

LINAPRAZAN GLURATE RECEIVES MARKETING APPROVAL IN CHINA

Cinclus Pharma, a clinical-stage pharmaceutical company developing molecules for the treatment of gastric acid-related diseases, today announced that its leading drug candidate, linaprazan glurate, has received its first marketing approval for the treatment of gastroesophageal reflux disease (GERD). The approval by the National Medical Products Administration (NMPA) paves the way for commercialization in the People's Republic of China in 2025.

The approved product was developed together with Cinclus Pharma's partner Jiangsu Sinorda Biomedicine Co., Ltd, ("Sinorda") in preclinical studies and independently developed in clinical phases in China by Sinorda. The approval of linaprazan glurate in China follows local clinical trials that demonstrated the drug's safety, efficacy, and ability to address a significant unmet need in GERD. Following the approval, pricing and reimbursement discussions will be initiated laying the foundation for expected product launch in China in 2025.

"We are thrilled to announce this highly significant marketing approval for linaprazan glurate in China, a market that represents an immense opportunity for expanding access to this innovative treatment. This achievement clearly reflects the strength of our partner Sinorda, our science, and takes us one important step closer to delivering a therapy meeting an unmet need in a global patient population," said Christer Ahlberg, CEO of Cinclus Pharma.

Cinclus Pharma has a license agreement with Sinorda for the development and commercialization of linaprazan glurate in China and other selected regions of Asia. Sinorda sub-licensed the manufacturing and industrial sales rights for linaprazan glurate in China, Hong Kong, Macau and Taiwan to SPH Sine Pharmaceutical Laboratories Co., Ltd, a company within the Shanghai Pharmaceuticals group, one of China's leading public pharmaceutical and healthcare companies.

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About Cinclus Pharma

Cinclus Pharma Holding AB (publ) is a late-stage clinical pharmaceutical company developing drugs for the treatment of acid-related diseases and disorders of the upper gastrointestinal tract. The company's leading drug candidate is linaprazan glurate, a prodrug of P-CAB linaprazan, which was originally developed by AstraZeneca. Linaprazan glurate has the potential to heal erosions in the esophageal mucosa and relieve symptoms of gastroesophageal reflux disease (GERD) more effectively than current treatments like proton pump inhibitors (PPI). The safety and efficacy of linaprazan and linaprazan glurate have been documented in over 30 phase I and two phase II studies involving more than 3,000 participants. Planning for phase III studies is currently underway, with an expected start in 2025. GERD affects approximately 133 million adults in the US and EU, and there is a significant need for new drugs to treat the most severe cases: around 10 million patients. Linaprazan glurate is developed to meet these needs. For more information, visit www.cincluspharma.com.

This information is information that Cinclus Pharma Holding AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2024-12-04 15:40 CET.

Attachments

Linaprazan glurate receives marketing approval in China