

PRESS RELEASE



Malmö, November 3, 2020

EMA confirms Mangoral eligible for the centralized regulatory procedure in the EU

Ascelia Pharma AB (publ) (ticker: ACE) today announced that it has received confirmation from the European Medicines Agency (EMA) that a Marketing Authorization Application (MAA) for Mangoral is eligible to be submitted in the European Union (EU) under the Agency's centralized procedure. Mangoral is Ascelia Pharma's lead drug candidate, currently in Phase 3 development.

The centralized procedure permits the submission of a single marketing application to the EMA that, if approved, allows the drug to be marketed in all EU member states, rather than requiring independent national procedures. The centralized process (Article 3(2)b) is granted to drug candidates that the agency considers as a therapeutic, scientific or technical innovation.

"We are pleased that the EMA regards Mangoral as being eligible for a centralized regulatory review, in accordance with our expectations. We appreciate that Mangoral, as a novel liver contrast agent to patients, is being classified in the therapeutic innovation category. Today's decision from the EMA marks yet another step in our market launch preparations", said CEO Magnus Corfitzen.

For further information, please contact:

Magnus Corfitzen, CEO

Email: moc@ascelia.com

Tel: +46 735 179 118

Mikael Widell, Head of IR & Communications

Email: mw@ascelia.com

Tel: +46 703 11 99 60

The information was submitted for publication, through the agency of the contact persons set out above, at 3.30pm CET on November 3, 2020.

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.

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

PRESS RELEASE



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.