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Malmö, 6 May 2020

# First participant enrolled in the clinical hepatic impairment study with Mangoral

**Ascelia Pharma AB (publ) (ticker: ACE) ("Ascelia") today announced that the first participant has been enrolled in the company's clinical study with Mangoral in volunteers with different degrees of hepatic impairment. Results from this hepatic study could potentially enable the use also in Mangoral's target population with impaired liver function.**

The overall objective of this special populations hepatic study is to assess the influence of hepatic impairment on the safety, pharmacokinetics and pharmacodynamics of the liver specific oral MRI contrast agent, Mangoral. Patients with moderate or severe hepatic impairment are not studied in the pivotal Phase 3 study SPARKLE, and since Mangoral is selectively taken up and excreted by the liver, the results from this hepatic study will generate important data regarding potential use also in the patient population with impaired liver function.

The open-label study will be performed on 24 healthy and hepatically impaired participants at the Texas Liver Institute, San Antonio, Texas. It is estimated to be completed during 2020.

"The initiation of the hepatic impairment study, which involves dosing and subsequent MRI scanning of study participants, is an important step to broaden the clinical package for regulatory submissions of Mangoral, ultimately aiming to bring a novel, safe and efficient MRI contrast agent to patients with a significant unmet medical need", said Carl Bjartmar, MD, PhD, Chief Medical Officer at Ascelia Pharma.

In February, the first patient was enrolled in the company's registration-enabling Phase 3 clinical study SPARKLE, assessing efficacy and safety of Mangoral in patients with severely reduced renal function and with known or suspected liver lesions. SPARKLE is a global multicentre study of Mangoral in up to 200 patients with severely reduced renal function and with known or suspected liver lesions. Ascelia Pharma expects to present full study report in first half of 2021.

"We are happy to now have initiated enrolment in our second clinical Mangoral study this year. The start of the hepatic impairment study shows we are making operational progress despite impact from Covid-19", said Magnus Corfitzen, CEO of Ascelia Pharma.

In addition to the ongoing SPARKLE and hepatic impairment studies, Ascelia Pharma is also preparing a clinical study of the effect of food intake on Mangoral uptake, planned to be completed during 2020. Together with already completed Phase 1 and 2 studies, these additional studies will ensure a comprehensive Mangoral data package for the regulatory submissions for market approvals, such as the New Drug Application (NDA) to be submitted to the US Food and Drug Administration (FDA).

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*This information is such information as Ascelia Pharma AB (publ) 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 8.00am CET on 6 May 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 (manganese chloride tetrahydrate) is a novel oral contrast agent for MRI-scans, currently being evaluated in the pivotal Phase 3 clinical study SPARKLE. Mangoral is developed to improve the visualisation of focal liver lesions (liver metastases or primary tumours) in patient with impaired kidneys that cannot tolerate current gadolinium contrast agents on the market. Oncoral is an oral chemotherapy tablet ready for Phase 2 for the treatment of gastric cancer. Ascelia Pharma is listed on Nasdaq Stockholm (ticker: ACE). For more information, please visit www.ascelia.com.