PRESS RELEASE

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Ascelia Pharma presented Orviglance Hepatic Impairment Data and hosted a Q&A with liver imaging experts at the 2023 ESGAR Annual Meeting

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 company's Hepatic Impairment Study were presented at the European Society of Gastrointestinal and Abdominal Radiology (ESGAR) Annual Meeting in Valencia, Spain, June 13-16, 2023. The company also hosted Q&A session with experts to discuss liver imaging and the unmet need for patients with severe kidney impairment. The Q&A is now available online at https://www.ascelia.com/.

The results from the Hepatic Impairment Study were presented at the ESGAR Annual Meeting, with a poster titled *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*.

As previously communicated, the results of the Hepatic Impairment Study showed 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 suggest that Orviglance can be used in patients with any degree of hepatic impairment.

Ascelia Pharma also hosted a Q&A session during ESGAR with two experts in liver imaging, Dr. Nikolaos Kartalis of Department of Radiology Huddinge, Karolinska University Hospital, and Dr. Alessandro Furlan of Radiology, Abdominal Imaging Division of University of Pittsburg Medical Center.

"We are honored to have been given the opportunity to chair this debate on liver imaging and unmet needs for patients with two of the leading key experts in liver imaging and to share with the medical community that Orviglance has the potential to also be used in patients with any degree of hepatic impairment, said Julie Waras Brogren, Deputy CEO and CCO of Ascelia Pharma. "These are part of the steps preparing us for launching Orviglance. The first step is our headline results from SPARKLE, the pivotal Phase 3 study for Orviglance. We are on track for announcing results during the middle of this year," she continued.

In the Q&A session, moderated by Director of Global Medical Affairs at Ascelia Pharma, Dr. Nadilka Hettiarachchige, Dr. Kartalis and Dr. Furlan discussed the role of liver imaging in cancer care, the clinical practice for patients with severe kidney impairment and the trends ahead.

“With the improvement of the treatment and introduction of new treatment methods… we have a tendency to see these patients quite often. So, we follow these patients; we see them many times”, said Dr. Kartalis.

Dr. Furlan added: “It’s not infrequent to find patients that on top of having metastatic disease also have impaired renal function. In my institution, for patients that have reduced renal function, we would reduce the amount of gadolinium that we inject, since we still do not have an alternative - a non-gadolinium-based contrast agent that we can use”, and continued “we don’t have that yet in the market, but it would certainly be a great tool to have in our box”.

The video is available on the website of Ascelia Pharma at **https://www.ascelia.com**/ along side our updated company presentation.

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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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