PRESS RELEASE

07 March 2022 18:39:00 CET

Ascelia Pharma suspends clinical activities in Russia

Ascelia Pharma AB (publ) (ticker: ACE) today announced that due to the Russian invasion of Ukraine, all clinical activities in Russia in the ongoing Phase 3 study SPARKLE are being suspended. As a consequence, the expected recruitment completion for the SPARKLE study is extended to 2022 (previously H1 2022).

The consequences of Russia's invasion of Ukraine are both grave and concerning. Because of the escalating situation, Ascelia Pharma has decided to suspend all clinical activities, including patient enrolment, in Russia. We are mindful of the patients and the Russian medical staff with whom we have worked with.

Ascelia Pharma is committed to completing the SPARKLE study as fast as possible. We are working with the already active study hospitals to accelerate enrolment as well as expanding the number of participating hospitals.

Among the 47 clinical sites currently open in the SPARKLE study globally, 13 are located in Russia. The decision to suspend clinical activities in Russia may extend the timeline for completing patient recruitment in the study. The expected recruitment completion is therefore extended to 2022 (previously H1 2022). As previously communicated, Ascelia Pharma has sufficient financing to complete the SPARKLE study.

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This information is information that Ascelia Pharma is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2022-03-07 18:39 CET.

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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