

Edgar Filing: AETERNA LABORATORIES INC - Form 6-K

AETERNA LABORATORIES INC
Form 6-K
May 18, 2001

LOGO OF
AETERNA LABORATORIES INC.

PRESS RELEASE
For Immediate Release

AETERNA'S NEOVASTAT SHOWS ABILITY TO INCREASE THE ANGIOSTATIN LEVEL
IN MICE WITH IMPLANTED HUMAN BRAIN CANCER CELLS

DATA ON THIS ADDITIONAL MECHANISM OF ACTION PRESENTED AT ASCO
MEETING IN SAN FRANCISCO

SAN FRANCISCO, CALIFORNIA , MAY 14, 2001 - Today, AETerna Laboratories Inc. (NASDAQ: AELA, TSE: AEL) presented new data showing that Neovastat/AE-941 is able to increase the level of angiostatin in mice with implanted human glioblastoma, a form of brain cancer. Results on this additional mechanism of action of Neovastat were presented in San Francisco at the American Society of Clinical Oncology (ASCO) Annual Meeting on "New Drugs in Cancer Therapy" by Professor Francois Berger, MD, PhD, neuro-oncologist and investigator of this study at the INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM), in Grenoble, France.

The study consisted in injecting human glioblastoma cells (cancer cells) into the brain of nude mice. The mice were then given Neovastat in order to test its antitumoral activity. Not only did results show an antitumoral activity in Neovastat, but it also uncovered a new element of its activity which increases tissue type Plasminogen activator (tPA), an enzyme involved in the production of angiostatin. This increased tPA activity resulted in an increase in endogenous (produced by the body) angiostatin at the tumor site.

"These results are significant since this model is very aggressive and few agents are capable of improving survival time," declared Dr. Berger.

"Neovastat's activation of tPA translates into a multifunctional impact including inhibition of angiogenesis and tumor infiltration. These two effects might have an important contribution in improving survival in this model."

"Glioblastomas are one of the most vascularized tumor and are VEGF-dependent. The use of an antiangiogenic agent containing several mechanisms of action, such as Neovastat, may prove effective in increasing survival time in glioblastoma patients," added Dr. Berger.

"Neovastat does not contain angiostatin, but rather agents which induce the production of endogenous angiostatin at the tumor site," said Dr. Pierre Falardeau, AETerna's Vice President of Scientific Affairs. "This particular mechanism of action further strengthens Neovastat's position as a unique angiogenesis inhibitor with multiple mechanisms of action since it has been previously shown to block the VEGF (Vascular Endothelial Growth Factor) signaling pathway, selectively inhibit matrix metalloproteinases (MMPs 2, 9 and 12) and induce endothelial cell apoptosis (programmed cell death). Therefore,

Edgar Filing: AETERNA LABORATORIES INC - Form 6-K

instead of blocking only one of the multistep process of angiogenesis, Neovastat's several mechanisms of action could act together in a synergistic fashion to induce a more complete inhibition of angiogenesis," concluded Dr. Falardeau.

ABOUT AETERNA AND NEOVASTAT/AE-941

AEterna Laboratories Inc. is a Canadian biopharmaceutical company and a frontrunner in the field of antiangiogenesis. Its lead product, Neovastat/AE-941, is being investigated in three major therapeutic areas: oncology, dermatology and ophthalmology.

Neovastat is a novel antiangiogenic product with multiple mechanisms of action that block angiogenesis -- the process involved in the formation of new blood vessels which are needed in order for cancer tumors and other pathological conditions to develop.

Neovastat is currently used in two Phase III pivotal clinical trials for the treatment of lung and kidney cancer as well as in a Phase II pivotal trial for the treatment of multiple myeloma, a form of blood cancer. These trials are currently held in more than 125 clinical institutions in Canada, the U.S. and in several European countries. For more information, please call 1-888-349-3232 (North America).

AEterna is listed on the Toronto Stock Exchange under the symbol AEL and on Nasdaq under the symbol AELA.

AEterna's news releases and additional information are available on its Web site at www.aeterna.com.

SAFE HARBOR STATEMENT

This press release contains forward-looking statements, which are 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 the business opportunities in the pharmaceutical industry, uncertainties related to the regulatory process and general changes in economic conditions. Investors should consult the Company's ongoing 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.

-30-

FOR MORE INFORMATION, CONTACT:

CANADA
Paul Burroughs
Director of Communications
AEterna Laboratories Inc.
Tel.: 418-652-8525, ext. 406
Fax: 418-577-7700
E-mail: paul.burroughs@aeterna.com

USA
Investor and Media Relations:
Ms. Lisa Lindberg
The Investor Relations Group Inc.
Tel.: 212-825-3210
Fax: 212-825-3229
E-mail: TheProTeam@aol.com

Edgar Filing: AETERNA LABORATORIES INC - Form 6-K

LOGO OF
AETERNA LABORATORIES INC.

