

65 patients have completed the SPARKLE study

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced that by December 29, 2022, 65 patients have completed the pivotal Phase 3 clinical SPARKLE study with the lead candidate drug Orviglance.

On December 6, 2022, Ascelia Pharma announced that 58 patients had completed the SPARKLE study, which will include 80 patients in total. Since this announcement, 7 more patients have completed the study. The company expects to complete patient enrollment by February/March 2023 with topline results by mid-2023.

The SPARKLE study is the third and last of three clinical studies that form the Phase 3 program for Orviglance, the company's orphan liver imaging agent.

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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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