**PRESS RELEASE**

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# Covid-19 extends recruitment period of SPARKLE study

**Ascelia Pharma AB (publ) (ticker: ACE) today announced that the continued global impact of the Covid-19 pandemic could extend the recruitment period of the clinical phase 3 study SPARKLE with up to 6 months. The recruitment is now expected to be completed during H1 2022. Ascelia Pharma has a solid cash position supporting operations well into 2023.**

Ascelia Pharma is making steady progress in the ongoing pivotal Phase 3 SPARKLE study with its lead compound Orviglance (former working name Mangoral). Nevertheless, the Covid-19 pandemic continues to substantially impact healthcare systems globally, including the conduct of clinical trials. Especially in the U.S., an important country in the SPARKLE study, the increasing infection rates are impacting clinical study activities. In this context, the company expects that the recruitment timeline could be extended up to 6 months into H1 2022 (previously H2-2021).

"Covid-19 has continued to be a challenge for clinical research globally since the outbreak early 2020. Some patients cannot or are unwilling to visit hospitals for clinical tests. Our SPARKLE study is no exception. We have adapted our operational procedures including adding more study sites and made good progress despite the pandemic. However, the continued high infection rates in countries where SPARKLE is ongoing are negatively impacting study sites' ability and recruitment pace to conduct clinical research and patient enrollment as planned. Our team, together with our study sites, continue to assess and implement possible mitigations to accelerate patient recruitment", said Carl Bjartmar, Chief Medical Officer at Ascelia Pharma.

"The medical need for a safe and effective liver specific contrast agent is strong and the value that Orviglance can provide to patients and the healthcare system is significant. We are committed to bringing Orviglance to the patients in need and we have a strong cash position well into 2023 providing a solid foundation", said Magnus Corfitzen, CEO of Ascelia Pharma.

Following the completion of the SPARKLE study, Ascelia Pharma plans to submit a New Drug Application to the FDA with a subsequent launch expected in H2 2023.

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*This information is information that Ascelia Pharma 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 2021-08-18 19:10 CEST.*

**About Us**

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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 – Orviglance (previously referred to as 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 http://www.ascelia.com.

**About Orviglance** (previously referred to as Mangoral)
Orviglance (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. Orviglance, 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.

**About Oncoral**
Oncoral is a novel irinotecan chemotherapy tablet developed initially for the treatment of gastric cancer. Irinotecan chemotherapy has an established potent anti-tumor effect. Oncoral is a daily tablet with the potential to offer better patient outcomes with improved safety following the daily dosing at home compared to intravenous high-dose infusions at the hospital. Following successful Phase 1 results, Oncoral is now prepared for Phase 2 clinical development.

**Attachments**

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