



Mesothelioma Articles

Alfacell Provides Update on the ONCONASE Phase IIIb Registration Trial

BLOOMFIELD, N.J., June 22 /PRNewswire-FirstCall/ -- Alfacell Corporation (Nasdaq: ACEL) today provided an update on the status of the ongoing confirmatory Phase IIIb registration trial evaluating ONCONASE(R) (ranpirnase), the Company's lead investigational drug candidate, as a treatment for unresectable [malignant mesothelioma](#) (UMM):

Rolling New Drug Application (NDA) for the ONCONASE UMM indication: The Company has now completed nearly all of the key requirements of the Chemistry, Manufacturing and Controls (CMC) section of the NDA, and expects to file the CMC submission by the end of the third quarter of 2006. Once accepted by FDA, the CMC section can be used for future ONCONASE filings for major cancer indications.

The company continues to allow access to ONCONASE in key US sites and international sites in the MM program, as a result accrual has been optimized and the required 316 events to initiate the final analysis is projected to occur earlier than previously estimated. Overall, the Company remains on track to file the NDA no later than mid-2007.

About ONCONASE

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 latter has enabled the Company to complete and submit sections of the New Drug Application (NDA) on an accelerated, rolling basis.

The Company is also conducting an ONCONASE Phase I / II trial in Non-Small Cell Lung Cancer (NSCLC). The NSCLC market is expected to exceed \$4 billion by 2012.

About Alfacell Corporation

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

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.

Contact:

Alfacell Corporation:

Kuslima Shogen

Robert Love

(973) 748-8082

info@alfacell.com

Investor/Media Relations:
Elite Financial Communications
Dodi Handy
(407) 585-1080
acel@efcg.net

Source: <http://www.prnewswire.com/>

www.MIRG.org