

Malmö, 20 May 2020

Updated SPARKLE timelines due to Covid-19 impact

Ascelia Pharma AB (publ) (ticker: ACE) (“Ascelia Pharma”) today announced updated timelines for the completion and top line results of the pivotal Phase 3 study SPARKLE with the lead compound Mangoral, which are now expected in H2 2021 instead of H1 2021 as previously communicated. The expected addition of three to six months reflects the impact of the Covid-19 pandemic.

Ascelia Pharma is making good progress towards making Mangoral available to physicians and patients as a safe and effective imaging drug used in liver MRI for patients with severe kidney insufficiency or acute kidney injury. However, the Covid-19 pandemic is impacting the pace of the patient inclusion-rate in the SPARKLE study. Also related to the Covid-19 challenges, one of the clinical research organisations (CRO) contracted for the study is experiencing liquidity challenges, and Ascelia Pharma is currently working to find a constructive and sustainable solution to mitigate any possible negative impact on the SPARKLE study.

In light of these consequences of the Covid-19, the timeline is estimated to be delayed with three to six months compared to what has previously been communicated.

“The Covid-19 situation has impacted most pharma- and biotech organisations within drug development and clinical research including the SPARKLE study. We therefore consider it prudent to update our timelines. The underlying fundamentals for Mangoral development and the significant unmet medical need Mangoral is addressing remain completely unchanged. We continue to operate effectively on our clinical development activities, including the other Mangoral studies, as well as our pre-commercial activities,” said Magnus Corfitzen, CEO at Ascelia Pharma.

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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 6.00pm CET on 20 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.

PRESS RELEASE



Mangoral is a novel contrast agent for MR-scans, currently 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.