PRESS RELEASE

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Ascelia Pharma Announces Start of Image Reading Phase and Re-confirms Phase 3 SPARKLE Results by 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 image reading phase has started as planned and re-confirms the May 2024 timeline for headline results from SPARKLE, the pivotal Phase 3 study for the orphan diagnostic drug candidate Orviglance®. Interaction with the FDA has not led to changes in the plans for the re-evaluation.

As part of the preparations for the SPARKLE image re-evaluation, the new independent readers have successfully completed the training program according to plan. The image reading process has now started and the first patient images have been evaluated. The re-evaluation is on track to report headline results by May 2024, as previously communicated.

Ascelia Pharma has also interacted with the FDA in relation to the need for a re-evaluation. Based on this, no changes to the re-evaluation process were made.

“The most important factors for obtaining consistent results are the selection and training of readers, and the scheduling and monitoring of the image reading flow. In the re-evaluation, we have diligently developed these elements to ensure that reliable results will be obtained by May 2024”, says Andreas Norlin, CSO of Ascelia Pharma.

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 result from the SPARKLE study. A positive result would together with the other available data support a regulatory approval for Orviglance.

“We are dedicated to making Orviglance available for cancer patients with kidney impairment. Today’s announcement marks an important milestone towards being able to report efficacy results from SPARKLE. The planning and preparation phase of the re-evaluation is now completed, and the start of the image reading puts us on track for reporting results by May next year”, says Magnus Corfitzen, CEO of Ascelia Pharma.

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About us

About Ascelia Pharma

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® (Mangoral) and Oncoral – in clinical development. Ascelia Pharma has its global headquarters in Malmö, Sweden, and is listed on Nasdaq Stockholm (ticker: ACE). For more information, please visit www.ascelia.com.

About Orviglance

Orviglance (manganese chloride tetrahydrate) is a novel oral contrast agent for magnetic resonance imaging (MRI) 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.

Attachments

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