PRESS RELEASE

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Third US patent strengthens patent protection for Ascelia Pharma's Oncoral (daily tablet irinotecan)

Ascelia Pharma AB (publ) (ticker: ACE) announced today the decision of the US Patent and Trademark Office (USPTO) to allow the issuance of a third patent covering the composition of Oncoral.

Ascelia Pharma has received a positive Notice of Allowance from the United States Patent and Trademark Office (USPTO) for United States patent application no. 17/865,734 for Oncoral. Oncoral is Ascelia Pharma's investigational oral daily irinotecan chemotherapy with potential to offer both better efficacy and safety compared to intravenous high-dose chemotherapy infusions at the hospital.

"We are very pleased with the continued development of the patent portfolio for Oncoral and view the decision of the USPTO as recognition of the innovation behind our novel oral formulation of irinotecan. The opportunity to strengthen the patent protection for Oncoral adds further value to the development and commercialization opportunities for Oncoral and for Ascelia Pharma", said Julie Waras Brogren, Deputy CEO and Chief Commercial Officer of Ascelia Pharma.

The new patent covers the tablet composition and will provide protection until 2035 plus potential extension in the US. It broadens the scope of Ascelia Pharma's patent protection for Oncoral beyond the already-granted US patents US 10,143,657 and US 11,419,825, which broadly cover the solid oral composition of Oncoral as well as the method of using Oncoral. Outside the US, Oncoral is covered by patents in selected European countries and in Japan, China and Canada.

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About Us

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, has been granted an Orphan Drug Designation by the US Food and Drug Administration (FDA). A pivotal clinical program of nine studies, including the global Phase 3 study SPARKLE, have been completed.

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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