

## **Aeterna Zentaris: Article on Phase 2 Results for Zoptarelin Doxorubicin in Endometrial Cancer Published in the International Journal of Gynecological Cancer**

### **Release Date:**

Tuesday, February 4, 2014 8:08 am EST

### **Terms:**

[2014](#) <sup>[1]</sup>

### **Dateline City:**

QUÉBEC CITY

Aeterna Zentaris Inc. (NASDAQ: AEZS, TSX: AEZ) (the "Company") today announced that an article on Phase 2 results for zoptarelin doxorubicin (AEZS-108) in endometrial cancer has been published in the February issue of the International Journal of Gynecological Cancer. Zoptarelin doxorubicin, is the Company's cytotoxic peptide conjugate which specifically targets luteinizing hormone-releasing hormone ("LHRH") receptors. The article, "Efficacy and Safety of AEZS-108 (LHRH Agonist Linked to Doxorubicin) in Women With Advanced or Recurrent Endometrial Cancer Expressing LHRH Receptors: A Multicenter Phase 2 Trial (AGO-GYN5)", Emons G., Gorchev G., Harter P., Wimberger P., Stähle A., Hanker L., Hilpert F., Beckmann M.W., Dall P., Gründker C., Sindermann H., Sehouli J., outlines results of this study which had been previously presented at the European Society of Gynaecological Oncology's ("ESGO") annual meeting in September 2011. The article is currently available at this [link](#).

"These encouraging results were the basis for our current Phase 3 ZoptEC (Zoptarelin doxorubicin in Endometrial Cancer) trial in women with advanced, recurrent or metastatic endometrial cancer who have progressed and have received one chemotherapeutic regimen with platinum and taxane", stated David Dodd, President and CEO of Aeterna Zentaris. "This compound's innovative targeted approach potentially offers a much needed novel treatment option for women with endometrial cancer and could provide the Company with a significant market opportunity."

### **Phase 2 Study Results and Conclusion**

Forty-four patients were entered onto the study at 8 centers in Germany and 3 centers in Bulgaria. Forty three of these patients were eligible. Two patients had a complete remission (5%) and 8 achieved a partial remission (18%). Stable disease for at least 6 weeks was observed in 44%. The median time to progression (TTP) was 7 months and median overall survival (OS) was 15 months. The most frequently reported grade 3 or 4 adverse effects were neutropenia (12%) and leucopenia (9%).

Data showed that zoptarelin doxorubicin has clinically meaningful activity with low toxicity in women with advanced or recurrent LHRH receptor positive endometrial cancer, supporting the principle of receptor mediated targeted chemotherapy.

### **Current ZoptEC Phase 3 trial in endometrial cancer**

This is an open-label, randomized, multicenter Phase 3 trial currently being conducted under a Special Protocol Assessment, comparing zoptarelin doxorubicin with doxorubicin as second line therapy for advanced, recurrent or metastatic endometrial cancer. The first patient was dosed in July 2013 and recruitment is ongoing at multiple sites in North America, Europe and Israel. The primary efficacy endpoint is improvement in median Overall Survival. Lead investigators are David Scott Miller, MD, from the University of Texas Southwestern Medical Center, in Dallas, Texas, and Hani Gabra, MD, from the Imperial College London Hammersmith Campus in London, England.

Selected as the contract clinical development organization, Ergomed has agreed to assume 30% (up to US\$10 million) of the clinical and regulatory costs for this trial. Details for this trial are available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) <sup>[2]</sup> (NCT01767155).

### **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, resulting in a more targeted treatment with less damage to healthy tissue. The Company is currently conducting a Phase 3 trial in endometrial cancer under a Special Protocol Assessment, while zoptarelin doxorubicin is also in an investigator-initiated Phase 2 trial in prostate cancer. Aeterna Zentaris owns the worldwide rights to this compound.

### **About Endometrial Cancer**

Endometrial cancer is the most common gynecologic malignancy in developed countries 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. According to the American Cancer Society, an estimated 49,560 new cases of endometrial cancer in the U.S., and 35,600 in Europe were expected during 2013, with about 20% of recurring disease.

### **About Aeterna Zentaris Inc.**

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

endocrinology. The Company's pipeline encompasses compounds from drug discovery to regulatory approval. For more information, visit [www.aezsinc.com](http://www.aezsinc.com) [3].

## 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 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 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:

Investor Relations  
Ginette Beaudet Vallières  
Investor Relations Coordinator  
(418) 652-8525 ext. 265  
[gvallieres@aezsinc.com](mailto:gvallieres@aezsinc.com) [4]

or  
Media Relations  
Paul Burroughs  
Director of Communications  
(418) 652-8525 ext. 406  
[pburroughs@aezsinc.com](mailto:pburroughs@aezsinc.com) [5]

## Ticker Slug:

*Ticker:* AEZS  
*Exchange:* NASDAQ  
*Ticker:* AEZ  
*Exchange:* TSX

---

**Source URL:** <http://ir.aezsinc.com/press-release/2014/aeterna-zentaris-article-phase-2-results-zoptarelin-doxorubicin-endometrial>

## Links:

[1] <http://ir.aezsinc.com/category/press-release-category/2014>

[2] <http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.clinicaltrials.gov&esheet=51255324&newsitemid=20160107006392&lan=en-US&anchor=www.clinicaltrials.gov&index=1&md5=e3eff7eecff0adb971767fe14314876e>

[3] <http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.aezsinc.com&esheet=51255324&newsitemid=20160107006392&lan=en-US&anchor=www.aezsinc.com&index=2&md5=838cf950740dc9355ae0dbae549279a6>

[4] <mailto:gvallieres@aezsinc.com>

[5] <mailto:pburroughs@aezsinc.com>