



Mesothelioma Articles

Alfacell Completes Non-Clinical Section of Rolling NDA for Lead Anticancer Drug ONCONASE

BLOOMFIELD, N.J.--(BUSINESS WIRE)--Oct 2, 2006 - Alfacell Corporation (NASDAQ: ACEL) today announced that the company has completed the non-clinical section of the rolling submission of a New Drug Application (NDA) in preparation for its submission to the U.S. Food and Drug Administration (FDA) for its lead anticancer compound, ONCONASE (ranpirnase). ONCONASE, first in class in the ribonuclease family, is currently the subject of a randomized Phase III clinical trial in combination with doxorubicin as a potential treatment for patients with unresectable [malignant mesothelioma](#) (UMM). The company will submit the chemistry, manufacturing and controls (CMC) section of the NDA after completion of a review by external regulatory consultants. The company anticipates completing the NDA submission for ONCONASE in combination with doxorubicin pending the review of final results of the ongoing Phase III trial in 2007.

"The CMC section is the second of three parts necessary to complete the NDA submission. We are very pleased that we continue to make such good progress in advancing ONCONASE toward the market," commented Dr. Kuslima Shogen, Chairman and Chief Executive Officer of Alfacell. "The coming year promises to be of seminal importance for Alfacell as we expect to have the final data on overall survival from our ONCONASE pivotal trial and complete the NDA filing."

The FDA granted Fast Track designation to ONCONASE as a treatment for patients with UMM in September 2003. The FDA's fast track programs are intended to expedite the review of drugs to treat serious or life-threatening conditions and those that demonstrate the potential to address unmet medical needs.

The rolling submission process enables companies that have been granted Fast Track designation to submit sections of the NDA to the agency as they become available, allowing the review process to begin before the complete dossier has been submitted.

Review of Interim Data from Phase IIIb Trial

In April, 2006 Alfacell released interim data from the company's ongoing Phase IIIb randomized clinical trial of ONCONASE and doxorubicin for the treatment of malignant mesothelioma. The study reached the first interim analysis at 105 events (patient deaths) of the total 316 patients enrolled. Interim data demonstrate that the overall median survival time (MST) favored the ONCONASE plus doxorubicin treatment group (12 months) over the doxorubicin group (10 months).

In addition, the interim analysis also showed that at one-year, 47% of the ONCONASE plus doxorubicin-treated patients were alive as compared to 36% of the patients treated with doxorubicin. Patients evaluable for clinical response (those with evidence of tumor regression or stabilization of disease for a minimum of 3 months) showed a seven-month difference in the MST (17 vs. 10 months) favoring the ONCONASE plus doxorubicin group vs. the doxorubicin group. The analysis of safety data revealed that ONCONASE when given with doxorubicin did not increase the number or severity of known doxorubicin-associated side effects. The most frequent side effects reported for both treatment groups included nausea, fatigue and alopecia. The incidence of these events was comparable for both treatment groups.

About ONCONASE(R)

ONCONASE is a first-in-class therapeutic from Alfacell's proprietary ribonuclease (RNase) technology platform. ONCONASE has been shown to target tumor cells while sparing normal cells. ONCONASE is internalized by endocytosis and released into the cytosol of the cancerous cell, where it selectively degrades tRNA beyond repair. In doing so, ONCONASE inhibits protein synthesis, stops cell cycle proliferation, and induces apoptosis (programmed cell death).

ONCONASE has previously been granted Orphan Drug designation from EMEA and TGA (Australia), as well as Fast Track status by the FDA. The Company is also conducting an ONCONASE Phase I / II trial in Non-Small Cell Lung Cancer (NSCLC).

About Alfacell Corporation

Alfacell Corporation is a biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for cancer and other life-threatening diseases, using its proprietary ribonuclease (RNase) technology platform. For more information, please visit <http://www.Alfacell.com>.

Safe Harbor

This press release includes statements that may constitute "forward- looking" statements, usually containing the words "believe," "estimate," "project," "expect" or similar expressions. Forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from the forward-looking statements. Factors that would cause or contribute to such differences include, but are not limited to, uncertainties involved in transitioning from concept to product, uncertainties involving the ability of the Company to finance research and development activities, potential challenges to or violations of patents, uncertainties regarding the outcome of clinical trials, the Company's ability to secure necessary approvals from regulatory agencies, dependence upon third-party vendors, and other risks discussed in the Company's periodic filings with the Securities and Exchange Commission. By making these forward-looking statements, the Company undertakes no obligation to update these statements for revisions or changes after the date of this release.

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