PRESS RELEASE

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Ascelia Pharma provides clarifications around the intra-reader variability in read-out of images in the SPARKLE study

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today provided clarifications around intra-reader variability in scoring of images from the pivotal Phase 3 study SPARKLE with the liver imaging candidate drug Orviglance®.

Based on the questions Ascelia Pharma received after the announcement on August 8, 2023, the company would like to provide the following clarification to support the understanding of the issue with intra-reader variability in scoring of images.

- The two readers with high level of intra-reader variability had variability in **all** image series. The high level of intra-reader variability was also seen in the unenhanced images.
- When measuring effects in clinical trials, it is critical that the method of measurement can be trusted. FDA guidance for ensuring this in imaging studies is to examine how much individual readers vary their evaluation of the same set of images at two different time points. Small differences (low intra-reader variability) are expected and considered acceptable, but when the difference is large (high intra-reader variability), it is considered unacceptable, and hence the data cannot be used to generate a result.
- With a high level of intra-reader variability, we do not know the true values which can be used for analysis of the data.

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.

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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

Ascelia Pharma provides clarifications around the intra-reader variability in read-out of images in the SPARKLE study