

AETERNA LABORATORIES INC

Form 6-K

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LOGO OF  
AETERNA LABORATORIES INC.

PRESS RELEASE  
FOR IMMEDIATE RELEASE

AETERNA: PHASE I/II STUDY RESULTS IN PROSTATE CANCER CONFIRM NEOVASTAT'S SAFETY  
PROFILE AND DOSE-RELATED ACTIVITY

Results presented at the Annual Meeting of the Canadian Urological Association

TORONTO, ONTARIO, JUNE 26, 2001 - AEterna Laboratories Inc. (TSE: AEL, NASDAQ: AELA) announced today that results from a Phase I/II clinical study in 48 evaluable patients suffering from metastatic refractory prostate cancer, confirm Neovastat's safety profile and dose-related activity. Results of the study, held in Canada and the United States, showed no dose-limiting toxicity, excellent patient compliance while improved conditions or disease stabilization were noted in patients as indicated by Prostate Specific Antigen (PSA) levels. This dose-dependent benefit was noted in 20% of patients given the low-doses of Neovastat and in 45% of patients administered the high-doses. Furthermore, pain reduction or stability was observed in over 80% of patients and global health status was stable or improved in approximately 50% of patients. Results were presented at the Annual Meeting of the Canadian Urological Association in Toronto, by Dr. Fred Saad of the Centre Hospitalier de l'Universite de Montreal (CHUM) in Canada.

"Results of this study are very encouraging," said Dr. Saad. "A dose-dependent effect was often found in very ill patients and their quality of life was improved. These findings further support the ongoing clinical trials of Neovastat in oncology."

The study also corroborates results from prior Phase I/II clinical trials which demonstrated Neovastat as a safe compound with clinical benefits. "In Phase II trials in oncology, a statistically significant increase in median survival time was found in metastatic renal cell carcinoma patients and in non-small-cell lung cancer patients receiving a high dose of Neovastat," noted Dr. Claude Hariton, Vice President, Clinical and Regulatory Affairs at AEterna. "All these positive results lead us to consider exploring the use of Neovastat for many different cancer indications and by pursuing our clinical development strategy which focuses on oncology, we have the opportunity of being among the first to bring an antiangiogenic agent onto the market," concluded Dr. Hariton.

To date, more than 700 patients have received Neovastat as part of AEterna's clinical program in 140 clinical centers across Canada, the United States and Europe. "Studies have repeatedly demonstrated that Neovastat is a very convenient oral formulation which may be used safely for different indications, thus representing a tremendous benefit for cancer

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patients and a potential market opportunity for our pharmaceutical partners," said Gilles Gagnon, AEterna's Vice President and Chief Operating Officer.

### MORE ABOUT THE TRIAL

As part of AEterna's clinical Phase I/II development program, 48 evaluable patients with metastatic prostate cancer refractory to standard therapies took part in the trial conducted across Canada and the United States. Neovastat was used as a monotherapy treatment. Objectives of the trial were to determine the maximum tolerated dose of Neovastat, its safety profile and signs of clinical benefit after 84 days of treatment. Based on Prostate Specific Antigen (PSA) levels (stable or decrease of at least 25%), improved disease status or stable disease was noted in 17 out of 38 patients (45%) receiving the highest doses and in 2 out of 10 patients (20%) receiving the lowest doses.

Prostate cancer is one of the most common cancer in men. In North America, 1 out of 10 men will develop the disease at some point in his life, most after age 65. In the United States, an estimated 198,100 new cases of prostate cancer will be diagnosed in 2001, and 31,500 persons will die of the disease according to the American Cancer Society.

### 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 (VEGF receptor, MMP's 2, -9, -12, apoptosis of endothelial cells, tPA inducer to produce angiostatin) that blocks angiogenesis, the process involved in the formation of new blood vessels which are needed in order for cancerous 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 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 140 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](http://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.

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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.

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