PRESS RELEASE

Malmö, 7 May 2019

Ascelia Pharma received supportive feedback from EMA on the phase 3 program for Mangoral®

Ascelia Pharma AB (publ) (ticker: ACE) today announced that the company has completed constructive discussions with the European Medicines Agency (EMA) regarding the clinical development program for Mangoral® as a contrast agent in patients with focal liver lesions and severe renal impairment. Ascelia Pharma will now finalise preparations for the clinical Phase 3 study and expects to enrol the first patient during the second half of 2019.

Mangoral is an oral contrast agent for liver MRI developed to facilitate the visualisation of focal liver lesions, including liver metastases, using Magnetic Resonance Imaging (MRI) in adult patients where use of the current gold standard – gadolinium-based contrast agents – may be medically inadvisable or cannot be administered.

The global multi-center Phase 3 study will be conducted in the target patient population, where standard of care currently is unenhanced MRI without a contrast agent, which has lower appropriateness rating compared to any contrast enhanced procedure. As previously confirmed with the US Food and Drug Administration (FDA), the primary endpoint of the study will be lesion visualisation of combined MRI (Mangoral-enhanced MRI plus unenhanced MRI) as compared to unenhanced MRI.

During the discussions with the EMA, the planned phase 3 program was presented and the EMA emphasised the value of the information relating to Mangoral's impact on patient management, and Ascelia Pharma clarified that the Phase 3 study will generate such data. Ascelia Pharma believes that the recommendations provided by the EMA will be addressed by data generated by the planned phase 3 program and existing data.

"We are delighted to initiate this Phase 3 study of Mangoral, which aims to confirm the excellent data observed in our Phase 2 studies in order to support approval", said Magnus Corfitzen, CEO of Ascelia Pharma.

"In addition, we are grateful for the constructive discussions we had with the EMA and are pleased that the agency also recognises the unmet need for a liver MRI contrast agent for patients who are at risk of serious side effects from the gadolinium-based contrast media available on the market today. Given the robust trial design, we believe that a successful study will enable approval of a safe and efficacious non-gadolinium liver contrast agent for patients in the Mangoral target population with severely impaired kidney function or acute kidney injury who currently lack any imaging drug."

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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 5.50 p.m. CET on 7 May 2019.

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 visualisation 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