Æterna Zentaris

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Aeterna Zentaris and Orient EuroPharma Co., Ltd. Sign Exclusive License Agreement for Zoptrex™ in Taiwan and Southeast Asia

Release Date:
Friday, July 1, 2016 8:30 am EDT

Terms:

Aeterna Zentaris [1] AEZ [2] AEZS [3] CFDA [4] China Pharmaceutical Company [5] IND [6] Sinopharm A-Think [7] Zoptrex [8]

Dateline City:
CHARLESTON, S.C.

CHARLESTON, S.C.--(BUSINESS WIRE [9])--Aeterna Zentaris Inc. (NASDAQ: AEZS) (TSX: AEZ) (the "Company") and Orient EuroPharma Co., Ltd. ("OEP") today announced the signing of an exclusive license agreement between the Company and Cyntec Co., Ltd., an affiliate of OEP ("Cyntec"), for the Company's lead anti-cancer compound, Zoptrex™ (zoptarelin doxorubicin), for the initial indication of endometrial cancer, for Taiwan and nine countries in Southeast Asia (the "Territory"). Zoptrex™, a novel synthetic peptide carrier linked to doxorubicin as a New Chemical Entity (NCE), is currently in a fully-enrolled Phase 3 clinical trial in endometrial cancer. The Company expects to complete the Phase 3 clinical trial in the third quarter of 2016 and, if the results of the trial warrant doing so, to file a new drug application for Zoptrex™ in the first half of 2017.

Under the terms of the License Agreement, Aeterna Zentaris will be entitled to receive a non-refundable upfront payment in consideration for the license to Cyntec of the Company's intellectual property related to Zoptrex™ and the grant to Cyntec of the right to commercialize Zoptrex™ in the Territory. Cyntec has also agreed to make additional payments to the Company upon achieving certain pre-established regulatory and commercial milestones. Furthermore, the Company will receive royalties on future net sales of Zoptrex™ in the Territory. Cyntec will be responsible for the development, registration, reimbursement and commercialization of the product in the Territory.

David Dodd, President and CEO of the Company, stated, "We are very excited about this arrangement with OEP. It is an important step in our strategy of leveraging our pipeline to secure future revenues with strategic development and commercial licensees for specific regions of the world. We are very pleased that OEP's affiliates will commercialize Zoptrex™ in the Territory, providing women with advanced endometrial cancer a significant treatment option. Their experience and commitment to ensuring the success of Zoptrex™ in their Territory is most assuring. We look forward to similar, additional agreements as we progress towards the completion of the pivotal Phase 3 trial and the subsequent reporting of top-line results later this year."

Commenting on the signing of the agreement, Peter Tsai, Chairman and CEO of OEP stated, "With our advantage of the comprehensive sales network and operation over Southeast Asia market which we have cultivated for years, we successfully signed the partnership with Aeterna Zentaris and the outstanding endometrial cancer treatment. The exclusive license agreement gives us more confidence in exploring the Asian market with a stronger product portfolio."

About Zoptrex™

Zoptrex™ is a complex molecule that combines a synthetic peptide carrier with doxorubicin, a well-known chemotherapy agent. The synthetic peptide carrier is [D-Lys^6]-LHRH, a modified natural hormone believed to have a strong affinity for the LHRH receptor. The design of the compound allows for the specific binding and selective uptake of the cytotoxic conjugate by LHRH receptor-positive tumors. Potential benefits of this targeted approach include enhanced efficacy and a more favorable safety profile with lower incidence and severity of side effects as compared to doxorubicin.

About Orient EuroPharma Co., Ltd.

Founded in 1982, Orient EuroPharma Co., Ltd (OEP) was officially listed in the Gre-Tai Securities market in 2003, and consolidated net sales exceeded $5 billion in the 2014 financial year. Currently, OEP has more than 800 staffs worldwide, in which over 40% are overseas employees. OEP's products include pharmaceuticals, cancer drugs, cosmeceutical, infant & adult nutrition and healthcare products. OEP also established a subsidiary company focused on developing and manufacturing new drugs. OEP is one of multinational pharmaceutical companies able to integrate pharmaceutical research & development, clinical trial, manufacture and marketing in Taiwan.

About Aeterna Zentaris Inc.

Aeterna Zentaris is a specialty biopharmaceutical company engaged in developing and commercializing novel treatments in oncology, endocrinology and women's health. We are engaged in drug development activities and in the promotion of products for others. We are now conducting Phase 3 studies of two internally developed compounds. The focus of our business development efforts is the acquisition or license of products that are relevant to our therapeutic areas of focus. We also intend to license out certain commercial rights of internally developed products to licensees in territories where such out-licensing would enable us to ensure development, registration and launch of our product candidates. Our goal is to become a growth-oriented specialty biopharmaceutical company by pursuing successful development and commercialization of our product portfolio, achieving successful commercial presence and growth, while consistently delivering value to our shareholders, employees and the medical providers and patients who will benefit from our products. For more information, visit www.aezsinc.com [10].

Forward-Looking Statements

This press release contains forward-looking statements made pursuant to the safe harbor provisions of the US Securities Litigation Reform Act of 1995. Forward-looking statements may include, but are not limited to statements preceded by, followed by, or that include the words “expects,” “believes,” “intends,” “anticipates,” and similar terms that relate to future events, performance, or our results. Forward-looking statements involve known and unknown risks and uncertainties that could cause the Company's actual results to differ materially from those in the forward-looking statements. Such risks and uncertainties include, among others, the availability of funds and resources to pursue R&D projects and clinical trials, the successful and timely completion of clinical studies, the risk that safety and efficacy data from any of our Phase 3 trials may not coincide with the data analyses from previously reported Phase 1 and/or Phase 2 clinical trials, the rejection or non-acceptance of any new drug application by one or more regulatory authorities and, more generally, uncertainties related to the regulatory process, the ability of the Company to efficiently commercialize one or more of its products or product candidates, the degree of market acceptance once our products are approved for commercialization, the ability of the Company to take advantage of business opportunities in the pharmaceutical industry, the ability to protect our intellectual property, the potential of liability arising from shareholder lawsuits and general changes in economic conditions. Investors should consult the Company's quarterly and annual filings with the Canadian and US securities commissions for additional information on risks and uncertainties relating to forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements. The Company does not undertake to update these forward-looking statements. We disclaim any obligation to update any such factors or to publicly announce the result of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, except if required to do so.

Language:
English

Contact:

Aeterna Zentaris Inc.
Philip A. Theodore, 843-900-3223
Senior Vice President
IR@aezsinc.com [11]

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[11] mailto:IR@aezsinc.com