P R E S S R E L E A S E
FOR IMMEDIATE RELEASE

AETERNA'S PATIENT RECRUITMENT HAS REACHED THE HALFWAY MARK
IN ITS PHASE III TRIAL IN RENAL CELL CARCINOMA

THIS STUDY IS CURRENTLY BEING HELD AT
SOME 50 INVESTIGATIVE CENTRES IN
NORTH AMERICA AND EUROPE

SAN FRANCISCO, CALIFORNIA, MAY 15, 2001 - AETerna laboratories inc. (NASDAQ: AELA; TSE: AEL) announced today that patient recruitment in the Phase III trial in renal cell carcinoma is more than half completed and trial is proceeding according to schedule. Led by an international team of oncology experts, the trial which involves 280 patients, is being conducted at some 50 investigative centres in Canada, the U.S., and Europe. The study aims at evaluating the efficacy of Neovastat in prolonging survival in patients who have failed to respond to standard immunotherapy treatments. In march 2000, U.S. and Canadian health authorities gave AETerna the green light to undertake this study, and in the following months, European authorities followed suit. Results of the study are expected by the end of 2002.

The current status of the ongoing Phase III trial was presented at an Investigators' Meeting held during the American Society of Clinical Oncology (ASCO) Annual Meeting in San Francisco by the three principal investigators: Dr. Ronald Bukowski, Director of Experimental Therapeutics Program at the Cleveland Clinic Cancer Center in the United States, Dr. Gerald Batist, Director of the McGill Centre for Translational Research in Cancer, and Professor at the Department of Oncology and Medicine at McGill University in Montreal, Canada, and Dr. Bernard Escudier, Head of Immunotherapy and Innovative Therapy Unit at the Institut Gustave-Roussy in Villejuif, France.

"We are pleased to announce that patient recruitment has reached the halfway mark in this trial. We wish to thank the investigators in North America and Europe for their commitment which allowed AETerna to reach this important milestone," emphasized Dr. Bukowski. "This study offers an exciting opportunity to demonstrate a potential therapeutic benefit of angiogenesis inhibition, leading to better management of renal cell carcinoma."

"We are encouraged by Neovastat's positive results obtained in Phase I/II trials in advanced cancer patients," added Dr. Claude Hariton, Vice President, Clinical and Regulatory Affairs of AETerna. "These data strongly support the current development program in oncology and further increase the interest Neovastat has created within the international medical community."

"We are confident that the support of recognized experts from both continents will allow us to successfully complete our three ongoing pivotal clinical trials within the targeted schedule, therefore improving our position to be among the first to bring an angiogenesis inhibitor to market," concluded Gilles Gagnon, Vice President and Chief Operating Officer at AETerna.

ABOUT RENAL CELL CARCINOMA AND THE NEOVASTAT ONGOING TRIAL

Renal cell carcinoma is the most common type of kidney cancer in adults. There are about 34,000 new cases of renal cell carcinoma in North America each year and about 38,000 new cases in Europe. The five-year mortality rate for this disease is approximately 90%. The therapies currently available are effective in

Edgar Filing: AETERNA LABORATORIES INC - Form 6-K

less than 20% of the cases and are associated with a large number of serious side effects.

AEterna's Phase III kidney cancer trial will involve approximately 280 patients who have failed to respond to standard immunotherapy treatments. Patients will fall into one of two groups: one will be given Neovastat, while the second group will be given a placebo. Neither doctors nor patients will know who is receiving the Neovastat treatment until the end of the study, which should be completed by the end of 2002.

For further information regarding the trial, you may call 1-888-349-3232 in North America (see AEterna's website at www.aeterna.com for more detailed information).

ABOUT AETERNA AND NEOVASTAT/AE-941

AEterna Laboratories Inc. is a Canadian biopharmaceutical company and a frontrunner in the field of antiangiogenesis. Its lead product, Neovastat/AE-941, is being investigated in three major therapeutic areas: oncology, dermatology and ophthalmology.

Neovastat is a novel antiangiogenic product with multiple mechanisms of action that block angiogenesis -- the process involved in the formation of new blood vessels which are needed in order for cancer tumors and other pathological conditions to develop.

Neovastat is currently investigated in two Phase III pivotal clinical trials for the treatment of lung and kidney cancers as well as in a Phase II pivotal trial for the treatment of multiple myeloma, a form of blood cancer. These trials are currently held in more than 125 clinical institutions in Canada, the U.S. and in several European countries.

AEterna is listed on the Toronto Stock Exchange under the symbol AEL and on Nasdaq under the symbol AELA.

AEterna's news releases and additional information are available on its Web site at www.aeterna.com.

SAFE HARBOR STATEMENT

This press release contains forward-looking statements, which are 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 the business opportunities in the pharmaceutical industry, uncertainties related to the regulatory process and general changes in economic conditions. Investors should consult the Company's ongoing 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.

Edgar Filing: AETERNA LABORATORIES INC - Form 6-K

FOR MORE INFORMATION, CONTACT:

CANADA

Paul Burroughs
Director of Communications
AETerna Laboratories Inc.
Tel.: 418-652-8525, ext. 406
Fax: 418-577-7700
E-mail: paul.burroughs@aeterna.com

USA

Investor and Media Relations:
Ms. Lisa Lindberg
The Investor Relations Group Inc.
Tel.: 212-825-3210
Fax: 212-825-3229
E-mail: TheProTeam@aol.com

GERMANY

Investor Relations and Media
Ms. Ursula Fessele
Value Relations IR Services
Tel.: 49-6196-8800-218
Fax: 49-6196-8800-447
E-mail: u.fessele@vrrir.de