PRESS RELEASE

Malmö, September 18, 2020

First commercial scale manufacturing of Mangoral

Ascelia Pharma AB (publ) (ticker: ACE) ("Ascelia") today announced that the company has reached a key achievement with the first commercial scale manufacturing of its lead compound Mangoral, currently in pivotal Phase 3 development. The commercial scale manufacturing is an important step towards market launch.

The milestone was reached in close collaboration with the manufacturing partner Cambrex, based in Whippany, New Jersey, US. All quality and manufacturability requirements were met and reproduced for this full-scale manufacture. High-quality manufacturing is key to patient safety and an important requirement for regulatory approval and commercialization of new drugs.

"As a pharmaceutical company, we have a strong commitment to develop and manufacture products that are safe for patients and comply with the rigorous requirements of the industry. We are very pleased with our progress in supply chain development, and these results will form an important part of the regulatory submissions for market approvals, such as the New Drug Application (NDA) to be submitted to the US Food and Drug Administration (FDA). We progress as planned with our manufacturing and there is still work to do, but this first and reproduceable commercial scale manufacturing is an important step towards a product approval and launch, which we expect in late 2022 or beginning of 2023," said Magnus Corfitzen, CEO at Ascelia Pharma.

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About Ascelia Pharma
Ascelia Pharma is a biotech company focused on orphan oncology treatments. We develop and commercialize novel drugs that address unmet medical needs and have a clear development and market pathway. The company has two drug candidates – Mangoral and Oncoral – in clinical development. Ascelia Pharma has global headquarters in Malmö, Sweden, and is listed on Nasdaq Stockholm (ticker: ACE). For more information, please visit www.ascelia.com.

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About Mangoral

Mangoral (manganese chloride tetrahydrate) is a novel oral contrast agent for MR-imaging developed to improve the detection and visualization of focal liver lesions (including liver metastases and primary tumors) in patients with reduced kidney function. These patients are at risk of serious side effects from the currently available class of gadolinium-based contrast agents. Mangoral, which has been granted an Orphan Drug Designation by the US Food and Drug Administration (FDA), is currently in Phase 3 development, including the global multi-center SPARKLE study.