FDA Accepts Lundbeck Submission of New Drug Application for Intravenous Carbamazepine

Carbella™ (carbamazepine) Injection proposed as United States trade name

Deerfield, Ill. March 10, 2014 – Lundbeck LLC today announced that the U.S. Food and Drug Administration (FDA) has accepted for review a New Drug Application (NDA) for its investigational therapy intravenous carbamazepine, an intravenous formulation of the anti-epileptic drug (AED) carbamazepine. An action letter is anticipated before the end of 2014. Carbella™ is the proposed U.S. trade name for intravenous carbamazepine.

Oral carbamazepine is an important treatment option for people with epilepsy. However, intravenous carbamazepine formulations are currently not available for patients unable to take the medication by mouth. Intravenous carbamazepine received orphan drug designation from the U.S. FDA in 2013 and is proposed for use as replacement therapy in adults who are on a stable maintenance oral dose of carbamazepine to control certain seizure types, when oral carbamazepine administration is temporarily not feasible.

“Lundbeck has a long-term commitment to helping people with epilepsy, and today is an important milestone toward helping those who may need other options for receiving carbamazepine,” said Torsten Meldgaard Madsen, chief medical officer and vice president of Lundbeck’s US drug development. “We are proud of our portfolio of therapies for people living with epilepsy, and we hope to be able to provide intravenous carbamazepine as another important treatment option.”

About Lundbeck in the U.S.
Lundbeck in the U.S., headquartered in Deerfield, Illinois, is a wholly-owned subsidiary of H. Lundbeck A/S in Denmark. Lundbeck is committed to accelerating advances in brain disorders, including our work on therapies for people with challenging seizure disorders.

With a special commitment to the epilepsy community, Lundbeck actively supports and participates in hundreds of community-based initiatives each year. Learn more about our epilepsy community programs at http://www.lundbeck.com/us/our-commitment/community-involvement.

About H. Lundbeck A/S
H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) is a global pharmaceutical company specialized in brain diseases. For more than 50 years, we have been at the forefront of research within neuroscience. Our development and distribution of pioneering treatments continues to make a difference to people living with brain diseases. Our key areas of focus are alcohol dependence, Alzheimer’s disease, depression/anxiety, epilepsy, Huntington’s disease, Parkinson’s disease, schizophrenia and stroke.

Our nearly 6,000 employees in 57 countries are engaged in the entire value chain throughout research, development, production, marketing and sales, and are committed to improving the quality of life of people living with brain diseases. Our pipeline consists of several late-stage development programs and our products are available in more than 100 countries. We have research centers in China, Denmark and the United States, and production facilities in China, Denmark, France, Italy and Mexico. Lundbeck generated revenue of approximately DKK 15 billion in 2013 (EUR 2.0 billion; USD 2.7 billion).

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Sources

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