

Press Release

For immediate release

Aeterna Zentaris Reports Final Results of a Randomized, Double-Blind, Placebo-Controlled Phase 2 Study of Perifosine in the Treatment of Advanced Metastatic Colorectal Cancer

Data Reported at ASCO Confirm a Statistically Significant Improvement in Both Time to Tumor Progression and Overall Survival in the Perifosine + Capecitabine Arm Versus Placebo + Capecitabine Arm

Quebec City, Canada, Tuesday, June 8, 2010 - Aeterna Zentaris Inc. (NASDAQ: AEZS, TSX: AEZ) (the "Company"), a late-stage drug development company specialized in oncology and endocrine therapy, today reported final results on the clinical activity of perifosine (KRX-0401), the Company's novel, potentially first-in-class, oral anticancer agent that inhibits Akt activation in the phosphoinositide 3-kinase (PI3K) pathway, in combination with capecitabine (Xeloda[®]) as a treatment for advanced, metastatic colorectal cancer. Abstract #3531, entitled, "*Final results of a randomized Phase 2 study of perifosine in combination with capecitabine (P-CAP) versus capecitabine plus placebo (CAP) in patients with second- or third-line metastatic colorectal cancer (mCRC)*" is being presented today in a poster discussion held during the 2010 Annual Meeting of the American Society of Clinical Oncology (ASCO) held in Chicago.

Study Design

In this randomized, double-blind, placebo-controlled study conducted at 11 centers across the United States, heavily pre-treated patients with second- or third-line metastatic colorectal cancer were randomized to receive capecitabine (a chemotherapy used in advanced metastatic colorectal cancer which is marketed by Roche as Xeloda[®]) at 825 mg/m² BID (total daily dose of 1650 mg/m²) on days 1 – 14 every 21 days plus either perifosine or placebo at 50 mg daily. The study enrolled a total of 38 patients, 34 of which were third-line or greater. Median age of patients was 65 (32-83); 61% of the patients were male. Of the 38 patients enrolled, 35 patients were evaluable for response (20 patients on the perifosine + capecitabine arm and 15 patients on the placebo + capecitabine arm). Three patients on the placebo + capecitabine arm were not evaluable for response (2 patients were inevaluable due to toxicity (days 14, 46) and 1 was inevaluable due to a new malignancy on day 6). All patients in the perifosine + capecitabine arm were evaluable for response.

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The patients in the study were heavily pre-treated, with the arms well-balanced in terms of prior treatment regimens. The prior treatment regimens for all 38 patients are shown in the table below. Notably, all of the patients (with the exception of one CAP arm patient) had been treated with FOLFIRI and/or FOLFOX, almost 80% treated with Avastin[®], and half treated with an EGFR antibody:

Prior RX	P-CAP (n=20)	CAP (n=18)	All Patients (n=38)
FOLFIRI	18 (90%)	16 (89%)	34 (89%)
FOLFOX	15 (75%)	13 (72%)	28 (74%)
FOLFIRI & FOLFOX	13 (65%)	12 (67%)	25 (66%)
Avastin [®]	15 (75%)	15 (83%)	30 (79%)
EGFR Antibody (1)	9 (45%)	10 (56%)	19 (50%)
5-FU Refractory Status	14 (70%)	13 (72%)	27 (71%)
Third Line or >	18 (90%)	16 (89%)	34 (89%)

(1) Prior treatment with Erbitux[®] and/or Vectibix[®]

The primary endpoint of this study was to measure Time to Progression (TTP). Overall Response Rate (ORR), defined as Complete Response (CR) + Partial Response (PR) by RECIST, and Overall Survival (OS) were measured as secondary endpoints.

Study Results

The P-CAP arm demonstrated a statistically significant advantage for TTP and OS, as well as for the percentage of patients achieving Stable Disease (SD) or better lasting 12 or more weeks, as compared to the CAP arm. The P-CAP arm demonstrated a greater than 60% improvement in OS, a more than doubling of median TTP, and almost a doubling of the percentage of patients achieving SD or better. In addition, the ORR was 20% (including one CR, and durable responses) in the P-CAP arm versus 7% in the CAP arm.

The final efficacy results are as follows:

All evaluable patients (n=35):

Group	n	CR n (%)	PR n (%)	Duration of Response	> SD (min 12 wks) n (%) p=0.036	PD< 12 wks n (%)	Median TTP Wks p=0.0012	Median OS* Months p=0.0161
P-CAP	20	1 (5%)	3 (15%)	CR: 36 m	11 (55%)	5 (25%)	28 [95% CI (12-48)]	17.7 [95% CI (8.5-24.6)]
				PR: 21, 19, 11 m				
CAP	15	0	1 (7%)	PR: 7 m	5 (33%)	9 (60%)	11 [95% CI (9-15.9)]	10.9 [95% CI (5.-16.9)]

*Survival is calculated from date of randomization until the date of death from any cause, whether or not additional therapies were received after removal from treatment.

