Vivesto signs Apealea option agreement with Zhida Pharmaceutical

Solna, Sweden, November 7, 2024 – Vivesto AB, an oncology-focused research and development company, today announced that it has entered into an agreement with Zhejiang Zhida Pharmaceutical Ltd (Zhida Pharma) - a China based pharmaceutical company - which includes an option to enter into an already finalized license agreement for Vivesto's anticancer product Apealea® (paclitaxel micellar) with milestone payments worth of up to USD 5.85 million and sales royalties.

In the agreement Zhida Pharma has, after a regulatory due diligence, the option to enter a fully negotiated license agreement that grants Zhida Pharma the exclusive rights for the development, production and commercialization of Apealea, a proprietary formulation of paclitaxel, in China, Hong Kong, Macau and Taiwan. The terms of such a license agreement include milestone payments with a potential of up to USD 5.85 million depending on Zhida Pharma's achievement of future sales, clinical development, regulatory approval, and market authorization milestones, as well as high single-digit to low double-digit royalties on sales of Apealea.

"We are very excited to enter into this agreement with Zhida Pharma and on the potential of having Apealea launched in these large markets. There is a significant market opportunity in ovarian cancer for an approved product and, depending on whether they exercise the option, we believe Zhida Pharma has the resources and know-how to bring Apealea to the market quickly," said Erik Kinnman, CEO of Vivesto. "Their focus on commercialization and solid production capabilities are an excellent combination, making Zhida Pharma a perfect partner for Vivesto and the future for our paclitaxel portfolio. We look forward to the partnership."

Zhida Pharma will under the option agreement bring the existing Apealea documentation provided by Vivesto to a Pre-IND Meeting with the National Medical Products Administration in China (NMPA) to determinine the regulatory submission requirements for Apealea. After the meeting, which is expected to take place during the first half of 2025, Zhida Pharma has the option to enter into the license agreement. Within the license agreement, Zhida Pharma will be responsible for all regulatory application processes in China, Hong Kong, Macau and Taiwan, including the submission of the approval application to the NMPA.

"Apealea is a strong match for the medical need we see in our region and a good fit for our production capabilities," said Paul Geng, Director of Zhida Pharma. "We look forward to discussions with the regulators and the potential license agreement with Vivesto."

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About Vivesto AB

Vivesto is a Swedish development company that aims to offer new treatment options for hard-to-treat cancers where there are major medical needs and significant market potential. The project portfolio consists of Cantrixil and Docetaxel micellar, which are being developed for blood cancer and prostate cancer, respectively, and the veterinary oncology program Paccal Vet (paclitaxel micellar), which is being evaluated in a pilot clinical trial in dogs with splenic hemangiosarcoma following splenectomy. Vivesto's shares are traded on Nasdaq Stockholm (ticker: VIVE). Visit www.vivesto.com for more information about Vivesto.

About Apealea
Apealea is a patented, water-soluble, intravenously injectable formulation of paclitaxel, developed using Vivesto's proprietary technology platform – XR-17 – which facilitates the solubility of paclitaxel. Paclitaxel is a chemotherapy medication used to treat a number of types of cancers. Apealea was previously approved by the European regulatory authority EMA for use in combination with carboplatin for the treatment of adult patients with first relapse of platinum-sensitive epithelial ovarian cancer, primary peritoneal cancer and fallopian tube cancer. Apealea has also received orphan drug designation from the US regulatory authority FDA for the treatment of epithelial ovarian cancer, which could entail several potential benefits, including seven years of market exclusivity.

About Zhejiang Zhida Pharmaceutical Ltd
Founded in 2018 and based in Shaoxing, China, Zhida Pharma is a pharmaceutical company that focuses on the research and development of nano-drug delivery platform technology, complex formulation manufacturing and commercialization of R&D projects. The company's core technologies include nanoliposome drug delivery platform, albumin nanoparticle drug delivery platform, peptide nano drug delivery platform and high-efficiency in vivo nucleic acid drug delivery platform. At present, it has a production line of nanoliposome drugs that has passed GMP verification, providing users with drug delivery products. The company's first approved product, Doxorubicin hydrochloride liposome injection, has been approved for listing 2024 and reached approx. USD 14.5 million in sale during the first 6 months, while the company's second product, Irinotecan liposome, is expected to begin sale by Q4 2025. Zhida Pharma is privately owned by its founders, employees and the investors: Sinopharm-CICC Capital, Zhuzhou SAH Innovation & Entrepreneur Investment Co. Ltd, Wenzhou Investment and China Merchants Capital.

This information is information that Vivesto AB 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 2024-11-07 10:54 CET.

Attachments

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