for the U.S. commercialization of OLEPTRO(TM). Such alternatives range from out-licensing the product to a distribution partner while retaining the right to some degree of co-promotion, through to a full co-promotion arrangement under which Labopharm would share the sales function with a partner. The Company currently expects to finalize the commercialization plan for OLEPTRO(TM) in the near term.

Labopharm expects OLEPTRO(TM) to be available for prescription in the U.S. later this year, with specific timing for its launch to be determined within the context of the final commercialization plan. The Company believes it is well advanced in its preparations for the U.S. launch of OLEPTRO(TM). The Company has completed market research with physicians and third-party payors, developed a positioning and marketing campaign for OLEPTRO(TM), and finalized product manufacturing and packaging arrangements.

About the OLEPTRO(TM) Pivotal Study

An eight-week randomized, double-blind, two-arm, multi-centre study in patients with unipolar major depressive disorder demonstrated OLEPTRO(TM)'s efficacy as a treatment for depression. The primary efficacy endpoint of the study was to compare the change in the Hamilton Rating Scale for Depression (HAMD-17) total score from baseline to the end of the study in the OLEPTRO(TM) group versus the placebo group. The results of this study, which are published in the May 2009 issue of Psychiatry, include the following:

- Statistical significance was achieved for the primary endpoint (p value of 0.012). - The overall discontinuation rate in the study was 25 percent with 21 percent in the placebo group and 30 percent in the OLEPTRO(TM) group. - In the OLEPTRO(TM) group, four percent of patients discontinued treatment due to somnolence or sedation.

"Our research in the clinical study leading up to FDA approval showed that OLEPTRO(TM) was well-tolerated and demonstrated a significantly greater improvement in the HAMD-17 primary efficacy end point over placebo," said Dr. David Sheehan, University Health Professor and Director of the Depression and Anxiety Disorders Research Institute, University of South Florida College of Medicine. "When given at the recommended daily dose range, OLEPTRO(TM) was an appropriate monotherapy for patients with MDD."

Labopharm will conduct a post-approval pediatric study. The FDA has asked Labopharm to provide data from a long-term maintenance study and an additional in-vitro alcohol dissolution study.

About Major Depressive Disorder

Approximately two times more prevalent in women than men, MDD often co-exists with other illnesses. Research shows that only approximately 65 percent of individuals with MDD are diagnosed and, of those patients, 90 percent are treated with medication.

Treating MDD with antidepressant medications is challenging for physicians because patient response to antidepressant drug therapy varies significantly. Research has shown that as many as 28 percent of patients being treated with antidepressants stop taking their medication within the first four weeks of treatment and as many as 44 percent stop within the first 12 weeks. Reasons for discontinuing antidepressant treatment can include suboptimal efficacy, the exacerbation of symptoms such as sleep disturbance, agitation, and sexual dysfunction, and adverse events such as weight gain.

The FDA's decision represents the first regulatory approval for Labopharm's novel, once-daily formulation of trazodone. The formulation is currently under regulatory review in Canada.

Important Safety Information About Treatment with OLEPTRO(TM)

For more complete information about the use of OLEPTRO(TM), please see the FDA-approved Prescribing Information and Medication Guide which will be posted on the FDA website (http://www.accessdata.fda.gov/Scripts/cder/DrugsatFDA/).

Black Box Warning Warning: Suicidality and Antidepressant Drugs See full prescribing information for complete boxed warning Increased risk of suicidal thinking and behavior in children, adolescents and young adults taking antidepressants for major depressive disorder (MDD) and other psychiatric disorders. OLEPTRO(TM) is not approved for use in pediatric patients.