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Of notable interest were the patients who were previously refractory to a 5-FU based regimen. The P-CAP arm again demonstrated a statistically significant increase in both TTP and OS compared to the CAP arm. The final data is illustrated below:

5-FU refractory patients (n=25):

Group	n (%)	PR n (%)	Duration of Response	≥ SD (min 12 wks) n (%) p=0.066	PD <12 wks n(%)	Median TTP Weeks p=0.0004	Median OS Months P=0.0112
P-CAP	14 (70%)	1 (7%)	19 m	8 (57%)	5 (36%)	18 [95% CI (12-36)]	15.1 [95% CI (7.3-22.3)]
CAP	11 (73%)	0	-	3 (27%)	8 (73%)	10 [95% CI (6.6-11)]	6.6 [95% CI (4.7-11.7)]

All 38 patients were evaluable for safety. The P-CAP combination was well-tolerated with Grade 3 and 4 adverse events of > 10% incidence for the P-CAP arm versus CAP arm as follows: hand-foot syndrome (30% vs. 0%), anemia (15% vs. 0%), fatigue (0% vs. 11%) and abdominal pain (5% vs. 11%). Of note, incidence of Grade 1 and 2 hand-foot syndrome was similar in both the P-CAP and CAP arms (25% vs. 22%, respectively). Hand-foot syndrome is a reported adverse event with capecitabine monotherapy. Patients who remained on treatment longer in the Phase 2 study had a greater chance to develop hand-foot syndrome, as illustrated by a median time to onset of Grade 3 and 4 hand-foot syndrome in the P-CAP arm of 19 weeks.

Based on the Phase 2 data, a Phase 3 randomized double-blind trial comparing perifosine + capecitabine vs. placebo + capecitabine in patients with advanced refractory colorectal cancer (X-PECT trial : *Xeloda*[®] + *Perifosine Evaluation in Colorectal cancer Treatment*), under Special Protocol Assessment (SPA) from the FDA, is open and enrolling patients at multiple centers throughout the US.

Juergen Engel, Ph.D., President and Chief Executive Officer of Æterna Zentaris, commented, "We are very pleased with the positive final data of this Phase 2 study, as they continue to demonstrate perifosine's potential as novel agent for the treatment of colorectal cancer. They are also encouraging regarding our current Phase 3 trial in this same indication, since its design is based on results of this Phase 2 trial."

A copy of the abstract can be accessed through the ASCO website, www.asco.org

About Perifosine

Perifosine, a novel, potentially first-in-class, oral Akt inhibitor, is currently in Phase 3 trials for advanced colorectal cancer and multiple myeloma, under Special Protocol Assessment and Fast Track designation granted by the Food and Drug Administration (FDA) for both indications. FDA has also granted perifosine orphan-drug status for multiple myeloma. Furthermore, the European Medicines Agency (EMA) has issued a positive Scientific Advice, as well as a positive opinion for Orphan Medicinal Product designation for perifosine in multiple myeloma. Perifosine is also in a Phase 1 trial in pediatric patients, as well as in other Phase 1 and Phase 2 trials for several other tumor types.

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Perifosine is licensed to Keryx Biopharmaceuticals Inc. (Keryx) (Nasdaq: KERX), in the United States, Canada and Mexico. Aeterna Zentaris has also out-licensed perifosine to Handok in South Korea, while retaining rights for the rest of the world.

About Colorectal Cancer

According to the American Cancer Society, colorectal cancer is the third most common form of cancer diagnosed in the United States. It is estimated that over 146,000 people were diagnosed with some form of colorectal cancer with over 49,000 patients dying from colorectal cancer in 2009. Surgery is often the main treatment for early stage colorectal cancer. When colorectal cancer metastasizes (spreads to other parts of the body such as the liver) chemotherapy is commonly used. Treatment of patients with recurrent or advanced colorectal cancer depends on the location of the disease. Chemotherapy regimens (i.e. FOLFOX or FOLFIRI either with or without bevacizumab) have been shown to increase survival rates in patients with metastatic/advanced colorectal cancer. Currently, there are seven approved drugs for patients with metastatic colorectal cancer: 5-fluorouracil (5-FU), capecitabine (Xeloda®), irinotecan (Camptosar®), oxaliplatin (Eloxatin®), bevacizumab (Avastin®), cetuximab (Erbix®), and panitumumab (Vectibix®). Depending on the stage of the cancer, two or more of these types of treatment may be combined at the same time or used after one another. For example, FOLFOX combines 5-FU, leucovorin and oxaliplatin and FOLFIRI combines 5-FU, leucovorin and irinotecan. Bevacizumab, a VEGF monoclonal antibody, is commonly administered with chemotherapy. Typically, patients who fail 5-FU, oxaliplatin, irinotecan, and bevacizumab-containing therapies, and who have wild-type KRAS status receive EGFR monoclonal antibody therapy with either cetuximab or panitumumab. Once patients progress on these agents, there are no further standard treatment options.

About Aeterna Zentaris Inc.

Aeterna Zentaris Inc. is a late-stage drug development company specialized in oncology and endocrine therapy. News releases and additional information are available at 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.

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