

**UPDATE ON PTL-202, A TREATMENT FOR PROGRESSIVE ORGAN SCARRING, A $1.1 BILLION OPPORTUNITY**

**VANCOUVER, BC, Canada – September 4, 2014 – Pacific Therapeutics Ltd. (CSE: PT) (OTC Markets: PCFTF) (Frankfurt: 1P3) (the “Company”)** is a clinical stage specialty pharmaceutical company focused on the repurposing and reformulation of existing FDA approved drugs for large markets. The Company’s lead programs focus on diseases of excessive scarring (fibrosis) and erectile dysfunction which are $1 billion plus market opportunities.

The value of a therapy for Idiopathic Pulmonary Fibrosis (IPF) was recently demonstrated by the $8.3 billion takeover of InterMune Inc. by Roche Holdings Inc. InterMune’s main asset is a drug that is approved in Europe and Canada to treat the orphan disease Idiopathic Pulmonary Fibrosis it is not approved in the US. IPF kills more patients per year than either prostate or breast cancer.

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. The Company has completed pre-clinical studies and an initial phase 1 clinical trial of the combination with positive results.

During the last six months as previously released:

* The patent covering the technology in PTL-202 has been granted by the European Patent Office and is now being validated in separate countries;
* The Company released 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.

The results of experiments in a standard animal model of pulmonary fibrosis induced by bleomycin 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. The results suggest PTL-202 is safe and effective agent for the treatment of pulmonary fibrosis;

* It has been confirmed that the incidence of IPF is on the increase. In an article by V. Navaratnam, K.M. Fleming, J. West, C.J.P. Smith, R.G. Jenkins, A. Fogarty and R.B. Hubbard published in Thorax in April, 2011 the authors revealed that in the UK deaths from IPF rose 6 fold from the period 1968-1972 to the period 2006 – 2008! In addition the incidence of IPF in primary care increased by 35% from 2000 to 2008. There was also an increased incidence in men.

Similarly in a review of the literature on incidence and prevalence of IPF by L. Nalysnyk J. Cid-Ruzafa, P. Rotella and D. Esser published in European Respiritory Review on December 1, 2012 found “IPF prevalence and incidence increase with age, are higher among males and appear to be on the increase in recent years. IPF is an orphan disease that affects a potentially increasing number of people in Europe and the USA”;

* 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. This is a tremendous initiative from the FDA to involve patients and other stakeholders in the drug development process.

**Market Opportunity**

Worldwide, there are over 5,000,000 people living with Idiopathic Pulmonary Fibrosis (IPF), (IPF Coalition).

There are 218,000 sufferers of Idiopathic Pulmonary Fibrosis (IPF) in the United States of which 85,000 are diagnosed (Datamonitor, Aug 2005). An aging population combined with improved diagnostics will increase the diagnosed population by 40% to 146,000 by 2015 in the USA were 40,000 new cases of IPF are diagnosed annually (InterMune 2006). The primary sufferers of pulmonary fibrosis are in the older populations between 50-70 years of age.

The IPF therapeutics market in the US is predicted to grow to nearly $500 million in 2015 and reach $696m in 2017, a CAGR of 154%. In contrast, the European IPF market was valued at a far stronger $43m in 2012, but is forecast to grow to $419m in 2017 at a CAGR of 58% (RnR Market Research, 2013).

*“It’s estimated that 45 % of all deaths are related to fibrotic changes” World Health Organization Feb, 2008.*

**Clinical Development**

As previously announced data from the phase 1 trial showed a synergistic relationship resulting in an increase in the Active Ingredients of PTL-202 in the blood and an increase in known therapeutic effects without any new side effects. These results may improve the competitiveness and commercial potential of PTL-202. With the combined positive phase 1 clinical results and positive efficacy results from the pre-clinical testing of PTL-202 in animals with pulmonary fibrosis in hand, the company intends to proceed to a second clinical trial of PTL-202.

