

**Press Release**

For immediate release

**Æterna Zentaris Partner Keryx Announces Positive Phase 2 Results for Perifosine as a Single Agent for the Treatment of Advanced Waldenstrom's Macroglobulinemia**

**Data Demonstrating a 35% Overall Response Rate with a Median Progression-Free Survival of 12.6 Months in Patients with Relapsed or Relapsed/Refractory Waldenstrom's Macroglobulinemia to be Published in the February 1, 2010 Issue of the Journal of Clinical Cancer Research**

**Québec City, Canada, January 29, 2010** – Æterna Zentaris Inc. (Nasdaq: AEZS; TSX: AEZ) (the "Company"), a late-stage drug development company specialized in oncology and endocrinology, today announced that an article entitled "*Clinical and Translational Studies of a Phase II Trial of the Novel Oral Akt Inhibitor Perifosine in Relapsed or Relapsed/Refractory Waldenstrom's Macroglobulinemia*," reporting Phase 2 data demonstrating the single agent activity of perifosine (KRX-0401) for the treatment of advanced Waldenstrom's Macroglobulinemia ("Waldenstrom's"), will appear in the February 1, 2010 issue of the Journal of Clinical Cancer Research. Perifosine, the Company's oral PI3K/Akt pathway inhibitor is currently being investigated in a Phase 3 trial, under Special Protocol Assessment, for the treatment of multiple myeloma. Like Multiple Myeloma and Non-Hodgkin's Lymphoma, Waldenstrom's is a hematologic disease in which the cancer cells target the bone marrow. There are currently no FDA approved drugs for the treatment of Waldenstrom's. Keryx Biopharmaceuticals, Inc. (NASDAQ: KERX) is Æterna Zentaris' partner and licensee for perifosine in the United States, Canada and Mexico. Perifosine is also out-licensed to Handok in South Korea while Æterna Zentaris retains rights for the rest of the world.

Dr. Irene Ghobrial, Assistant Professor of Medicine, Bing Center for Waldenstrom's Macroglobulinemia at Dana-Farber Cancer Institute, led the Phase 2 study in which 37 patients were treated with perifosine 150 mg daily for 6 cycles. In this study, 41% of the patients had 3 or more lines of prior therapy and 78% had 2 or more prior lines of therapy. Such prior therapies include nucleoside analogues, bortezomib, alkylating agents and rituximab, which are not approved for, but are often used in the treatment of Waldenstrom's. The median % involvement of the bone marrow with lymphoplasmacytic cells was 70%, indicating advanced disease. Stable or responding patients were allowed to continue therapy until progression. Of the 37 patients, 4 achieved a partial response (11%), 9 achieved a minimal response (24%), and 20 showed stable disease (54%). Overall, 89% (33/37) of patients treated with single agent perifosine were reported to have stable disease or better, while 11% (4 patients) demonstrated progression. The

median progression-free survival in the study was 12.6 months (90% C.I. (10.2, 22.7)), with a median overall survival of 26 months (90% C.I. (26 – upper limit not reached)). Perifosine was generally well-tolerated with gastrointestinal symptoms and fatigue reported as the most common adverse events related to therapy.

Also described in the article are translational studies using gene expression profiling and immunohistochemistry on pre- versus post-treatment patient samples conducted by Dr. Ghobrial. Results showed that in the majority of samples tested, there was a significant reduction of phospho-GSK3/β (downstream from Akt) using immunohistochemistry. Similarly, results demonstrated that perifosine significantly inhibited the expression of multiple members of the NF-κB family of genes, confirming previous *in vitro* studies showing activity of perifosine targeting this pathway.

“Perifosine as a single agent holds great promise in the treatment of patients with relapsed/refractory Waldenstrom’s Macroglobulinemia,” commented Dr. Ghobrial, who continued, “Responses were durable and occurred rapidly. The progression-free survival of 12.6 months is considered long compared to other targeted agents used in a similar population such as bortezomib (Velcade®) where the median time to progression was reported at 7.9 months. We look forward to further evaluating perifosine’s promise in this disease, either as a single agent or in combination with agents such as rituximab or bortezomib.”

Juergen Engel, President and CEO of Æterna Zentaris stated, “We are very pleased with these results as they provide additional evidence of perifosine’s potential as a novel approach in treating multiple types of cancer, both as a single agent and in combination therapy. We now look forward to the future late-stage development of this compound in Waldenstrom’s Macroglobulinemia, metastatic colon cancer as well as in multiple myeloma, for which perifosine is currently in an ongoing Phase 3 registration trial.”

## **About Waldenstrom’s Macroglobulinemia**

Waldenstrom’s Macroglobulinemia is a distinct lymphoproliferative disorder characterized by bone marrow infiltration with lymphoplasmacytic cells, along with an IgM monoclonal gammopathy. Waldenstrom’s affects an estimated 1,500 patients annually in the U.S. Despite advances in the therapy of Waldenstrom’s, the disease remains incurable, thereby necessitating the development of novel therapeutics. There are currently no FDA approved drugs for Waldenstrom’s, with nucleoside analogues, the proteasome inhibitor bortezomib (Velcade®), alkylating agents (chlorambucil) and rituximab (Rituxan®) often used to treat the disease.

## **About Perifosine**

Perifosine is a novel, potentially first-in-class, oral anticancer agent that modulates Akt and a number of other key signal transduction pathways including the JNK pathway, all of which are pathways associated with programmed cell death, cell growth, cell differentiation and cell survival. The effects of perifosine on Akt are of particular interest because of the importance of this pathway in the development of most cancers, with evidence that it is often activated in tumors that are resistant to other forms of anticancer therapy, and the difficulty encountered thus far in the discovery of drugs that will inhibit this pathway without causing excessive toxicity. High levels of activated Akt (pAkt) are seen frequently in many types of cancer and have been

correlated with poor prognosis. Perifosine is currently in a Phase 3 trial, under Special Protocol Assessment (SPA), in multiple myeloma for which it has received Orphan Drug and Fast Track designations from the FDA in this indication. Perifosine is also in Phase 2 clinical trials for several other tumor types.

## **About Æterna Zentaris Inc.**

Æterna Zentaris Inc. is a late-stage drug development company specialized in oncology and endocrinology. News releases and additional information are available at [www.aezsinc.com](http://www.aezsinc.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, 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. 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 except if we are required by a governmental authority or applicable law.

## **Investor Relations**

Dennis Turpin  
SVP and CFO  
(418) 652-8525 ext. 242  
[dturpin@aezsinc.com](mailto:dturpin@aezsinc.com)

## **Media Relations**

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