PRESS RELEASE

25 April 2023 07:30:00 CEST

Hepatic Impairment Study Accepted for Presentation at Major Radiology and Liver Conferences

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced that data from the Hepatic Impairment Study with Orviglance® have been accepted as poster presentations at both the ESGAR and the EASL scientific congresses; both to be held in June 2023.

The safety and signal intensity of Ascelia Pharma's novel manganese-based liver-specific MRI contrast agent, Orviglance® (manganese chloride tetrahydrate), have been studied in adult subjects with mild, moderate, or severe hepatic impairment – the Hepatic Impairment Study.

Results from the study, which were announced in 2022, have now been accepted as poster presentations at both the European Society of Gastrointestinal and Abdominal Radiology (ESGAR) Annual Meeting and the European Association for the Study of the Liver (EASL) Congress; both to be held in June 2023.

As previously communicated, 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. The data suggests that Orviglance® can be used in patients with any degree of hepatic impairment.

"We are very pleased to share the outcome of the Hepatic Impairment Study with the medical community within both radiology and hepatology. We look forward to discussing Orviglance data and potential for use in clinical practice with medical experts at these conferences." said Andreas Norlin, Chief Scientific Officer of Ascelia Pharma.

Presentation details

- Title: 'Safety and signal intensity of a novel liver-specific MRI contrast agent, Orviglance® (manganese chloride tetrahydrate), in adult subjects with mild, moderate, or severe hepatic impairment'

Conference details:

- The ESGAR Annual Meeting 2023 is to be held in Valencia, Spain from 13 to 16 June 2023.
    - Time of poster presentation: 13 June 2023; 9:00 - 18:00
- The EASL Congress 2023 is to be held in Vienna, Austria from 21 to 24 June 2023.
    - Time of poster presentation: 23 June 2023; 9:00 - 18:00

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.

Data from the Hepatic Impairment Study will be included in the marketing authorization application to health authorities, including the FDA and EMA.

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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, has been granted an Orphan Drug Designation by the US Food and Drug Administration (FDA). A pivotal clinical program of nine studies, including the global Phase 3 study SPARKLE, have been completed. Headline results from the Phase 3 study are expected mid-2023.

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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