PRESS RELEASE

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Welcome to Ascelia Pharma Investor Update: Bringing Orviglance to Patients

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today welcomes investors, analysts and media to the virtual update and live Q&A, where executive management further explains the strong Phase 3 headline results and plans for the upcoming regulatory and commercialization activities. Presentations are available on the Company's website and the live Q&A starts on Tuesday, 7 May at 14:00 CEST.

The online presentations and live event are available from this link and on the company's website (www.ascelia.com).

The pivotal Phase 3 study for Orviglance, SPARKLE, successfully met the primary endpoint and demonstrated that the company's magnetic resonance imaging (MRI) contrast agent, Orviglance significantly improved the visualization of focal liver lesions compared to unenhanced MRI. The results for all three readers had high statistical significance (P values <0.001).

These positive headline results from SPARKLE conclude clinical development of Orviglance with consistent positive efficacy and safety data from nine clinical studies with a total of 286 patients and healthy volunteers.

The Company will now focus on bringing Orviglance through the regulatory submission and approval process. In parallel, we will continue to advance launch readiness and dialogue with potential commercialization partners to make Orviglance available to patients who need high-quality liver imaging without gadolinium-related safety risk.

In the Investor Update executive management:

- Further explains the strong headline results
- Shares plans for the upcoming regulatory and commercialization activities
- Outlines value creation opportunities ahead for Ascelia Pharma

The following presentations are available in the Investor Update online:

Take Ascelia Pharma to the Next Level
Magnus Corfitzen, CEO shares his view on the strong headline results from SPARKLE and provides an overview of key next steps and milestones.

Our objective is to reach a timely submission and approval by the US FDA as an orphan drug with an optimal label for use in the target population. As we move our focus to the regulatory submission and approval, we will in parallel continue to advance launch readiness and our dialogue with potential commercialization partners,

“Ascelia has met another major milestone, and we look forward to meeting the next milestones on our journey to making Orviglance available to patients and transforming Ascelia to a commercial stage company”, he says.

Advance Orviglance from Phase 3 to Approval
CSO Andreas Norlin, explains the strong Phase 3 headline results where three out of three readers scored primary visualization variables significantly higher with Orviglance than without. These positive results mark the successful completion of clinical development for Orviglance.

The Company expects to submit the NDA file for FDA regulatory approval by mid-2025. The focus of the Company is now on completing preparations required prior to submission. These include:

- Full Clinical Study Report early Q4 2024
- Conclusions from FDA pre-submission meeting by Q1 2025

Progress Commercialization Readiness
Julie Waras Brogren, Deputy CEO describes how Orviglance aims to give patients with impaired kidney function access to safe and effective liver imaging to live longer and healthier lives. The unmet need for these patients represents an addressable market potential of USD 800 million globally.

The strategy, based on extensive market research, is in place for a focused, ambitious launch for a well-defined vulnerable patient population. The focus ahead is to progress launch readiness and establish commercial partnerships.

“Our commercialization strategy is to launch through partners with the potential for an Ascelia Pharma led launch in the US. The overall ambition is to secure the optimal balance between value creation, investment required and future revenues”, she says.

Contacts

Magnus Corfitzen, CEO
Email: moc@ascelia.com
Tel: +46 735 179 118

Julie Waras Brogren, Deputy CEO (Finance, Investor Relations & Commercial)
Email: jwb@ascelia.com
Tel: +46 735 179 116

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 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

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 successfully been completed with strong and consistent efficacy and safety results.

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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