

Edgar Filing: Aeterna Zentaris Inc. - Form 6-K

Benign Prostatic Hyperplasia

[AETERNA ZENTARIS LOGO]

AETERNA ZENTARIS INC. 1405 du Parc-Technologique Blvd.
Quebec (Quebec) Canada G1P 4P5 T 418 652-8525 F 418 577-7597
www.aeternazentaris.com

PRESS RELEASE
For immediate release

AETERNA ZENTARIS REPORTS STATISTICALLY SIGNIFICANT POSITIVE PHASE II DATA ON CETRORELIX IN BENIGN PROSTATIC HYPERPLASIA

Broad, seven-study Phase II program on cetorelix in BPH, endometriosis and uterine myoma now successfully completed.

Data demonstrated a dose-dependent, durable, and statistically significant improvement of clinical symptoms characteristic of BPH, as well as excellent safety and tolerability profile.

QUEBEC CITY, CANADA, OCTOBER 7, 2004 - AETerna Zentaris Inc. (TSX: AEZ; NASDAQ: AEZS) today announced statistically significant positive results from a randomized, double-blind, placebo-controlled Phase II trial designed to evaluate different dosage regimens of a depot formulation of cetorelix, a luteinizing hormone-releasing hormone (LHRH) antagonist, in 250 patients with symptomatic benign prostatic hyperplasia (BPH). These new data demonstrate a dose-dependent, durable and statistically significant (p less than 0.001) improvement of clinical symptoms characteristic of BPH, including IPSS (International Prostate Symptom Score), at all dosages except the lowest, as well as an excellent safety and tolerability profile. These positive results are consistent with data from earlier studies and provide the basis for further development of cetorelix in BPH through collaboration with Solvay Pharmaceuticals and Shionogi/Nippon Kayaku.

Benign prostate hyperplasia is characterized by an abnormal, but not malignant, testosterone-mediated growth of prostate tissue. BPH is estimated to affect approximately 33 million men over 60 years of age. In 2004, the amount spent on drug treatment for this condition is expected to be around US\$1.8 billion.

"We are very excited about the positive results from this new Phase II trial, the last one from a broad seven-study Phase II program evaluating cetorelix in a combination of indications, and believe it provides strong evidence for the efficacy and safety of cetorelix in BPH, endometriosis and myoma," said Prof. Jurgen Engel, Executive Vice President, Global R&D and Chief Operating Officer at AETerna Zentaris. "These results, in our opinion, compare very favorably to currently marketed therapies for BPH, which require daily administration. We look forward to continued advancement of this program by our development and marketing partners worldwide, and the initiation of pivotal programs on cetorelix, including in BPH."

Edgar Filing: Aeterna Zentaris Inc. - Form 6-K

"The successful completion of this latest trial is a remarkable achievement and confirms the excellent partnership we have built with AETerna Zentaris. We believe that the results of the

[AETERNA ZENTARIS LOGO]

extensive Phase II program will now allow us to finalize the development plans for the compound," stated Dr. Werner Cautreels, Solvay Pharmaceuticals' Global Head of R&D.

The randomized, double-blind, placebo-controlled trial enrolled patients with symptomatic and objectively defined BPH (decreased urine flow) and was conducted in Europe, under the coordination of Professor Frans MJ Debruyne from the Department of Urology, University Medical Center in Nijmegen. All eligible patients received two intramuscular injections of placebo, two weeks apart, during a run-in period. After the initial four-week run-in period, 250 patients with symptomatic BPH were randomized into five equal groups receiving either placebo injections or four different dosage regimens from 60 to 120 mg in two or three injections of a depot formulation of cetrorelix over the course of four weeks.

Patients were followed for up to 26 weeks after the last injection for efficacy and safety assessments, as well as for levels of testosterone and quality of life and sexual function. As early as one month following the initiation of therapy, the use of cetrorelix was associated with a dose-dependent, statistically significant improvement of clinical signs and symptoms, including IPSS and maximum uroflow, compared to placebo. Importantly, for all dosage regimens the therapeutic response lasted until the last observation point, i.e. 24 to 26 weeks following cessation of cetrorelix administration.

ABOUT AETERNA ZENTARIS INC.

AETerna Zentaris Inc. is a biopharmaceutical company focused in oncology and endocrine therapy. Its extensive portfolio, from drug discovery to marketed products, includes perifosine, an orally-active AKT inhibitor in several Phase II trials for multiple cancers, and cetrorelix, an LHRH antagonist already marketed for IN VITRO fertilization under the brand name Cetrotide(R), and also in advanced clinical development for the treatment of uterine myoma, endometriosis and benign prostatic hyperplasia (BPH).

AETerna Zentaris also owns 62% of Atrium Biotechnologies Inc., which develops, distributes and markets active ingredients, specialty fine chemicals, cosmetic and nutritional products for the cosmetics, chemical, pharmaceutical and nutritional industries.

News releases and additional information about AETerna Zentaris are available on its new Web site www.aeternazentaris.com.

FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements made pursuant to the safe harbor provisions of the U.S. Securities Litigation Reform Act of 1995. Forward-looking statements involve known and unknown risks and uncertainties, which 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 ability of the Company to take advantage of business opportunities in the pharmaceutical industry,

Edgar Filing: Aeterna Zentaris Inc. - Form 6-K

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 the forward-looking statements.

[AETERNA ZENTARIS LOGO]

Investors are cautioned not to rely on these forward-looking statements. The Company does not undertake to update these forward-looking statements.

-30-

CONTACTS:

MEDIA RELATIONS

Paul Burroughs
(418) 652-8525 ext. 406
paul.burroughs@aeternazentaris.com

INVESTOR RELATIONS

Jacques Raymond
(418) 652-8525 ext. 360
jacques.raymond@aeternazentaris.com

U.S. INVESTOR RELATIONS

Lippert/Heilshorn & Associates
Kim Golodetz
(212) 838-3777
kgolodetz@lhai.com

EUROPE

Matthias Seeber
+49 69 42602 3425
matthias.seeber@zentaris.de

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AETERNA ZENTARIS INC.

DATE: October 7, 2004

By: /s/ Mario Paradis

Mario Paradis
Senior Finance Director and
Corporate Secretary