Æterna Zentaris

Published on *Æterna Zentaris Investor Center* (http://ir.aezsinc.com) on 4/10/13 8:08 am EDT

Aeterna Zentaris and Ergomed Sign Co-Development and Profit Sharing Agreement for AEZS-108 in Endometrial Cancer

Release Date:
Wednesday, April 10, 2013 8:08 am EDT

Terms:
2013 [1]

Dateline City:
QUÉBEC CITY

All amounts are in US dollars

Aeterna Zentaris Inc. (NASDAQ: AEZS) (TSX: AEZ) (the "Company") today announced the signing of a co-development and profit sharing agreement with Ergomed Clinical Research Ltd. ("Ergomed") for AEZS-108 in endometrial cancer. Ergomed was selected as the contract clinical development organization to conduct the multicenter, multinational, randomized Phase 3 trial with AEZS-108 in endometrial cancer.

Under the terms of the agreement, Ergomed will assume 30% (up to $10 million) of the clinical and regulatory costs for the Phase 3 trial with AEZS-108 in endometrial cancer, which are estimated at approximately $30 million over the course of the study. Ergomed will receive its return on investment based on an agreed single digit percentage of any net income received by Aeterna Zentaris for AEZS-108 in this indication, up to a specified maximum amount.

Juergen Engel, Ph.D., President and CEO of Aeterna Zentaris stated, "We look forward to working with Ergomed which has a proven track record of delivering cost effective and efficient drug development services worldwide. This agreement is part of our non-dilutive strategy aimed at minimizing R&D costs while maximizing drug development efficiency. Our goal for AEZS-108 with this collaboration, is to provide a much needed new treatment option to women with late-stage endometrial cancer."

Miroslav Reljanovic, M.D., CEO of Ergomed said, "We are delighted to co-invest with Aeterna Zentaris in the development of AEZS-108 which has shown promising results in Phase 2 trials to date. This agreement is the fifth co-development deal we have signed to date, and demonstrates again the attractive alternative it offers to sophisticated drug developers, as they look to maximise investment returns. Ergomed is now established as one of the leading companies worldwide offering and completing deals under this innovative model."

The Study

This will be an open-label, randomized, multicenter Phase 3 trial conducted in North America, Europe, Israel and other countries under a Special Protocol Assessment, comparing AEZS-108 with doxorubicin as second line therapy for locally-advanced, recurrent or metastatic endometrial cancer. The trial will involve approximately 500 patients and the primary efficacy endpoint is improvement in median Overall Survival.

For more information on this trial, go to www.clinicaltrials.gov [2] NCT 01767155.

About AEZS-108 (doxorubicin peptide conjugate)

AEZS-108 represents a new targeting concept in oncology using a hybrid molecule composed of a synthetic peptide carrier and a well-known chemotherapy agent, doxorubicin. AEZS-108 is the first intravenous drug in advanced clinical development that directs the chemotherapy agent specifically to LHRH-receptor expressing tumors, resulting in more targeted treatment with less damage to healthy tissue. The product has successfully completed Phase 2 studies for the treatment of ovarian and endometrial cancer and the Company is currently planning a Phase 3 trial in endometrial cancer under a Special Protocol Assessment. AEZS-108 is also in Phase 2 trials in triple-negative breast cancer, prostate cancer and bladder cancer. AEZS-108 has been granted orphan drug designation by the FDA and orphan medicinal product designation from the European Medicines Agency for the treatment of ovarian cancer. Aeterna Zentaris owns the worldwide rights to AEZS-108.

About Endometrial Cancer

Endometrial cancer is the most common gynecologic malignancy and develops when abnormal cells amass to form a tumor in the lining of the uterus. It largely affects women over the age of 50 with a higher prevalence in Caucasians and a higher mortality rate among African Americans. Approximately one in 30 women is diagnosed with endometrial cancer every year. According to the American Cancer Society, an estimated 49,560 new cases of endometrial cancer in the U.S., and 35,600 in Europe, are expected during 2013, with about 20% of recurring disease.

About Aeterna Zentaris

Aeterna Zentaris is an oncology and endocrinology drug development company currently investigating treatments for various unmet medical needs. The Company's pipeline encompasses compounds at all stages of development, from drug discovery through to marketed products. For more information, visit www.aezsinc.com [3].

About Ergomed

Ergomed offers clinical development services for the biotechnology and pharmaceutical industry specializing in therapeutics for oncology, neurology and immunology. Ergomed also engages in shared risk ventures through co-development agreements. With its global infrastructure in Western and Eastern Europe, the Middle East and North America, Ergomed offers cost effective and efficient drug development. For further information, visit www.ergomed-cro.com [4].

Forward-Looking Statements

This press release contains forward-looking statements made pursuant to the safe harbour provisions of the U.S. 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, 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 take advantage of business opportunities in the pharmaceutical industry, uncertainties related to the regulatory process and general changes in economic conditions. Investors should consult the Company's quarterly and annual filings with the Canadian and U.S. securities commissions for additional information on risks and uncertainties relating to forward-looking statements. Investors are cautioned not to rely 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.

Language:
English

Contact:

Aeterna Zentaris Inc.
Investor Relations
Ginette Beaudet Vallières, Investor Relations Coordinator
418-652-8525 ext. 265
gvallieres@aezsinc.com [5]
or
Media Relations
Paul Burroughs, Director of Communications
418-652-8525 ext. 406
pburroughs@aezsinc.com [6]

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

Links:
[1] http://ir.aezsinc.com/category/press-release-category/2013
[2] http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.clinicaltrials.gov&esheet=51256922&newsitemid=20160111006236&lan=en-US&anchor=www.clinicaltrials.gov&index=1&md5=54e3710ab2f0555feebd2e6006fa0b08
[3] http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.aezsinc.com&esheet=51256922&newsitemid=20160111006236&lan=en-US&anchor=www.aezsinc.com&index=2&md5=2fb5de73122484be9e5c9dc7e7cffd85
[4] http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.ergomed-cro.com&esheet=51256922&newsitemid=20160111006236&lan=en-US&anchor=www.ergomed-cro.com&index=3&md5=0963c3d007162190d6a4b939d14d7eb2
[5] mailto:gvallieres@aezsinc.com
[6] mailto:pburroughs@aezsinc.com