PRESS RELEASE

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ASCELIA PHARMA PRESENTS RESULTS OF ORVIGLANCE FOOD EFFECT STUDY AT RSNA 2022 SHOWING STRONG LIVER ENHANCEMENT BOTH WITH LIGHT MEAL AND IN FASTING CONDITION

30 November 2022: Ascelia Pharma AB (publ) – a biopharmaceutical company focused on improving the life of people living with rare cancer conditions – is presenting results from its Orviglance* Food Effect study at the RSNA conference 2022– 27 November – 1 December Chicago, Illinois). The study evaluates the effect of food intake on the absorption and signal intensity of Orviglance, a manganese-based MRI contrast agent, and successfully concludes that image enhancement is not impacted by a light meal.

The Food Effect Study results show that intake of a light meal within 30 min prior to Orviglance administration provides similar image MRI enhancement of the liver compared to a fasting condition. In line with previous studies, the data also confirms strong image enhancement of the liver after Orviglance administration compared to an MRI image without a contrast agent. In clinical practice, the results support administration of Orviglance both after fasting or after consumption of a light meal.

The reporting of these final results for the Food Effect Study completes two of the three studies in Ascelia Pharma's ongoing Phase 3 clinical program for registration of Orviglance. As previously announced, the Hepatic Impairment Study successfully concluded that Orviglance is well tolerated in patients with liver (hepatic) impairment. The plan for the ongoing Phase 3 study, SPARKLE, required for regulatory submission, is to complete patient enrolment by the end of this year.

Magnus Corfitzen, CEO at Ascelia Pharma, said: "We are very pleased to be presenting the study as an oral presentation at the Radiological Society of North America's radiology conference, RSNA. The possibility for omitting a fasting condition improves the convenience for patients and eases the administration of Orviglance in clinical practice. Orviglance is being developed to address the unmet medical need of patients with poor kidney function who require liver imaging, and it is very encouraging that the study results support previous findings on the ability of Orviglance to provide strong image enhancement to liver MRI scans."

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

The Orviglance Food Effect study will be presented by Dr. Kohkan Shamsi at the RSNA on Wednesday, 30 November 2022 at 3,00pm ET.

For more information, visit www.ascelia.com.

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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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