Sumitomo Pharma

Press Release

November 22, 2023

Sumitomo Pharma Co., Ltd.

Sumitomo Pharma Announces the Approval of XENLETA® (lefamulin acetate) for the Treatment of Community-Acquired Pneumonia in China

Sumitomo Pharma (Suzhou) Co., Ltd. ("Sumitomo Pharma (Suzhou)"), wholly-owned subsidiary of Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura; "Sumitomo Pharma") in China, announced today that Sumitomo Pharma (Suzhou) has received the notification on November 17, 2023 from the National Medical Products Administration (NMPA) that XENLETA® (generic name: lefamulin acetate) was approved in China for the treatment of adults with community-acquired pneumonia in the formulation of injection and tablet on November 14, 2023.

Sumitomo Pharma (Suzhou) plans to launch XENLETA® in China in the future, but the launch target is currently under consideration. Sumitomo Pharma (Suzhou) sells the carbapenem antibiotic preparation MEPEM® (sold in Japan as MEROPEN®). Through the approval in China for XENLETA®, Sumitomo Pharma expects to make a contribution to the treatment of patients with community-acquired pneumonia in China by offering XENLETA® as a new treatment option.

Reference

About XENLETA® (generic name: lefamulin acetate)

XENLETA® is a pleuromutilin antimicrobial agent discovered and developed by Nabriva Therapeutics plc (Head Office: Dublin, Ireland; "Nabriva Therapeutics"). It is a novel treatment for infectious diseases with a mechanism of action that differs from existing antibiotics, and is less likely to develop resistance and cross-resistance. XENLETA® is designed to inhibit the synthesis of bacterial protein, which is required for bacteria to grow. XENLETA®'s binding occurs with high affinity, high specificity and at molecular sites that are distinct from other antibiotic classes.

XENLETA® has been approved for the indication of bacterial community-acquired pneumonia in adults by the U.S. Food and Drug Administration (FDA), Health Canada and the European Commission (EC). It is currently being marketed in the United States under the brand name XENLETA®.

Sumitomo Pharma (Suzhou) obtained the exclusive development and commercialization rights of XENLETA® in Chinese mainland, Taiwan, Hong Kong, and Macau in May 2021. Subsequently, in July 2023, Sumitomo Pharma acquired the asset of XENLETA® in Chinese mainland, Taiwan, Hong Kong, and Macau from Nabriva Therapeutics.

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