PRESS RELEASE

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Re-Evaluation Required After Intra-Reader Inconsistency in Scoring of Images from 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 reported the need for a re-evaluation of the collected images in the pivotal Phase 3 study SPARKLE with the liver imaging candidate drug Orviglance®. As per FDA guidance, a pre-defined number of patients were evaluated twice. This showed a high level of variability in the evaluation of images by some readers, which necessitates a re-evaluation of all images by a new group of independent radiology readers. Investors and analysts are invited to a presentation and Q&A session on Tuesday, August 8 at 08:00 CEST.

- The event can be accessed via the following link: Ascelia Pharma Investor Update SPARKLE Re-Evaluation Required
- Orviglance is in development as a first-in-class contrast agent for use in liver MRI in patients with impaired kidney function
- Orviglance has been granted FDA Orphan Drug Designation
- Patient recruitment and data collection for the Phase 3 data has successfully been completed
- All activities and resources are now fully focused on the re-evaluation
- A timeline and financial implications for the re-evaluation will be presented by mid-September

Ascelia Pharma completed the global multi-center SPARKLE study in early March 2023 with MRI data from 85 completed patients. Since then, the MRI images have been read and evaluated by three independent radiologists as required by regulatory standards.

During the evaluation of headline data, the company identified a high level of inconsistency in the image scoring by some individual readers, i.e., intra-reader variability. Intra-reader variability occurs when a reader reports different scores for the same image when seen at a different time point. This finding means that data from SPARKLE cannot be reported based on the performed reading.

The patient recruitment and collection and transfer of MR images to the central database has been correctly performed and the company does not see a need for a new clinical study.

Common adverse events in the SPARKLE study were in line with previous studies with Orviglance, such as mild to moderate nausea. No drug related serious adverse reactions were reported.

“It is highly unexpected that we cannot conclude on the efficacy of Orviglance based on the image evaluation by the blinded readers due to the low level of intra-reader consistency for some of the readers,” said Magnus Corfitzen, CEO of Ascelia Pharma.

“Our confidence in positive data for SPARKLE is unchanged and we are dedicated to making Orviglance available for the patients in need of a gadolinium free liver imaging agent”, he continued.

All efforts and resources in Ascelia Pharma will now be focused on planning and executing a re-evaluation of the images from SPARKLE. This includes a dialogue with the FDA. As a consequence, activities not related to the re-evaluation will be postponed and cost-saving initiatives will be taken. In mid-September, we will communicate a timeline and financial implications for the completion of the re-evaluation.

Ascelia Pharma invites investors, analysts and media to a presentation and Q&A session on Tuesday, August 8 at 08:00h CEST. The event can be accessed via the following link: **Ascelia Pharma Investor Update SPARKLE Re-Evaluation Required**

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This information was submitted for publication, through the agency of the contact persons set out above.

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.

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 2023-08-07 23:33 CEST.

Attachments

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