



April 27, 2018

The Drug Committee of Ministry of Health, Labour and Welfare in Japan has accepted a 2-year extension of market exclusivity of Lexapro®

- 1 *A two-year extension of the reexamination period by the Japanese Ministry of Health, Labour and Welfare (MHLW) has been discussed and accepted in the First Committee on Drug of MHLW*
- 1 *The acceptance is based on the fact that clinical development on pediatrics will be conducted in order to meet the unmet needs of depression in pediatrics*
- 1 *Japanese anti-depressant market was valued at approximately DKK 9 billion in 2017*

Valby, Denmark, 27 April 2018 - H. Lundbeck A/S (Lundbeck) today announced that Lexapro® (escitalopram oxalate), which is distributed by Mochida Pharmaceutical Co., Ltd. (Mochida) and Mitsubishi Tanabe Pharma Corporation (Mitsubishi Tanabe) in Japan, is expected to receive a final confirmation of the extension of the eight-year market exclusivity by the Japanese Ministry of Health, Labour and Welfare (MHLW).

The First Committee on Drug of MHLW on 27 April discussed and accepted the extension. The acceptance of such extension was based on the fact that clinical development on pediatrics would be conducted in order to meet the unmet needs of depression in pediatrics. The extended exclusivity will provide Lexapro two years of additional protection in the depression indication beyond the previous date of 21 April 2019. The revised date is now 21 April 2021.

The Japanese antidepressant market

In 2017, the Japanese anti-depressant market had a value of approximately DKK 9 billion. The three most sold antidepressants in Japan in 2017 were duloxetine, mirtazapine, and Lexapro.

The number of people diagnosed with depression in Japan is increasing every year and is currently estimated to exceed one million. Escitalopram has been very well received by patients and doctors worldwide for the treatment of depression.

About Lexapro Japan

In May 2002, Lundbeck entered a license agreement with Mochida for the development and commercialization of escitalopram in Japan. In January 2010, Mochida announced that the company had signed an agreement to co-market escitalopram in Japan with Mitsubishi Tanabe. In April 2011, Lexapro was approved by the Japanese Ministry of Health, Labour and Welfare for depression and depressed state and was subsequently launched in August 2011. In November 2015, Lexapro received the approval of an additional indication, social anxiety disorder (SAD) from MHLW.

The financial terms of the agreement have not been disclosed, but Lundbeck receives royalties on sales.

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About H. Lundbeck A/S

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) is a global pharmaceutical company specialized in psychiatric and neurological disorders. For more than 70 years, we have been at the forefront of research within neuroscience. Our key areas of focus are Alzheimer's disease, depression, Parkinson's disease and schizophrenia.

Our approximately 5,000 employees in 55 countries are engaged in the entire value chain throughout research,

development, manufacturing, marketing and sales. Our pipeline consists of several late-stage development programmes and our products are available in more than 100 countries. We have production facilities in Denmark, France and Italy. Lundbeck generated revenue of DKK 17.2 billion in 2017 (EUR 2.3 billion; USD 2.6 billion).

For additional information, we encourage you to visit our corporate site www.lundbeck.com and connect with us on Twitter at @Lundbeck.

Safe Harbor/Forward-Looking Statements

The above information contains forward-looking statements that provide our expectations or forecasts of future events such as new product introductions, product approvals and financial performance.

Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations and it may cause any or all of our forward-looking statements here or in other publications to be wrong. Factors that may affect future results include interest rate and currency exchange rate fluctuations, delay or failure of development projects, production problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Lundbeck's products, introduction of competing products, Lundbeck's ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, and unexpected growth in costs and expenses.

Certain assumptions made by Lundbeck are required by Danish Securities Law for full disclosure of material corporate information. Some assumptions, including assumptions relating to sales associated with product that is prescribed for unapproved uses, are made taking into account past performances of other similar drugs for similar disease states or past performance of the same drug in other regions where the product is currently marketed. It is important to note that although physicians may, as part of their freedom to practice medicine in the US, prescribe approved drugs for any use they deem appropriate, including unapproved uses, at Lundbeck, promotion of unapproved uses is strictly prohibited.

Attachment

- | [Lundbeck Lexapro-Japan UK Final](#)