## Embargoed until 00.01hrs December 14 2016

**Slough, U.K. December 14 2016** --- **Pulmagen Therapeutics (Asthma) Limited**, a UK-based drug development company, announces today positive data for PTR-36 (ADC3680), a once daily, orally administered CRTh2 antagonist in eosinophilic asthma patients in a 16-week Phase II double blind, placebo controlled study, that was conducted in Japan by Tokyo-based **Teijin Pharma Limited**, the core company of the Teijin Group's healthcare business. Pulmagen licensed its CRTh2 programme including PTR-36 for Japan to Teijin Pharma in 2012. Pulmagen is to seek a global partner for late stage clinical development.

The aim of this study was to collect efficacy and safety data for PTR-36, an oral chemoattractant receptor-homologous molecule expressed on Th2 cells (CRTh2) receptor antagonist, for the treatment of asthma.

This was an exploratory Phase II, double-blind, randomized, placebo-controlled multi-center study with inhaled corticosteroid (ICS) dose tapering and cessation. Patients with mild to moderate asthma (N = 158) had their long-acting  $\beta$ -agonists (LABA) discontinued and were standardised on a medium dose of ICS for 28 days prior to randomisation. At the start of the 16-week treatment period the dose of ICS was reduced to a low dose and patients were randomized (1:1:1) to two doses of PTR-36 (5 mg or 20 mg once daily) or to placebo for an initial 28 days after which the ICS was fully discontinued. Patients then remained on PTR-36 or placebo for a further 12 weeks. (Clinical trial registration number: JapicCTI-152857)

Results: Overall, and allowing for patient withdrawal in accordance with pre-determined early escape criteria, 91 patients completed the study. For the primary endpoint of change in morning peak expiratory flow (mPEF) from randomization to the last visit (week 16 for completed patients or the day determined as discontinuation date for withdrawn patients), there was a statistically significant difference between PTR-36 and placebo at both doses (p = 0.015, 5 mg; 0.027, 20 mg). A number of important secondary endpoints including time to first exacerbation, asthma control questionnaire (ACQ5 and 6) and use of short acting bronchodilators in the total population also achieved statistical significance. Subgroup analyses demonstrated patients with high blood eosinophils (>300 cells/ $\mu$ I) at baseline treated with PTR-36 (20mg) also had significant improvement in FEV<sub>1</sub> compared with placebo (p = 0.016).

Conclusions: A statistically significant difference in the primary endpoint (mPEF) between both doses of PTR-36 and placebo was observed in the general study population. Further subgroup analysis revealed that the effect of treatment with PTR-36 was greatest in patients with eosinophilic disease suggesting better asthma control when treated with PTR-36. PTR-36 also demonstrated a favourable safety profile with no adverse effects on any parameters including blood and liver markers.

Dr. Masanori Yamamoto, General Manager of Pharmaceutical Research & Development Division at Teijin Pharma said: "Having successfully achieved the intended primary endpoint of the study, Teijin Pharma will further concentrate on the preparation for the next clinical study in Japan. Under the joint collaboration with Pulmagen, we will seek to explore every aspect of PTR-36 in order to maximize its potential."

Dr. Mary Fitzgerald Executive VP Respiratory at Pulmagen said: "There remains an unmet medical need for severe eosinophilic asthma patients who are uncontrolled on standard of care therapies. This is a significant population of patients who are at the greatest risk of exacerbations, hospitalisation and death. Patients understand this and report a significant impact of their asthma on everyday functioning and quality of life. We are naturally pleased that the results from this study fully support the potential of PTR-36 (ADC3680) to offer a valuable treatment option for this group of patients. We have learned much about the

importance of this mechanism and its utility over the last few years and look forward to progressing our global partnering discussions to continue the rapid development of the programme."

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## **About Teijin Pharma Limited**

Teijin Pharma Limited, the core company of the Teijin Group's healthcare business, focuses on three key therapeutic areas: respiratory, bone/joint, and cardiovascular/metabolic diseases. As well as being a fully integrated pharmaceutical company with strong marketing positions particularly in the respiratory and bone/joint areas, the Teijin Group's healthcare business also has home healthcare business function including home oxygen in the former therapeutic area. The Teijin Group's health care business posted net sales of JPY 147.5 billion (USD 1.4 billion) and operating income of JPY 28.8 billion (USD 269 million) in the fiscal year ending March 31, 2016. Please visit <a href="https://www.teijin-pharma.com">www.teijin-pharma.com</a>

## **About Pulmagen Therapeutics (Asthma) Limited**

Pulmagen Therapeutics is a UK-based drug development company that focuses on the development of novel treatments for respiratory diseases. Pulmagen aims to progress its programs through Phase II proof-of-concept clinical trials and identify partners for late stage clinical development. The company has partnered respiratory drug development programs with a number of leading pharmaceutical and biotech companies. Under a license agreement in September 2012, Pulmagen licensed development and commercialization rights to its CRTh2 programme in Japan to Teijin Pharma. Please visit: <a href="https://www.pulmagen.com">www.pulmagen.com</a>.

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