Æterna Zentaris

Published on *Æterna Zentaris Investor Center* (http://ir.aezsinc.com) on 9/28/15 8:08 am EDT

Aeterna Zentaris' Zoptarelin Doxorubicin Meets Phase 2 Primary Endpoint in Men with Heavily Pretreated Castration and Taxane Resistant Prostate Cancer

Release Date:
Monday, September 28, 2015 8:08 am EDT

Terms:
2015 [1]

Dateline City:
QUEBEC CITY, Canada

Aeterna Zentaris Inc. (NASDAQ: AEZS) (TSX: AEZ) (the "Company") today announced that its lead oncology compound, zoptarelin doxorubicin (formerly AEZS 108), met the primary end-point of the investigator-driven and sponsored Phase 2 clinical trial in Castration and taxane Resistant Prostate Cancer (CRPC) and demonstrated good tolerability. The primary endpoint was Clinical Benefit (CB) defined as remaining progression-free by RECIST and Prostate Specific Antigen (PSA) after treatment for 12+ weeks.

Results were presented this morning by lead investigator, Jacek Pinski, MD, PhD, of the USC Norris Comprehensive Cancer Center, during a poster session at the 18th ECCO – 40th ESMO European Cancer Congress in Vienna, Austria.

David A. Dodd, Chairman and CEO of Aeterna Zentaris, commented, "We are encouraged with the Phase 2 results for zoptarelin doxorubicin in prostate cancer. Because luteinizing hormone-releasing hormone receptors are expressed in a great number of cancers including prostate cancer, we believe that zoptarelin doxorubicin, which specifically targets those receptors, may represent a novel targeted treatment for men with this disease. These Phase 2 results in prostate cancer, as well as prior positive Phase 2 results in endometrial and ovarian cancer, are further demonstration of the potential of this innovative compound in a variety of cancer indications for both men and women."

Study Design

This was a single-arm Simon Optimum design Phase 2 study of zoptarelin doxorubicin in 25 patients with CRPC. Patients received zoptarelin doxorubicin (210 mg/m2) intravenously over 2 hours, every 3 weeks. The primary endpoint was CB, defined as remaining progression-free by RECIST and PSA after treatment for 12+ weeks. Secondary endpoints were progression free survival (PFS), best overall response, toxicity, pain and overall survival (OS).

Results

Twenty patients had measurable disease, with a median of 1 prior chemotherapy regimens and a median PSA of 255.8 ng/ml. Eleven patients experienced CB; 13 patients achieved stable disease. Median PFS and OS were 4.4 months (95% CI: 3.6, 5.5) and 6 months (95% CI: 4.2, 10.7) respectively. Forty-four percent of patients demonstrated improvement of pain score at 12 weeks. Maximal PSA response was stable in 20 patients. Zoptarelin doxorubicin demonstrated good tolerability with grade 3-4 hematologic (n=7) and grade 3 blood and lymphatic system disorders (n=5) adverse events as the most common events.

Titled, "A Phase 2 Trial of AEZS-108 in Castration- and Taxane-Resistant Prostate Cancer", Liu SV, Tsao Wei DD, Xiong S, Groshen S, Dorff TB, Quinn DI, Tai YC, Engel J, Hawes D, Schally AV, Pinski J, the poster is available at this link.

About Zoptarelin Doxorubicin

Zoptarelin doxorubicin represents a new targeting concept in oncology using a hybrid molecule composed of a synthetic peptide carrier and a well-known chemotherapy agent, doxorubicin. Zoptarelin doxorubicin is the first intravenous drug in advanced clinical development that directs the chemotherapy agent specifically to LHRH-receptor expressing tumors, which could result in a more targeted treatment with less damage to healthy tissue. The Company is currently conducting a fully-enrolled ZoptEC (Zoptarelin doxorubicin in Endometrial Cancer) Phase 3 trial in women with advanced, recurrent or metastatic endometrial cancer; results from a second interim analysis of this trial are expected in October 2015. Zoptarelin doxorubicin is also in an investigator initiated Phase 2 trial in prostate cancer. Aeterna Zentaris owns the worldwide rights to this compound except in China (including Hong Kong and Macau) where rights have been out-licensed to Sinopharm A-Think Pharmaceuticals, a subsidiary of Sinopharm, the largest medical and healthcare group in China and on Fortune's Global 500 list. On April 16, 2015, the Company announced the filing of a patent application intended to strengthen the exclusivity of zoptarelin doxorubicin through a unique, significantly lower cost in the manufacturing process.

About Prostate Cancer

According to the American Cancer Society, prostate cancer is the second most common cancer in men worldwide, affecting approximately one in six males. It is estimated that there will be approximately 220,800 new cases of prostate cancer in the United States in 2015. While prostate cancer is prevalent among men of all ages and races, African Americans and men older than 65 have a higher rate of diagnosis.

About Aeterna Zentaris

Aeterna Zentaris is a specialty biopharmaceutical company engaged in developing and commercializing novel treatments in

oncology, endocrinology and women's health. For more information, visit www.aezsinc.com [2].

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 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 ability of the Company to efficiently commercialize one or more of its products or product candidates, the ability of the Company to take advantage of business opportunities in the pharmaceutical industry, uncertainties related to the regulatory process, 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, unless required to do so by a governmental authority or by applicable law.

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Ticker Slug:
Ticker: AEZS
Exchange: NASDAQ
Ticker: AEZ
Exchange: TSX

Source URL: http://ir.aezsinc.com/press-release/2015/aeterna-zentaris-zoptarelin-doxorubicin-meets-phase-2-primary-endpoint-men

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