PRESS RELEASE

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Ascelia Pharma Submits Orviglance New Drug Application to the U.S. Food and Drug Administration

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced that the New Drug Application (NDA) for Orviglance® has been submitted to the US Food and Drug Administration (FDA).

The NDA for Orviglance has been submitted to the FDA. Ascelia Pharma seeks marketing approval for Orviglance as liver MRI contrast agent for patients with severe kidney impairment. The submission is based on the successful completion of the development program, including nine clinical studies with consistent positive efficacy and safety results.

“We are delighted to announce the submission of the NDA for Orviglance. This is a significant achievement for Ascelia Pharma”, said Magnus Corfitzen, CEO of Ascelia Pharma. “We now look forward to advancing Orviglance through the FDA review process.”

The FDA standard review timeline is 10 months.

Orviglance has been granted an Orphan Drug Designation by the FDA for use as a contrast agent for liver MRI in patients with severely impaired kidney function. These patients have the highest risk of developing the serious and potentially fatal condition Nephrogenic Systemic Fibrosis (NSF) after exposure to the gadolinium-based contrast agents normally used today. Regulatory bodies have issued warnings for the use of these agents in this vulnerable patient population. Orviglance aims to give patients with impaired kidney function access to safe and effective liver imaging. The unmet need for these patients represents a global annual addressable market potential of USD 800 million.

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. The New Drug Application (NDA) has been submitted to the FDA.

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.

Attachments

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