PRESS RELEASE

06 December 2022 08:00:00 CET

New Strong Orviglance Data Support Successful SPARKLE Completion with Substantially Fewer Patients

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced that new data show that the pivotal Phase 3 clinical SPARKLE study with the lead candidate drug Orviglance can be completed with 80 patients, with a complete patient enrollment expected in Feb-Mar 2023 and a subsequent topline readout by mid-2023

New data with the same image reading methodology as in the SPARKLE study with Orviglance demonstrate a strong and statistically significant effect of two to three times the effect level previously expected in SPARKLE. Therefore, a statistically significant positive outcome is likely to be obtained with substantially fewer patients, while maintaining conservative assumptions. Ascelia Pharma has thoroughly analyzed the new data and original assumptions with statisticians and regulatory experts to validate this important finding.

Ascelia Pharma has discussed the analysis with the US Food and Drug Administration (FDA) with the objective to decide on a smaller sample size in SPARKLE than initially planned. Based on these discussions, Ascelia Pharma has decided to change the patient enrollment target of SPARKLE to 80 patients.

“We are highly encouraged by the strong efficacy seen in the new statistical analysis of existing data. Our confidence in a successful study is strong, and we highly value the constructive dialogue with the FDA. The entire Ascelia team has worked very hard to complete SPARKLE despite the substantial structural sector challenges during the covid pandemic and beyond,” said CEO of Ascelia Pharma, Magnus Corfitzen.

Years of pandemic impact on clinical trial activities at hospitals, a change of Clinical Research Organization following a bankruptcy, and the discontinuation of 13 clinical sites in Russia are all factors that have significantly influenced patient enrollment in SPARKLE. In recent months, patient enrollment has shown a positive trend based on the opening of additional study sites and a launch of patient enrollment initiatives. To date, 58 patients have completed the study.

Ascelia Pharma expects to complete SPARKLE patient enrollment by February/March 2023 with topline results by mid-2023. We are also committed to providing updates on SPARKLE patient enrollment after the last Friday every month.

Two of the three clinical studies of the Phase 3 program for Orviglance are completed with successful results. The previously announced Food Effect study successfully concluded that Orviglance image enhancement was not impacted by a light meal. The Hepatic Impairment Study showed that Orviglance is well tolerated in patients with liver (hepatic) impairment. The completion of SPARKLE will finalize the Phase 3 program.

A presentation for analysts, investors and media will be held today 6 December at 10:00am CET. The event will be hosted by the company's CEO Magnus Corfitzen, Deputy CEO & CCO Julie Waras Brogren, CFO Déspina Georgiadou Hedin and CSO Andreas Norlin. The presentation will be held in English. The presentation can be followed live via the link: **https://ir.financialhearings.com/press-conference-december-2022**

It will also be possible to take part of the audiocast afterwards at the same address or at Ascelia Pharma's website: **https://www.ascelia.com/ir-media/financial-reports/**

To participate in the telephone conference, please use the dial-in details shown below:
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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, which has been granted an Orphan Drug Designation by the US Food and Drug Administration (FDA), is currently in Phase 3 development, including the global multi-center SPARKLE study.

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 2022-12-06 08:00 CET.

Attachments

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