

Aeterna Zentaris and Specialised Therapeutics Asia Sign Exclusive License Agreement for the Potential Marketing of Zoptrex™ in Australia and New Zealand

Release Date:

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Terms:

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Dateline City:

CHARLESTON, S.C. & SINGAPORE

CHARLESTON, S.C. & SINGAPORE--([BUSINESS WIRE](#) [11])--Aeterna Zentaris Inc. (NASDAQ: AEZS, TSX: AEZ) (the "Company") and Specialised Therapeutics Asia ("STA") today announced the signing of an exclusive license agreement for the Company's lead investigational anti-cancer compound, Zoptrex™ (zoptarelin doxorubicin), for the territories of Australia and New Zealand (the "Territory"). Zoptrex™, a novel synthetic peptide carrier linked to doxorubicin, is currently undergoing a fully-enrolled Phase 3 clinical trial to evaluate the compound in endometrial cancer. The Company expects to complete the Phase 3 clinical trial in 2016 and, if the results of the trial warrant doing so, to submit a new drug application for Zoptrex™ to the United States Food and Drug Administration (FDA) in the first half of 2017. Zoptrex™ is the Company's proposed tradename for zoptarelin doxorubicin. The proposed tradename is subject to approval by the FDA.

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 STA of the Company's intellectual property related to Zoptrex™ and the grant to STA of the right to commercialize Zoptrex™ in the Territory. STA has also agreed to make additional payments to the Company upon achieving certain pre-established regulatory and commercial milestones, as well as double-digit royalties on future net sales of Zoptrex™ in the Territory. STA will be responsible for the development, registration, reimbursement and commercialization of the product in the Territory. The Company and STA have also entered into a supply agreement, pursuant to which the Company will supply Zoptrex™ to STA for the duration of the license agreement.

David Dodd, President and CEO of the Company, stated, "I am very pleased that we have now concluded four agreements for the commercial rights to Zoptrex™, if approved, outside the United States. We believe that the interest in Zoptrex expressed by our licensees supports our view that Zoptrex™, if it is approved by the FDA for its initial indication, could be an important treatment option for women with the most severe form of endometrial cancer. We are particularly pleased to have a company of the caliber of STA as a licensee. STA enjoys the highest reputation in its markets and, with its existing portfolio of oncology products, it has the capability to position Zoptrex™ very well in the market."

STA Chief Executive Officer Mr. Carlo Montagner said Zoptrex™ had demonstrated great potential and was poised to add further value to the company's expanding oncology portfolio. "All results to date suggest Zoptrex™ is a potent new compound and we look forward to collaborating closely with Aeterna Zentaris to maximise its full potential in our key markets," he said.

About Zoptrex™

Zoptrex™ (zoptarelin doxorubicin) is a complex molecule that combines a synthetic peptide carrier with doxorubicin, a well-known chemotherapy agent. The synthetic peptide carrier is (D)-Lys⁶-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 Specialised Therapeutics Asia

Specialised Therapeutics Asia Pte Ltd ("STA") is an international biopharmaceutical company established to provide pioneering healthcare solutions to patients throughout South East Asia, as well as in Australia and New Zealand. The company is a close affiliate of Specialised Therapeutics Australia, which also collaborates with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life changing healthcare solutions to patients affected by a range of diseases. STA is committed to making new and novel therapies available to patients around the world, with a broad therapeutic portfolio spanning oncology, hematology, urology and ophthalmology. Additional information can be found at www.specialisedtherapeutics.com.au [12].

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 [13].

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.

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