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Uniquely devoted to the Canadian myeloma community

Æterna Zentaris Partner, Keryx, Announces Agreement with FDA on a Special Protocol Assessment for Phase 3 Trial with Perifosine (KRX-0401) for the Treatment of Multiple Myeloma

Quebec City, Canada, August 3, 2009

Æterna Zentaris Inc., a global biopharmaceutical company focused on endocrine therapy and oncology, today announced that Keryx Biopharmaceuticals, Inc., its partner and licensee for perifosine in the North American market, has reached an agreement with the U.S. Food and Drug Administration (FDA) regarding a Special Protocol Assessment (SPA) on the design of a Phase 3 trial for the Company's PI3K/Akt pathway inhibitor compound, perifosine (KRX-0401), in relapsed or relapsed/refractory multiple myeloma patients previously treated with bortezomib (Velcade®). The SPA provides agreement that the Phase 3 study design adequately addresses objectives in support of a regulatory submission. The study, entitled, "A Phase 3 Randomized Study to Assess the Efficacy and Safety of Perifosine Added to the Combination of Bortezomib and Dexamethasone in Multiple Myeloma Patients Previously Treated with Bortezomib", will be a double-blind, placebo-controlled study comparing the efficacy and safety of perifosine vs. placebo when combined with bortezomib and dexamethasone. The trial, powered at 90%, will enroll approximately 400 patients with relapsed or relapsed/refractory multiple myeloma. The primary endpoint is progression-free survival and secondary endpoints include overall response rate, overall survival and safety.

Juergen Engel, Ph. D., President and Chief Executive Officer of Æterna Zentaris commented, "We are very pleased and excited about perifosine moving forward into a Phase 3 trial. This represents a major milestone in our oncology drug development strategy which could hold great promise for patients with multiple myeloma."

About the Phase 3 Trial Design

The Phase 3 trial is a randomized (1:1), double-blind trial comparing the efficacy and safety of perifosine to placebo when combined with bortezomib and dexamethasone in approximately 400 patients with relapsed or relapsed/refractory multiple myeloma. Patients must have been previously treated with both bortezomib (Velcade®) and an immunomodulatory agent (Revlimid® or Thalomid®) and previously treated with one to four prior lines of therapy. The primary endpoint is progression-free survival and secondary endpoints include overall response rate, overall survival and safety.

About Multiple Myeloma

Multiple myeloma, a cancer of the plasma cell, is an incurable but treatable disease. Multiple myeloma is the second most-common hematologic cancer, representing 1% of all cancer diagnoses and 2% of all cancer deaths. According to the American Cancer Society, in 2009, there will be an estimated 20,580 new cases of multiple myeloma and an estimated 10,500 deaths from multiple myeloma in the United States. To date, several FDA approved therapies exist for the treatment of multiple myeloma. Despite this progress, patients continue to relapse, become refractory to prior treatments and eventually die from their disease. Thus, new therapies are needed to treat these patients and extend their survival.

About Perifosine

Perifosine is a novel, first-in-class, oral anti-cancer agent that modulates several key signal transduction pathways, including Akt, MAPK, and JNK that have been shown to be critical for the survival of cancer cells. Perifosine has demonstrated single agent anti-tumor activity in Phase 1 and Phase 2 studies and is currently being studied as a single agent and in combination with several forms of anti-cancer treatments for various forms of cancer. Most recently, positive results were reported for the single agent use of perifosine in patients with advanced metastatic renal cancer and in combination with capecitabine for advanced metastatic colon cancer (placebo-controlled), as well as for perifosine in combination with bortezomib +/- dexamethasone in relapsed and refractory myeloma.

About Special Protocol Assessments

The Special Protocol Assessment (SPA) process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a new drug application.

Final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 trial. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety. For more information on the Special Protocol Assessment process, please visit: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080571.pdf>