PRESS RELEASE

13 September 2023 16:00:00 CEST

Ascelia Pharma to Reach Headline Results from SPARKLE Re-Evaluation by May 2024 with Current Funding

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced the plan to complete, by May 2024, the required re-evaluation of images from the Phase 3 Study SPARKLE with the orphan drug candidate Orviglance, which is in development as a first-in-class contrast agent for use in liver MRI in patients with impaired kidney function. The re-evaluation can be completed with the company's currently available funding, while the commercialization strategy is expanded to also consider launching Orviglance in the US with a partner.

- Headline data from the re-evaluation of SPARKLE is expected by May 2024
- Headline data can be reached with current funding, with a runway into Q3 2024
- The commercialization strategy for Orviglance is expanded to also consider partnership opportunities for launch in the US

Ascelia Pharma has now completed the plan for the required re-evaluation of SPARKLE images. In the new plan, headline results from SPARKLE are expected by May 2024.

The headline results milestone can be reached with the company's currently available funding. In order to focus all resources and activities on the SPARKLE image re-evaluation, cost cutting initiatives have been taken, including a significant reduction of the organization, which was announced at the end of August. These initiatives extend the company's cash runway into Q3 2024.

"While the need to complete a re-evaluation of images from our SPARKLE study was unexpected, we are pleased that we now have clarity on what is required and how long it will take to reach headline results. Our entire team is focused on executing this plan and dedicated to ensuring the delivery of robust and conclusive results by May next year. We look forward to bringing Orviglance to patients in need and continue to have confidence in the commercial opportunity." said Magnus Corfitzen, CEO of Ascelia Pharma.

Ascelia Pharma completed the global multi-center SPARKLE study in early March 2023 with MRI data from 85 patients. During the evaluation of headline data in August 2023, the company identified a high level of inconsistency in the image scoring by two of the three individual readers, i.e., intra-reader variability. Intra-reader variability occurs when a reader reports different scores for the same image when seen twice at a different time point. The collection of MR images was correctly performed, and the company does not see a need for a new clinical study.

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. Orviglance aims to provide these patients with 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.

“Until now the commercial strategy has been focused on building our own launch organization in the US with selected outsourced operations. In light of the new timeline for Orviglance development, we now expand the commercialization strategy to also consider partnership opportunities for launch in the US,” said Julie Waras Brogren, Deputy CEO & Chief Commercial Officer.

Our confidence in the commercial potential of Orviglance is unchanged, but having a partner would significantly reduce our investments in the launch”, she continues.

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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

Ascelia Pharma to Reach Headline Results from SPARKLE Re-Evaluation by May 2024 with Current Funding