

# FDA TO HOST MEETING ON PATIENT FOCUSED DRUG DEVELOPMENT FOR IPF

**VANCOUVER, BC, Canada – July 16, 2014 – Pacific Therapeutics Ltd. (CSE: PT) (OTC: PCFTF) (Frankfurt: 1P3) (the “Company”)** The FDA registered notice in the July 8, 2014 edition of the Federal Register that on September 26, 2014, the FDA is conducting a public meeting on Patient-Focused Drug Development for idiopathic pulmonary fibrosis (IPF). FDA is interested in obtaining patient input on the impact of IPF on daily life and patients’ views on currently available therapies to treat the condition.



Doug Unwin CEO and President of the Company states "this is a tremendous initiative from the FDA to involve patients and other stakeholders in the drug development process. The company will continue to share further information regarding the FDA's decision to host this public meeting on IPF Patient-Focused Drug Treatment when it is announced.

Pacific Therapeutics Ltd. lead drug candidate for fibrosis (progressive scarring of the organ), PTL-202 is a combination of an FDA approved drug and an amino acid which is an extremely potent and important antioxidant.

Worldwide, there are over 5,000,000 people living with Idiopathic Pulmonary Fibrosis (IPF), (IPF Coalition). IPF therapy sales across the US, France, Germany, Italy, Spain, and the UK are forecast to rise to over \$1.1 billion by 2017, at a Compound Annual Growth Rate (CAGR) of 86.6% (RnR Market Research, 2013). IPF kills more patients per year than either prostate or breast cancer.

In addition to the \$1.1 billion IPF market opportunity, PTL-202 may be effective as a treatment for Liver Cirrhosis a \$1.56 billion global market opportunity in 2010, that is expected to grow to \$2.03 billion by 2017 (Global Data, Feb, 2011). "This growth is primarily attributed to the increasing prevalence of Liver Cirrhosis due to increase in alcoholic liver disease, nonalcoholic steatohepatitis (NASH) and the large group of patients who were originally infected with hepatitis virus, who will be entering their third decade of chronic liver infection" (Global Data, Feb, 2011).

## **ABOUT PACIFIC THERAPEUTICS LTD.**

The Company's lead programs focus on erectile dysfunction and diseases of excessive scarring (fibrosis). The Company's strategy includes reformulating approved drugs to increase efficacy and patient compliance, while reducing side effects, as well as completing the further clinical testing, manufacturing and other regulatory requirements sufficient to seek marketing

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authorizations. This strategy may reduce the risk, time and cost of developing therapies by avoiding the risks associated with basic research and using compounds with unknown safety and toxicity profiles.

In 2011 the total market for drugs to treat erectile dysfunction (“ED”) exceeded \$5 billion. Pacific Therapeutics Ltd. has reformulated an approved drug to treat ED using the Company’s proprietary oral dissolving technology (“sublingual formulation”). This is the first treatment to be developed by the Company using its sublingual platform technology. The sublingual formulation may improve on existing drugs for erectile dysfunction potentially acting faster and with fewer side effects.

The Company plans to build on the already significant development of the sublingual treatment with the initiation of a pivotal Bioequivalence trial. The trial design calls for the enrolment of 24 individuals and is planned to take only 4 months for completion. With successful results from this trial the Company will begin the application for marketing approval.

For further information visit our website at [www.pacifictherapeutics.com](http://www.pacifictherapeutics.com) or email us at [doug.unwin@pacifictherapeutics.com](mailto:doug.unwin@pacifictherapeutics.com)

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## **FORWARD LOOKING STATEMENTS**

Certain statements included in this press release constitute forward-looking information or statements (collectively, “forward-looking statements”), including those identified by the expressions “anticipate”, “believe”, “plan”, “estimate”, “expect”, “intend”, “may”, “should” and similar expressions to the extent they relate to the Company or its management. The forward-looking statements are not historical facts but reflect current expectations regarding future results or events. This press release contains forward looking statements. These forward-looking statements are based on current expectations and various estimates, factors and assumptions and involve known and unknown risks, uncertainties and other factors.

Readers should not place undue reliance on the Company’s forward-looking statements, as the Company’s actual results, performance or achievements may differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements if known or unknown risks, uncertainties or other factors affect the Company’s business, or if the Company’s estimates or assumptions prove inaccurate. Therefore, the Company cannot provide any assurance that such forward-looking statements will materialize. The Company does not undertake to update any forward-looking information, except as, and to the extent required by, applicable securities laws.

The Company is pleased to present the results of its pre-clinical studies of PTL-202. PTL-202 and its separate constituents were tested in 5 experiments in a recognized mouse model of pulmonary fibrosis. These studies provided the data required for the recently granted European patent covering the proprietary technology utilized in PTL-202.

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In order to support the use of PTL-202 for fibrosis treatment, we have conducted proof-of-concept animal studies to evaluate the relative efficacy of stand-alone or combination treatments in a standard animal model of pulmonary fibrosis induced by bleomycin. These studies strongly suggest that more than a single pathway is responsible for the therapeutic activities of the components of PTL-202, but it is likely that these 2 molecules exert potent antifibrogenic effect by affecting a complex network of pro-fibrosis cytokines such as TNF-alpha and TGF-beta1, proliferation of fibroblasts and synthesis of the extracellular matrix (ECM) components.

Analysis of the pathology of the lungs from the mice showed that the combination significantly reduced the damage to the lungs whereas the separate components did not. In addition the combination significantly improved lung weight in the mice whereas the separate components did not.

To quantify lung collagen content as an indicator of pulmonary fibrosis, the hydroxyproline content in the lung was measured. In the fibrotic stage of the fibrosis model hydroxyproline was significantly reduced by the combination.

Moreover, we found no deaths or abnormal reactions with a daily administration of PTL-202 during the experiments.

The results suggest PTL-202 is safe and effective agent for the treatment of pulmonary fibrosis.