PRESS RELEASE

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Ascelia Pharma receives conditional FDA acceptance for brand name Orviglance

Ascelia Pharma AB (publ) (ticker: ACE) today announced that the U.S. Food and Drug Administration (FDA) has conditionally accepted Orviglance® as the proposed brand name for manganese chloride tetrahydrate (Mangoral), the company's novel first-in-class MRI contrast agent for use in liver MR imaging in adults with severely impaired kidney function.

The name Orviglance was developed in accordance with FDA's guidance for the submission and evaluation of proprietary names and the name selection included a research study of healthcare practitioners across the U.S. to ensure accurate prescription and safety interpretation of the name.

In addition, Orviglance previously received an invented name approval from the European Medicines Agency (EMA).

"This is yet another important step towards making Orviglance available to patients as our U.S. and global commercialization preparations progress. We continue to focus on the completion of the ongoing Phase 3 program and subsequent regulatory submission, approval and launch of this first-in-class MRI contrast agent", said Julie Waras Brogren, Chief Commercial Officer of Ascelia Pharma.

Orviglance (previously referred to as Mangoral), which entered pivotal clinical studies in 2020, has been granted an Orphan Drug Designation (ODD) by the FDA and is targeted patients with poor kidney function who undergo an MRI scan of the liver to detect cancer.

As part of the launch plans for Orviglance*, Ascelia Pharma opened its US office in New Jersey earlier this year.

**Trademark is registered in Europe and several other markets and submitted for registration in the US.*

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About Us

Ascelia Pharma is a biotech company focused on orphan oncology treatments. We develop and commercialize novel drugs that address unmet medical needs and have a clear development and market pathway. The company has two drug candidates – Mangoral and Oncoral – in clinical development. Ascelia Pharma has global headquarters in Malmö, Sweden, and is listed on Nasdaq Stockholm (ticker: ACE). For more information, please visit http://www.ascelia.com.

About Mangoral

Mangoral (manganese chloride tetrahydrate) is a novel oral contrast agent for MR-imaging developed to improve the detection and visualization of focal liver lesions (including liver metastases and primary tumors) in patients with reduced kidney function. These patients are at risk of serious side effects from the currently available class of gadolinium-based contrast agents. Mangoral, which has been granted an Orphan Drug Designation by the US Food and Drug Administration (FDA), is currently in Phase 3 development, including the global multi-center SPARKLE study.

About Oncoral

Oncoral is a novel irinotecan chemotherapy tablet developed initially for the treatment of gastric cancer. Irinotecan chemotherapy has an established potent anti-tumor effect. Oncoral is a daily tablet with the potential to offer better patient outcomes with improved safety following the daily dosing at home compared to intravenous high-dose infusions at the hospital. Following successful Phase 1 results, Oncoral is now prepared for Phase 2 clinical development.

Attachments

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