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ASIA EDITION

Lumosa to initiate bridging study of analgesic injection in the US

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Lumosa Announces FDA Acceptance of IND Application for LT1001



Opioid misuse, addiction, and overdoses have caused significant social and economic burdens leading to the opioid crisis. LT1001 (brand name Naldebain®) is a prodrug of nalbuphine, an abuse-free analgesic that has been marketed worldwide for decades. Naldebain® is developed by Taiwan based biotech company Lumosa Therapeutics as the world's first extended-release analgesic injection for the relief of moderate/severe post-operative pain for 7 days without the side effects associated with opioids. Naldebain® was approved by the Taiwan Food and Drug Administration (TFDA) in March 2017.

A considerable amount of clinical data and use experience have accumulated since product launch. With confirmed safety and efficacy data of over 20 thousand users, Naldebain® is an attractive pain management solution for the opioid crisis.

To facilitate licensing negotiation and shorten the development time to market, Lumosa obtained consent from the US FDA in 2017 to allow the development of LT1001 through 505(b)(2) pathway, a development process with reduced number of human clinical trials required for the drug approval. The US FDA has recently accepted the IND (investigational new drug) application of the comparative bioavailability study.

Lumosa will initiate the study shortly to bridge the clinical data of LT1001 and nalbuphine in the US. The trial will fulfill the pre-market confirmatory trial required under the 505(b)(2) guideline. Subsequently, a confirmatory trial according to the 505(b)(2) pathway will be conducted before the submission of a new drug application (NDA) to the US FDA for marketing authorization approval.

Lumosa anticipates the enrollment of the pharmacokinetic study to be completed in the first half of 2020. In the meantime, licensing negotiation with potential US partners will take place in order to expedite the time to market for LT1001 and to compete in the US analgesics market. The completion of the bridging study would most likely speed up the licensing process. Lumosa has obtained patent protection up to 2035 in the US, with the patents in European Union, China, Japan and other

major pharmaceutical markets currently under review by the respective authorities.

The US prescription opioid sales volume in 2015 was calculated to be US$ 7.1 billion using the information listed in the white paper "FDA Analysis of Long-Term Trends in Opioid Analgesic Products: Quantity, Sales, and Price Trends," published in 2018 by the US FDA. The advantages and competitiveness of Naldebain® have drawn the interests of numerous prospective partners. Lumosa is actively engaged in licensing negotiations in various regions worldwide.