PRESS RELEASE

Malmö, 13 January 2020

Five sites now opened in the pivotal Phase III clinical study SPARKLE for lead drug candidate Mangoral

Ascelia Pharma AB (publ) (ticker: ACE) today informed that there are a number of sites now open for enrolment of patients in both the US and Europe in the global pivotal Phase III clinical study SPARKLE with Mangoral®. Enrolment of the first patient is expected shortly.

SPARKLE is a global multicenter and registration enabling study of Mangoral in up to 200 patients with severely reduced renal function and with known or suspected liver metastases. Ascelia Pharma expects top line results to be obtained by the end of 2020 or beginning of 2021.

Following national approvals in the US by the FDA, in Germany by BfArM and in Sweden by Läkemedelsverket, five sites were opened during December 2019 and January 2020 and are now ready to recruit patients. The current sites open for recruitment are Yale University School of Medicine in Connecticut, University of Wisconsin and Southwest Medical Imaging in Arizona in the US, as well as Karolinska University Hospital in Sweden and Universitätsmedizin Göttingen in Germany. Additional sites will be opened for recruitment shortly.

Mangoral is the first oral imaging drug being developed for liver MRI. In addition, Mangoral is covered by an Orphan Drug Designation in the US, targeting the large unmet need in patients which cannot tolerate currently available contrast agents on the market due to impaired kidney function.

SPARKLE aims to demonstrate the efficacy and safety of Mangoral compared to unenhanced liver MRI, with each patient being his/her own control subject. Primary efficacy, in terms of lesion visualisation compared to unenhanced MRI, will be evaluated by three independent blinded readers.

Liver MRI will be performed before and within few hours after oral Mangoral administration, and basic safety parameters will be evaluated for up to 5 days after administration of Mangoral. Further details of the SPARKLE study can be found at www.clinicaltrials.gov, with the identifier NCT04119843.

“We are very pleased with the interest from premier hospitals globally to participate in the study. It is a decisive step as we accelerate the development of Mangoral through the Phase III clinical program, which is fully financed through the share issue in conjunction with our IPO in 2019. We are proud to collaborate in the SPARKLE study with world class radiologists at the leading hospitals, which is a testimony to the unique value provided by Mangoral and the unmet need for these patients,” said Magnus Corfitzen, CEO of Ascelia Pharma.

For more information, please contact:
Magnus Corfitzen, CEO
Email: moc@ascelia.com
Tel: +46 735 179 110

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Mikael Widell, IR & Communications Manager
Email: mw@ascelia.com
Tel: +46 703 11 99 60

The information was submitted for publication, through the agency of the contact person set out above, at 3.30 p.m. CET on 13 January 2020.

About Ascelia Pharma
Ascelia Pharma is an oncology-dedicated orphan drug development company located in Malmö, Sweden. The company's strategy is to develop drugs, which target unmet medical needs, have an established mode of action and a relatively low development risk. Ascelia Pharma has two drug candidates – Mangoral® and Oncoral – currently under development.

Mangoral is a novel contrast agent for MR-scans and is ready for Phase III clinical studies. Mangoral is developed to improve the visualization of focal liver lesions (liver metastases) in patient with impaired kidneys that cannot tolerate current gadolinium contrast agents on the market. Oncoral is an oral chemotherapy tablet ready for Phase II for the treatment of gastric cancer. Ascelia Pharma is listed on Nasdaq Stockholm (ticker: ACE). For more information, please visit www.ascelia.com.