**PRESS RELEASE**

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# Ascelia Pharma Signs Clinical Collaboration Agreement With Taiho Oncology, Inc. for the Development of Oncoral in Combination with LONSURF®

**Ascelia Pharma AB (publ) (ticker: ACE) today announced that it has signed a clinical collaboration agreement with Taiho Oncology Inc., a subsidiary of Taiho Pharmaceutical Co., Ltd. The collaboration concerns an upcoming global Phase 2 clinical study in gastric cancer. In this all-oral combination study, Ascelia Pharma's irinotecan chemotherapy tablet Oncoral (ASC-201) will be evaluated in combination with Taiho Oncology's LONSURF® (trifluridine and tipiracil) film-coated tablets for oral use. The combination of Oncoral and LONSURF is investigational at this time and not approved for use in gastric cancer or any other disease.**

As part of the agreement, Taiho Oncology will supply LONSURF as well as provide scientific expertise for the study. Depending on the results, the collaboration may be extended for further development of the two agents. Ascelia Pharma retains full development and commercialization rights to Oncoral.

"This is an important agreement for Ascelia Pharma, which shows the potential for Oncoral to be a new treatment regimen for gastric cancer. We believe this investigational all-oral tablet combination has the potential to provide a significant treatment benefit to patients suffering from this very aggressive cancer form where there is a massive unmet medical need," said Magnus Corfitzen, CEO of Ascelia Pharma.

Following an initial dose-escalation the Phase 2 study will be a randomized controlled multicenter study of Oncoral added to LONSURF compared to LONSURF alone. The primary endpoint will be progression-free survival, with secondary endpoints including response rate, overall survival, pharmacokinetics, safety, and tolerability.

The study is planned to start in H2 2021 and will include approximately 100 patients with metastatic gastric cancer. The initial portion of the planned global study will be conducted at hospitals and clinics in Europe.

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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 2021-09-21 07:30 CEST.*

## About us

### 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 – Orviglance® (Mangoral) and Oncoral – in clinical development. Ascelia Pharma has its global headquarters in Malmö, Sweden, and is listed on Nasdaq Stockholm (ticker: ACE). For more information, please visit www.ascelia.com.

### About Taiho Oncology Inc.

The mission of Taiho Oncology, Inc. is to improve the lives of patients with cancer, their families and their caregivers. The company specializes in the development of orally administered anti-cancer agents and markets these medicines for a range of tumor types in the U.S. Taiho Oncology's growing pipeline of antimetabolic and selectively targeted anti-cancer agents are led by a world-class clinical development organization. Taiho Oncology is a subsidiary of Taiho Pharmaceutical Co., Ltd. which is part of Otsuka Holdings Co., Ltd. Taiho Oncology is headquartered in Princeton, New Jersey and oversees its parent company's European and Canadian operations, which are located in Zug, Switzerland and Oakville, Ontario, Canada. For more information, visit www.taihooncology.com

### 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.

### About LONSURF

LONSURF consists of a thymidine-based nucleoside analog, trifluridine, and the thymidine phosphorylase (TP) inhibitor, tipiracil, which increases trifluridine exposure by inhibiting its metabolism by TP. Trifluridine is incorporated into DNA, resulting in DNA dysfunction and inhibition of cell proliferation. In the EU, LONSURF is indicated as monotherapy for the treatment of adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents and LONSURF is indicated as monotherapy for the treatment of adult patients with metastatic gastric cancer including adenocarcinoma of the gastroesophageal junction, who have been previously treated with at least two prior systemic treatment regimens for advanced disease.

LONSURF was discovered and developed by Taiho Pharmaceutical. In June 2015, Taiho Pharmaceutical and Servier entered into an exclusive license agreement for the co-development and commercialization of LONSURF in Europe and other countries outside of the United States, Canada, Mexico and Asia.

***Please see full Summary of Product Characteristics for Europe:*** *https://www.ema.europa.eu/en/medicines/human/EPAR/lonsurf*