PRESS RELEASE

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Ascelia Pharma Announces Acceptance of SPARKLE Phase 3 Data for Presentation at the Society of Abdominal Radiology Congress 2025

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced that two scientific abstracts with clinical data from the SPARKLE Phase 3 study with Orviglance have been accepted as an oral presentation and a scientific poster at the Society of Abdominal Radiology Congress, taking place from 16-21 February 2025 in Tucson, AZ, US.

The two abstracts highlight the positive outcomes of the SPARKLE Phase 3 study. In the study Orviglance was shown to enhance the detection of suspected or known liver lesions, including small-sized lesions, and consistently shows positive results in visualizing lesions in both patients with hepatocellular carcinoma (HCC, primary liver cancer) and those with liver metastases. The study includes patients with severe renal impairment who currently lack an alternative to gadolinium-based contrast MRI.

The abstract “Improved detection of focal liver lesions with manganese-based contrast agent in patients with severe kidney impairment: evidence from the SPARKLE study” was accepted as an oral presentation and “Hepatocellular carcinoma (HCC) and hepatic metastases: visualization with manganese-based contrast agent enhanced liver MRI in patients with severe kidney disease, evidence from the SPARKLE study” is to be presented in the abstracts section.

“The acceptance of these abstracts by the Society of Abdominal Radiology Congress is a key achievement. This prestigious event is renowned for being an important gathering for experts and professionals in the field of abdominal radiology, offering unparalleled opportunities for learning, networking, and showcasing groundbreaking research” says Andreas Norlin, CSO Ascelia Pharma.

The oral presentation abstract will be held on Sunday February 16, 2025, from 10:43 AM and will be part of the Clinical Practice Improvement session.

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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 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.

Attachments

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