

Malmö, 19 February 2020

## First patient enrolled in pivotal Phase III clinical study SPARKLE with lead candidate Mangoral

**Ascelia Pharma AB (publ) (ticker: ACE) today announced that the first patient has been enrolled in the company's global pivotal Phase III clinical study SPARKLE with Mangoral in patients with severely reduced renal function and with known or suspected liver lesions.**

"It is an important event for patients seeking a safe agent to detect liver lesions that this pivotal Phase III study is now enrolling study subjects. We see the interest from premier hospitals and expert doctors to participate as a testimony to the unique potential offered by Mangoral and the large unmet medical need for these patients. The addressable market for Mangoral is \$350-500 million annually, and Mangoral, if approved, will be the only product on the market for this patient segment. We are excited to now be one step closer to launch Mangoral to the market, which we expect to happen in 2022," said Magnus Corfitzen, CEO of Ascelia Pharma.

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 unmet need in patients who cannot tolerate currently marketed contrast agents due to impaired kidney function.

"Liver metastases and primary liver malignancies are very serious manifestations of cancer. It is therefore essential to early and accurately detect and diagnose liver lesions to be able to offer patients the best treatment options. This can have significant impact on patient survival", said Dr. Carl Bjartmar, Chief Medical Officer of Ascelia Pharma.

"Mangoral has the potential to fill this specific unmet medical need for patients that today are restricted from using currently available contrast agents for liver imaging. The management of these patients today is an MRI of the liver without any contrast agent. Mangoral offers the potential for improved liver images in this patient group and may consequently enable better treatment options which ultimately can improve their chances of survival", he continued.

SPARKLE is a global multicenter, registration-enabling study of Mangoral in up to 200 patients with severely reduced renal function and with known or suspected liver lesions. Ascelia Pharma expects full study report in first half of 2021.

The study aims to demonstrate the efficacy and safety of Mangoral in terms of improved lesion visualization as compared to unenhanced MRI, with each patient being their own control subject. Primary efficacy, in terms of lesion visualization compared to unenhanced MRI, will be evaluated by three independent blinded readers.

MRI will be performed before and shortly after oral Mangoral administration, and basic safety parameters will be evaluated for five days following administration. Further details of the SPARKLE study can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov), with the identifier NCT04119843.

# PRESS RELEASE



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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 person set out above, at 6.30 p.m. CET on 19 February 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](http://www.ascelia.com).