



NeoPharm Announces IND Filing for IL13-PE38QQR for the Treatment of Idiopathic Pulmonary Fibrosis

LAKE BLUFF, Ill., Jan 04, 2010 (BUSINESS WIRE) -- NeoPharm, Inc. (Other OTC: NEOL.PK), announced today that it has filed an investigational new drug application (IND) with the U.S. Food and Drug Administration (FDA) for IL13-PE38QQR (IL13-PE) for the treatment of Idiopathic Pulmonary Fibrosis (IPF). IPF is the most deadly disease of the lungs in humans with very high morbidity. There is currently no proven effective treatment for the cure of this disease.

The studies that NeoPharm has performed in animals and in ex-vivo human tissue have shown that the receptors for interleukin 13 (IL13) are significantly over-expressed in pulmonary fibroblasts. The recombinant protein, IL13-PE, has demonstrated selective cytotoxicity to the IL13 receptor-expressing fibroblasts, thereby ameliorating the histopathological evidence of IPF in animal models.

In this Phase I clinical study, the IL13-PE will be administered into the lungs as an inhaled, aerosolized liquid. Six doses of the drug with sequential increment will be administered in a total of 32 patients. The objective of the study is to assess the safety and the maximum tolerated dose, along with efficacy in patients with advanced IPF.

Dr. Aquilur Rahman, President and CEO commented, "The submission of this IND is a major milestone for the Company. We anticipate conducting this study through a collaboration with **IPFnet**, a collaborative group of clinical sites formed under the auspices of National Heart Lung and Blood Institute (NHLBI), a part of the National Institutes of Health (NIH). It is expected that six to eight sites will be performing these clinical studies with the coordinating center role being assumed by the Duke Clinical Research Institute (DCRI)". Dr. Rahman further commented, "We are fortunate to have these prestigious centers interested in our clinical trials to hopefully make a difference in the survival and quality of life for these extremely sick patients".

About NeoPharm, Inc.

NeoPharm, Inc., based in Lake Bluff, Illinois, is a publicly traded biopharmaceutical company dedicated to the research, development and commercialization of new and innovative cancer and other drugs for therapeutic applications. Additional information, including ongoing clinical trials, can be obtained by visiting NeoPharm's web site at www.neopharm.com.

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The Company has tried to identify such forward-looking statements by use of such words as "expects," "intends," "projects," "hopes," "anticipates," "believes," "could," "may," "evidences" and "estimates," and other similar expressions, but these words are not the exclusive means of identifying such statements. Such statements include, but are not limited to, any statements relating to the Company's drug development programs including, but not limited to, the development of IL13-PE, the initiation, progress, and outcomes of clinical trials of the Company's drug product candidates including, but not limited to IL13-PE, and any other statements that are not historical facts. Such statements involve risks and uncertainties, including, but not limited to, risks and uncertainties relating to difficulties or delays that may arise in the development, testing, regulatory approval, production, and marketing of the Company's drug and non-drug compounds, including, but not limited to, IL13-PE, the Company's possible need to reduce its funding of certain of its development projects in order to conserve its cash resources, the ability of the Company to procure additional future sources of financing, unexpected adverse side effects or inadequate therapeutic efficacy of the Company's drug product candidates, including, but not limited to, IL13-PE, that could slow or prevent products coming to market, uncertainty regarding the Company's ability to commercialize any of its drug product candidates, including, but not limited to, IL13-PE, and other risks of the type previously detailed from time to time in filings the Company formerly made with the Securities and Exchange Commission ("SEC"). Such statements are based on management's current expectations, but actual results may differ materially due to various factors, including those risks and uncertainties mentioned or referred to in this press release. At the Company's request, the Company's obligation to file reports with the SEC was suspended effective February 12, 2009. For the foregoing reasons, you should not rely on these forward-looking statements or our previously filed SEC reports as a prediction of actual future results.

SOURCE: NeoPharm, Inc.

NeoPharm, Inc.
Martin K. McCarthy
847-887-0800

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