FDA Accepts Lundbeck Resubmission of New Drug Application for Carnexiv™ (carbamazepine)

Intravenous form of carbamazepine under FDA review for use in adults with certain seizure types who are unable to take their oral carbamazepine

Deerfield, Ill. April 22, 2016 – Lundbeck today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the resubmission of the New Drug Application (NDA) for intravenous carbamazepine, an intravenous formulation of the anti-epileptic drug (AED) carbamazepine. An action letter is anticipated before the end of 2016. Lundbeck's resubmission was in reply to the Complete Response Letter from the FDA issued in 2014 requesting additional data associated with the Chemistry, Manufacturing and Controls (CMC) of the product. The proposed U.S. trade name, Carnexiv™, is under consideration with the FDA as well.

Oral carbamazepine is an important treatment option for people with epilepsy. However, intravenous carbamazepine formulations are currently not available for patients who are unable to take the medication by mouth. Intravenous carbamazepine received orphan drug designation from the 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.

“As a company committed to helping people living with epilepsy, we have developed intravenous carbamazepine in the U.S. to address this unmet medical need,” said Daniele Bravi, Chief Medical Officer, U.S. Drug Development. “Intravenous carbamazepine could provide a valuable option for those who temporarily cannot take their oral carbamazepine.”

“Lundbeck has worked diligently to address the FDA’s request for additional CMC data, and we are pleased that the FDA has accepted our file for review,” added Gregg Pratt, Vice President of U.S. Regulatory Affairs.

About Lundbeck
Lundbeck 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 research focus are depression, schizophrenia, Parkinson's disease and Alzheimer's disease.

An estimated 700 million people worldwide are living with psychiatric and neurological disorders and far too many suffer due to inadequate treatment, discrimination, a reduced number of working days, early retirement and other unnecessary consequences. Every day, we strive for improved treatment and a better life for people living with psychiatric and neurological disorders — we call this Progress in Mind.

Our approximately 5,300 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 programs and our products are available in more than 100 countries. We have research centers in China and Denmark and production facilities in China, Denmark, France and Italy. Lundbeck generated core revenue of DKK 14.6 billion in 2015 (EUR 2 billion; USD 2.2 billion).

In the U.S., Lundbeck employs nearly 1,000 people focused solely on accelerating therapies for brain disorders, including epilepsy. With a special commitment to the lives of patients, families and caregivers, Lundbeck U.S. actively engages in hundreds of initiatives each year that support our patient communities.

To learn more, visit us at www.lundbeckus.com and connect with us on Twitter at @LundbeckUS.
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