

Vivesto licenses Apealea to China's Zhida Pharmaceutical

Solna, Sweden, March 17, 2025 – Vivesto AB, an oncology-focused development company, today announced it entered a licensing agreement with Zhejiang Zhida Pharmaceutical Ltd (Zhida Pharma) for the development, production and commercialization of Vivesto's anticancer product Apealea® (paclitaxel micellar) in China, Hong Kong, Macau and Taiwan. The terms include upfront and milestone payments worth of up to USD 5.85 million, as well as sales royalties when the product reaches the market.

Vivesto announced in November 2024 it had signed an option agreement with Zhida Pharma regarding Apealea pending Chinese regulatory due diligence. Vivesto will now receive an upfront payment of USD 250,000 as Zhida Pharma exercises its option and moves into a full license agreement, with additional milestone payments worth up to USD 5.6 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 look forward to working closely with Zhida Pharma to support the company as they prepare documentation for the Chinese authorities ahead of a pre-IND meeting and IND application," said Erik Kinnman, CEO of Vivesto. "Zhida Pharma is an excellent partner for Vivesto, with its robust production capacity, drug development and commercial expertise, experience and network including the field of oncology. The agreement highlights and validates the commercial interest of our proprietary and unique paclitaxel formulation."

Within the license agreement, Zhida Pharma will be responsible for all regulatory application processes in China, Hong Kong, Macau and Taiwan, including a pre-IND meeting with the National Medical Products Administration (NMPA) and the submission of the Investigational New Drug (IND) application to the Centre for Drug Evaluation (CDE). Vivesto will support Zhida Pharma with additional documentation regarding Apealea ahead of the process with Chinese authorities.

"We are excited to enter into this agreement with Vivesto. Apealea is a strong fit to our existing portfolio of nano drug delivery platforms. There is a clear market opportunity in ovarian cancer in these regions, and we see a significant commercial potential in Apealea," said Margaret Chen, CEO at Zhida Pharma. "We will work closely with the Vivesto team to prepare all documentation required by the regulatory authorities and to secure manufacturing capabilities to enable the fastest route for Apealea to reach the market, providing ovarian cancer patients with a safe alternative to current paclitaxel treatments."

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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 2025-03-18 07:15 CET.

Attachments

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