PRESS RELEASE

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Ascelia Pharma achieves Last Patient Last Visit (LPLV) in the Orviglance Phase 3 SPARKLE Study which now includes 85 completed patients.

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced that the Last Patient Last Visit (LPLV) has now been completed and 85 patients in total have successfully completed the pivotal phase 3 clinical study SPARKLE with the lead candidate drug Orviglance®.

"As previously communicated, we expected the final number of patients included in the SPARKLE study to be slightly above 80 as patients who had already consented to participate would be allowed to complete the study. I'm pleased to announce today that 85 patients have completed the study. Reaching LPLV for SPARKLE is a big and important step in the clinical process, and we look forward to sharing the study data as soon as the analysis of images and data are complete", said Jennie Wilborgsson, VP, Clinical Development of Ascelia Pharma.

Next step will be the evaluation of the magnetic resonance imaging (MRI) images by independent radiologists as required by regulatory standards and in the study protocol. The headline results from the SPARKLE study are expected in mid-2023.

"This is a major milestone for Ascelia Pharma, and we look forward to the next steps and ultimately be able to bring Orviglance through the regulatory process and make it available to patients for whom the use of gadolinium-based products may be medically inadvisable", said Magnus Corfitzen, CEO of Ascelia Pharma.

About the SPARKLE study
The global multi-center SPARKLE study aims to demonstrate that Orviglance improves the detection and visualization of focal liver lesions, including liver metastases and primary tumors, in patients with severe kidney impairment. It is the last of nine studies in the extensive clinical development program for Orviglance, which will enable Ascelia Pharma to complete a New Drug Application (NDA) submission to the FDA.

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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.

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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