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**FDA Advisory Committee provides opinion on Serdolect® for the treatment of schizophrenia**

H. Lundbeck A/S (LUN.CO; LUN DC) announced today that the Psychopharmacology Drug Advisory Committee (PDAC) appointed by the U.S. Food and Drug Administration (FDA) voted unanimously that Serdolect® (sertindole) is efficacious in the treatment of patients with schizophrenia, though they did not find the data robust enough to support an additional regulatory claim related to treatment of suicidal behaviour in schizophrenia. The majority of the committee voted against its use in a broad schizophrenia population due to safety concerns, however a majority of the committee voted that there may be subpopulations in which the therapy is beneficial with appropriate labeling and risk management tools. Lundbeck will work closely with the agency to define the appropriate indication and risk management program to support approval of Serdolect®.

The FDA is not bound by the committee’s recommendation, but usually follows its advice. The target Prescription Drug User Fee Act (PDUFA) date for the Serdolect® application is May 15, 2009. If approved, Lundbeck Inc., the company’s wholly owned U.S. subsidiary, will market the product.

"We are pleased with the Advisory Committee’s recommendation in support of the efficacy of Serdolect® in the treatment of schizophrenia and the acknowledgement of its potential safe use in the right populations with appropriate risk management measures as it is important for patients to have multiple treatment options," said Executive Vice President Anders Gersel Pedersen, Head of Drug Development at Lundbeck. "There continues to be a significant unmet medical need for a less sedating treatment for people with schizophrenia who may experience impaired cognition with other existing therapies and for a medication to treat suicidality in schizophrenia. We will continue to work closely with the FDA as the agency moves toward an action on the new drug application for Serdolect®."

The committee reviewed comprehensive data from clinical trials. Results from short-term, double-blind, fixed-dose, placebo- and active-controlled studies demonstrated that Serdolect® was superior to placebo in treating the positive and negative symptoms associated with acute exacerbation of schizophrenia.

With nearly 10,000 patients and approximately 15,000 patient years of exposure, the Sertindole Cohort Prospective (SCoP) study showed that the all-cause mortality with Serdolect® was comparable to that with risperidone. During randomised treatment (only Serdolect® or risperidone), the all-cause mortality rate for Serdolect® was 0.63 deaths per 100 patient years, which was the same as that observed for risperidone.
The outcome of the SCoP study further confirmed that although a higher cardiovascular event rate is seen for patients treated with Serdolect®, the event rate related to arrhythmia remains very low.

**About Serdolect®**
Serdolect® has an inhibitory effect on central dopamine D2 and serotonin 5HT2 receptors as well as on alpha-adrenergic receptors. Serdolect® is an antipsychotic drug for the treatment of schizophrenia without sedative effect and with placebo level extrapyramidal symptoms (EPS). The safety and efficacy of Serdolect® have been studied extensively and the studies demonstrate that:

- Serdolect® reduces the positive and negative symptoms associated with acute exacerbation of schizophrenia.
- Data suggest that Serdolect® may reduce the risk of suicide and suicide attempt in patients with schizophrenia, including those at high risk of suicide.
- Serdolect® is well tolerated and non-sedating, and has a placebo-level incidence of EPS.
- Serdolect®'s effect on the QT interval is well characterised, non-clinically and clinically, and the risk of arrhythmia is low.
- The outcome of the SCoP study, a large, simple, randomised, mortality study, confirmed that all-cause mortality for Serdolect® in patients with schizophrenia is comparable to a standard treatment (risperidone).

The efficacy, tolerability and safety of Serdolect® has through daily clinical practice been characterised in more than 40,000 patient years exposure.

Serdolect® received marketing approval for the treatment of schizophrenia from the European Commission on 20 December 2005. Serdolect® is launched in 40 countries worldwide. It is not yet approved for use in the United States.

Serdolect® derives from Lundbeck's in-house research and the company holds the global rights.

**Important Safety Information**
Serdolect® (sertindole) has been shown to prolong the QT interval in a dose dependent manner. Some drugs that prolong the QT interval have been associated with the occurrence of Torsades de Pointes and with sudden unexplained death. Serdolect® is contraindicated in patients with a history of QT prolongation and in patients with clinically significant cardiovascular disease. Serdolect® should not be initiated in patients with a prolonged QT interval and should be discontinued in patients who are found to have persistent QTc measurements > 500 msec.

Serdolect® is also contraindicated in patients receiving drugs known to significantly prolong the QT interval, in patients treated with potent inhibitors of CYP3A, in patients with uncorrected hypokalemia and hypomagnesaemia and in patients with severe hepatic impairment. Increased mortality has been reported in elderly patients with dementia-related
psychosis who receive anti-psychotic agents. Neuroleptic malignant syndrome, tardive
dyskinesia, hyperglycemia and diabetes mellitus, orthostatic hypotension, seizures and
hyperprolactinemia have also been reported with Serdolect® use.

About schizophrenia
Schizophrenia is a serious and often chronic mental disorder affecting up to one percent of
the world's population. In many patients the disorders start during late adolescence or early
adulthood leading to severe changes in the patient's way of thinking and perceiving the
outside world.

During the course of the illness, periods during which the patient is in an acute psychotic
condition and suffering from definite hallucinations and delusions alternate with more stable
periods during which the patient experiences a significant reduction in symptoms. However,
even in stable periods, many patients have difficulty in establishing social contact, completing
an education programme or holding a normal job. Schizophrenia patients may have
significant difficulties in performing daily activities necessary for independent living. The
occurrence of suicide and suicidal behaviour is a major burden for patients, families and
society. Suicide is a leading cause of premature deaths among patients with schizophrenia.
Schizophrenia is also associated with increased medical morbidity like respiratory or
cardiovascular diseases which all contribute to a significantly lower life expectancy.

The disorder is often disabling and produces important emotional and financial hardship for
the patient and the patient's family. Furthermore, schizophrenia causes a major economic
burden to society, not only due to the direct treatment costs but also because of a reduced
ability to work forcing many patients to claim disability or pensions.

Financial guidance
Lundbeck expects to provide financial guidance in connection with the half-year report 2009
at the latest.
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About Lundbeck
H. Lundbeck A/S (LUN.CO, LUN DC, HLUKY) is an international pharmaceutical company engaged in the research and development, production, marketing and sale of pharmaceuticals for the treatment of psychiatric and neurological disorders. In 2008, the company's revenue was DKK 11.3 billion (approximately EUR 1.5 billion or USD 2.2 billion). The number of employees is approx 5,500 globally. For more information, please visit www.lundbeck.com.