PRESS RELEASE

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Ascelia Pharma meets major milestone with patient enrollment completion for Orviglance Phase 3 Study, SPARKLE

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced the successful completion of the patient enrollment in the company's pivotal phase 3 clinical study SPARKLE with the lead candidate drug Orviglance®.

"We are very pleased to have reached our enrollment target of 80 patients in the SPARKLE study within our recently updated timelines. This is a major milestone in the history of Ascelia Pharma and a key step on the journey to making Orviglance available to patients around the world. The headline results from this pivotal study are expected in mid-2023", said Magnus Corfitzen, CEO of Ascelia Pharma.

Orviglance, which has been granted an Orphan Drug Designation by the US Food and Drug Administration (FDA), is the first contrast agent in development for use in liver magnetic resonance imaging (MRI) in patients with severely impaired kidney function. These patients have the highest risk of developing the serious and potentially fatal condition Nephrogenic Systemic Fibrosis (NSF) after exposure to the currently available gadolinium-based contrast agents. For this reason, regulatory bodies have issued warnings for their use in this patient population.

The 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.

"On behalf of the entire Ascelia Pharma team, I would like to thank patients, investigators, and other collaborators who have been involved in SPARKLE. We have succeeded in enrolling 80 patients in a rare disease clinical study under highly challenging circumstances, including a global pandemic and the invasion of Ukraine. Based on strong results in earlier clinical studies, we are optimistic of a positive outcome of SPARKLE and look forward to the next steps in bringing Orviglance through the regulatory process and making it available to patients for whom the use of gadolinium-based products may be medically inadvisable", said Magnus Corfitzen.

Patient screening and enrollment in SPARKLE will now be stopped, although a few patients who have already consented will be allowed to complete their participation in the study. The final number of patients in SPARKLE is therefore expected to be slightly above 80. The focus will now switch to evaluation of the MRI images by independent radiologists as required by regulatory standards and in the study protocol.

The SPARKLE study 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.

Orviglance aims to give cancer patients with poor kidney function access to safe and effective liver imaging to live longer and healthier lives. The unmet need for these patients represents an addressable market potential of USD 500-600 million in the US, Europe and Japan.

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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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