

Malmö, 2 March, 2021

Ascelia Pharma opens US office in preparation for Mangoral launch

Ascelia Pharma AB (publ) (ticker: ACE) today announced that it has expanded its operations and established a US legal entity and office in Woodbridge, New Jersey, in preparation for US launch of its lead candidate drug, the liver contrast agent Mangoral. It is currently in pivotal clinical Phase 3 studies with market launch scheduled for Q4 2022 or H1 2023.

The opening of a US office in Woodbridge, NJ, with an important proximity to the pharma and biotech community and competences in the area, including Princeton, is a central part of preparing for Ascelia Pharma's market launch on the important US market, where the company plans to set up its own commercial operations and sales team.

"Opening our US office is an important step in our launch preparations for Mangoral. The size, maturity and market access opportunity make the US the most important market for Mangoral. Building our own commercial operations is the next important step to engage more closely with key partners and the clinical community on the journey to make Mangoral available to physicians and patients in the US", said Julie Waras Brogren, Chief Commercial Officer of Ascelia Pharma.

Market intelligence shows that around 400 hospitals and clinics in the US care for around 75% of the target patient population that Ascelia Pharma expects to reach at launch with a focused team of around 20 sales representatives.

Mangoral, which entered pivotal clinical studies in 2020, has been granted an Orphan Drug Designation (ODD) by the US Food and Drug Administration (FDA) and is targeted for patients with poor kidney function which undergo an MRI scan of the liver. The ongoing pivotal Phase 3 study SPARKLE is expected to be completed in H2 2021. Ascelia Pharma thereafter plans to submit the New Drug Application (NDA) to the FDA in H1 2022 and to launch in Q4 2022 or H1 2023.

The addressable market for Mangoral is around \$500-600 million annually in key markets, of which the US represents the largest individual market. With own commercial activities, Ascelia Pharma has the opportunity to build an attractive top line and retain the full value within the company.

"Establishing Ascelia Pharma Inc. is a key milestone in our development and underlines our ambition to build our own commercial organization in the US. With Mangoral we have the opportunity to truly improve the health and life of people living with an unmet need through a product where the need and potential value is clearly recognized by key decision makers, including regulators, payers and clinicians", said Magnus Corfitzen, CEO of Ascelia Pharma.

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PRESS RELEASE



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The information was submitted for publication, through the agency of the contact person set out above, at 9.30 am CET on 2 March, 2021.

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 – 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 www.ascelia.com.

About Mangoral

Mangoral (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. Mangoral, 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.