A phase 1 clinical trial is usually intended to test for the safety and toxicity of a new drug being developed. In the case of PTL-202 a combination of approved drugs, the safety profile and toxicity are already well known as the individual active ingredients have been on the market for many years. The question is, if when given in combination, are there synergistic effects or new side effects? The phase 1 clinical trial of PTL-202 was designed to test for interaction between the Active Ingredients combined in PTL-202 for synergistic effects and new side effects.

The clinical trial provided definite evidence of synergy and will allow patients to take smaller doses improving the likelihood of marketing approval. Trial results showed that when given in combination, to healthy males, the amount of the Active Ingredients in the blood of the test subjects was much higher than if the same amount of one of the Active Ingredients alone had been given to the test subjects. In addition the known therapeutic effects such as vasodilation were also enhanced. The increase in known therapeutic effect was consistent with an increased amount of Active Ingredient in the blood. The good news is that the planned final dose in the end product may be much smaller than had originally been planned. This change will result in a smaller, easier to swallow pill and improved patient compliance, regulatory acceptance and potentially improved commercial potential.

Another positive result from the phase 1 trial was that no additional side effects were reported. The side effects such as dizziness and nausea were consistent with the higher amounts of the Active Ingredients from the combination that were in the blood at peak concentrations. This result may bode well for regulatory approval as no new side effects were evident.

The Company’s proprietary once a day dosage will be more convenient for the patient and may improve efficacy as well as patient compliance. Given the positive synergistic effects indicated in the phase 1 trial, it is very important that the final dosage and formulation of PTL-202 be precise. If the ratio of Active Ingredients in the combination is not precise or the Active Ingredients are released into the body to quickly, the drug’s effectiveness may be reduced or patients may not take their medication due to an increase in side effects. This requirement for precise delivery of the Active Ingredients provides a barrier to entry as it may prevent patients taking existing marketed formulations of the Active Ingredients to attain the same therapeutic effect. In addition none of the approved forms of the Active Ingredients are available as a once a day pill like the company is developing. Existing approved forms of the Active Ingredients are required 2 or 3 times a day and may release the Active Ingredients to quickly resulting in high levels of the drugs in the blood at one time increasing side effects. In addition the reduced chance of side effects may provide physicians with additional incentives to prescribe PTL-202. The planned unique slow release formulation and ratio of Active Ingredients will create an added barrier to competition over and above that provided by patent protection, improving commercial potential.

**What’s next?**

In addition to having completed the above successful clinical trial and pre-clinical studies the once a day formulation of PTL-202 has been completed. The next step is to use the results from the phase 1 study to fine tune the amount of Active Ingredients in the final formulations. The fine tuning of the dosage will lead to a regulatory filing, potential dose ranging and proof of principal clinical trial. Data from a proof of principal trial may lead to sale of PTL-202 to a commercialization partner.

Given the issuance of the European patent on the technology utilized by PTL-202, further clinical studies may be conducted with the intent of having PTL-202’s initial approval in Europe.

**ABOUT PACIFIC THERAPEUTICS LTD.**

Pacific Therapeutics Ltd is a clinical stage specialty pharmaceutical company focused on the identification and development of drug candidates suitable for reformulation and repurposing. Its lead programs focus on erectile dysfunction and diseases of excessive scarring (fibrosis).

In 2011 the total market for drugs to treat erectile dysfunction (“ED”) exceeded $5 billion. Pacific Therapeutics Ltd. has finalized a definitive agreement to license an oral dissolving technology (“sublingual formulation”) of an approved drug to treat erectile dysfunction (ED).

Sales of the market leader alone exceeded $1.9 billion in 2011. The sublingual formulation improves on existing drugs for erectile dysfunction potentially acting faster and with fewer side effects. As large pharmaceutical companies lose their patents on these drugs the opportunity has developed for innovative formulations of drugs for ED. This is a very exciting development for Pacific Therapeutics Ltd. as it shortens the time to market for the Company’s first product and may add significantly to future revenues.

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 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.

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