PRESS RELEASE

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Ascelia Pharma Announces Successful Final Results from Orviglance Hepatic Impairment Study

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced the final results of the Hepatic Impairment Study confirming that the company's lead drug candidate, the magnetic resonance imaging (MRI) contrast agent Orviglance®, is well tolerated in patients with hepatic impairment.

The reporting of final results for the Hepatic Impairment Study marks the completion of the second of three studies in the ongoing Phase 3 clinical program for registration of Orviglance, Ascelia Pharma's investigational MR-imaging agent used in the visualization and detection of cancer in the liver in patients with reduced kidney function. The previously announced Food Effect study successfully concluded that Orviglance image enhancement was not impacted by a light meal. The plan for the ongoing Phase 3 study, SPARKLE, required for a subsequent regulatory submission, is to complete patient enrollment by the end of this year. Data from the Hepatic Impairment Study will be included in the marketing authorization application to health authorities, including FDA and EMA.

As communicated earlier and in line with expectations, the results show that Orviglance is well tolerated in patients with liver (hepatic) impairment, with only mild to moderate transient, gastrointestinal adverse events reported, such as nausea. No new safety concerns were identified. The data confirmed there was no renal excretion of Orviglance, and that excretion is primarily occurring via the liver also in this subgroup of patients.

"We are very pleased with the outcome of the Hepatic Impairment Study, which is part of the ongoing phase 3 clinical program for Orviglance. These results show that Orviglance is well tolerated in patients with impaired liver function. The results add to our previous knowledge about the image enhancement that Orviglance provides to liver MRI by demonstrating potential utility also in patients with hepatic impairment. This is important since Orviglance is selectively taken up and excreted by the liver," said Carl Bjartmar, Chief Medical Officer of Ascelia Pharma.

The study was performed at the Texas Liver Institute in the US in patients with mild, moderate, or severe hepatic impairment, respectively, as defined by the Child-Pugh score. The volunteers were divided into three severity groups, each of which had 6 participants, who were matched to a control group with normal hepatic function.

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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 – Orviglance (previously referred to as 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 Orviglance (previously referred to as Mangoral)
Orviglance (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. Orviglance, 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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