PRESS RELEASE

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Ascelia Pharma Reports SPARKLE Image Reading Completion and Expects Headline Results First Half of May 2024

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced that the SPARKLE image reading by the independent readers has been successfully completed as planned. Headline results for the pivotal SPARKLE Phase 3 study of the orphan diagnostic drug candidate Orviglance® are now expected during the first half of May 2024 .

As part of the ongoing Phase 3 study SPARKLE image re-evaluation, the independent readers have completed the reading of all images according to plan. The image reading phase has therefore now been successfully completed. The final steps of the re-evaluation include data quality control and statistical analysis conducted by third parties.

The re-evaluation is on track for Ascelia Pharma to receive and report headline results by the first half of May 2024, which is in the beginning of the previously guided period.

Ascelia Pharma successfully completed patient enrollment in the Phase 3 study for Orviglance in March 2023. In early August, it was discovered that high intra-reader variability in the study image scoring by the independent radiologists prevented evaluation of the efficacy data from SPARKLE. Due to this finding, a new evaluation of the images with new independent readers was decided and is now underway. The purpose of the re-evaluation of the SPARKLE images is to obtain a scientifically valid and reliable efficacy result from the SPARKLE study. A positive result would together with the other available data support a regulatory approval for Orviglance.

“I am very pleased that the image re-evaluation has progressed according to our timelines. The image reading phase is a critical part of the re-evaluation and is now behind us. We all look forward to executing on the opportunities ahead for Ascelia Pharma – starting with the announcement of headline results during the first half of May 2024”, says Magnus Corfitzen, CEO Ascelia Pharma.

Orviglance has been granted an Orphan Drug Designation by the US Food and Drug Administration (FDA) for liver imaging in patients with severely impaired kidney function. With Orviglance, these patients can gain access to effective liver imaging without gadolinium-related safety risks. The unmet need for these patients represents an addressable market potential of USD 800 million globally; almost half of which is in the US.

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 clinical program of nine studies, including the pivotal global Phase 3 study SPARKLE, has been completed. Results from the Phase 3 study are not yet available.

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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