Warning and Precautions

- Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behaviour, or unusual change in behaviour, whether or not they are taking antidepressant medications. Patients should be monitored for clinical worsening and suicidality and for the appearance of any of the following symptoms: anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia, hypomania, and mania. Families and caregivers should be alerted about the need to monitor patients. - The development of a potentially life-threatening serotonin syndrome, or neuroleptic malignant syndrome (NMS)-like reactions has been reported with antidepressants, and may occur with OLEPTRO(TM), particularly with concomitant use of other serotoninergic drugs. Treatment with OLEPTRO(TM) and any concomitant serotonergic or antidopaminergic agents, including antipsychotics, should be discontinued immediately and supportive treatment should be initiated. - A major depressive episode may be the initial presentation of bipolar disorder. Prior to initiating treatment, patients should be adequately screened to determine if they are at risk for bipolar disorder and monitored for mania/hypomania. OLEPTRO(TM) is not approved for use in treating bipolar depression. - Experience with administration of immediate-release trazodone products indicates that there may be an increased risk for QT interval prolongation. QT prolongation may lead to Torsades de pointes and even death especially in susceptible individuals, such as those with hypokalemia, hypomagnesemia, or a genetic predisposition to prolonged QT/QTc. - Patients with pre-existing cardiac disease may be at more risk for arrythmias. Concomitant administration of drugs that prolong the QT interval or that are inhibitors of CYP3A4 may increase the risk of cardiac arrhythmia in these patients. - Orthostatic hypotension and syncope have been reported in patients receiving trazodone hydrochloride. - Drugs that interfere with serotonin reuptake, including trazodone hydrochloride may increase the risk of bleeding events. Concomitant use with NSAIDs, aspirin, or other drugs that affect coagulation may compound this risk. - Serious, sometimes fatal, reactions have been reported when serotonergic drugs are used in combination with monoamine oxidase inhibitor(s). Therefore, OLEPTRO(TM) should not be used concomitantly or within 14 days of monoamine oxidase inhibitors. - Rarely, cases of priapism can occur in men receiving trazodone. OLEPTRO(TM) should be used with caution in men who have predisposing conditions. - There is a risk of hyponatremia when taking antidepressants. Elderly patients may be at greater risk, as well as patients taking diuretics or who are volume-depleted. - OLEPTRO(TM) has the potential to impair judgment, thinking, and motor skills. Advise patients to use caution before driving and when operating machinery. - Discontinuation symptoms may occur with abrupt discontinuation, and may include anxiety, agitation and sleep disturbance. Upon discontinuation, taper OLEPTRO(TM) and monitor for symptoms.

Adverse Reactions

The most common adverse reactions (incidence greater than or equal to five percent and twice that of placebo) are: somnolence/sedation, dizziness, constipation, blurred vision.

These are not all the possible adverse events of OLEPTRO(TM).

About Labopharm Inc.

Headquartered in Laval, Canada with US offices in Princeton, New Jersey, Labopharm is an emerging leader in optimizing the performance of existing small molecule drugs using its proprietary controlled-release technologies. The Company's lead product, a unique once-daily formulation of tramadol, is now available in 17 countries around the world, including the U.S., Canada, major European markets and Australia. Its second product, OLEPTRO(TM), a novel formulation of trazodone for the treatment of major depressive disorder in adults, has received regulatory approval in the U.S. and is under regulatory review in Canada. Labopharm has initiated the European regulatory approval process for its third product, a twice-daily formulation of tramadol-acetaminophen. The Company also has a pipeline of follow-on products in both pre-clinical and clinical development. Labopharm's vision is to become an integrated, international, specialty pharmaceutical company with the capability to internally develop and commercialize its own products. For more information, please visit www.labopharm.com.

This press release contains forward-looking statements, including statements concerning the market opportunity for OLEPTRO(TM), statements concerning partnering discussions and commercialization plan for OLEPTRO(TM), and statements concerning the Company's pipeline of product candidates, which reflect the Company's current expectations regarding future events. These forward-looking statements involve risks and uncertainties, many of which are beyond the Company's control. Actual events could differ materially from those projected herein and depend on a number of risks and uncertainties, including risks related to the Company's ability to complete a partnering transaction and the terms of any such collaboration, if any, risks related to the market acceptance of the Company's products and the speed of adoption by clinicians, risks related to intellectual property protection and potential infringement of third-party rights, risks related to research and development of pharmaceutical products and regulatory approvals, and risks associated with intense competition in the pharmaceutical industry generally. For additional disclosure regarding these and other risks faced by Labopharm Inc., see the disclosure contained in its public filings in the U.S. with the Securities and Exchange Commission (SEC) and in Canada with the Canadian Securities Administrators (CSA), available on the Investor Relations section of the Company's website at www.labopharm.com and on the SEC's website at www.sec.gov and on the CSA's website at www.sedar.com. Investors are cautioned not to place undue reliance on these forward-looking statements. Unless required by law, the Company undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events, or circumstances or otherwise.

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CONTRAMID(R) is a registered trademark of Labopharm Inc.

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