



Skyepharma acquires a novel inhaled therapy platform

New product opportunity - SKP-2075 - to be developed as an anti-inflammatory treatment for COPD

LONDON, UK, 13 August, 2014 - Skyepharma PLC (LSE SKP), the expert oral and inhalation drug delivery company, today announces that it has acquired the global rights and related intellectual property (including granted patents and patent applications) to a novel inhaled therapy platform from Pulmagen Therapeutics (Synergy) Limited ("Pulmagen").

Skyepharma will apply its proven expertise in inhaled drug development to develop a first product (SKP-2075) for chronic obstructive pulmonary disease (COPD) through to the completion of a phase II efficacy and safety trial sized to produce clinically significant data. It will then seek to out-licence SKP-2075 to a pharmaceutical partner for late-stage development and commercialisation.

Pulmagen will receive a share of Skyepharma's potential future revenues and launch milestones from the successful exploitation of the acquired platform as described in more detail below.

Pulmagen discovered that the inhalation of an ultra-low dose of theophylline, which is prescribed as an oral bronchodilator for severe asthma and COPD, together with an established inhaled corticosteroid (ICS) has an effect of unlocking the anti-inflammatory potential of ICS in the treatment of COPD. Based on preliminary data, the inhalation of an ultra-low dose of theophylline with an ICS is predicted to deliver efficacy with an appropriate tolerability and safety profile. Pulmagen has already conducted a phase II clinical trial in moderate to severe COPD patients where the observed treatment difference in lung function supported the hypothesis.

Pulmagen and Skyepharma believe that the use of ultra-low dose inhaled theophylline to increase sensitivity to ICS could have applications in a range of COPD products, including combinations involving ICS, especially for patients whose condition is inadequately controlled by available therapies. The approach may also have potential for certain patients with bronchial asthma.

Peter Grant, CEO of Skyepharma, commented, *"Pulmagen has already demonstrated better lung function with a nebulised form of SKP-2075 compared with ICS alone and this supports the concept that an ultra-low dose of inhaled theophylline could potentiate the effectiveness of inhaled corticosteroids in patients with COPD. If successful, SKP-2075 could offer COPD patients an important new treatment option and Skyepharma with a patented therapy platform from which to develop further products. Following our recent capital raise we set out how our stronger balance sheet will enable us to leverage our capabilities for both inhaled product development and oral drug delivery, and this project is an excellent example of our ability to drive our next phase of growth."*

Dr Christopher Ashton, CEO of Pulmagen, said, *"We believe this approach to inhaled corticosteroid-sensitisation has significant potential in COPD and Skyepharma has exactly the right expertise to take SKP-2075 and the related platform to the next stages of development."*

Expected timing and key financial terms

Skyepharma will commence development of SKP-2075 in the second half of 2014 and aims to have results of the phase II efficacy and safety trial available in 2017. The Group anticipates spending approximately £14 million to develop SKP-2075 up to completion of the phase II trial. Skyepharma plans to fund this development work from its own resources and cash-generation in line with the previous guidance given by the Board for the Group's future net expenditure on research and development.

The consideration payable to Pulmagen depends upon how Skyepharma commercialises SKP-2075 and other products developed using the therapy platform. Should Skyepharma out-licence products developed using the platform, Pulmagen will be paid a proportion of Skyepharma's licensing income which varies according to the amount of work which has been carried out by Skyepharma on the first product developed under the agreement at the time the product is out-licensed. This proportion starts at a substantial minority of licensing income and would be halved if relevant products are licensed out by Skyepharma after completion of the planned clinical study. Alternatively, should Skyepharma market relevant products itself, Pulmagen would be entitled to a low single digit percentage of net sales. In both cases Pulmagen is entitled to certain launch milestones in specified countries.

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About Skyepharma

Skyepharma combines proven scientific expertise with validated proprietary drug delivery technologies to develop innovative oral and inhalation pharmaceutical products. The Group is eligible for revenues from 16 approved products in the areas of inhalation, oral, topical and injectable drug delivery as well as generating income from the development of further products and technology licenses. The products developed by the Group are marketed throughout the world by big pharma as well as speciality pharmaceutical companies. For more information, visit www.skyepharma.com

About Pulmagen Therapeutics (Synergy) Limited

Pulmagen is a UK-based drug development company that focuses on the development of novel treatments for respiratory diseases. Pulmagen was formerly named Argenta Discovery Limited, becoming Pulmagen following the sale of its drug discovery division to Galapagos in February 2010. Pulmagen traces its roots back to August 2000 when Argenta was formed. For more information, visit www.pulmagen.com

About COPD

COPD is a chronic, life-threatening lung disease that interferes with normal breathing and typically worsens over time. The main symptoms include shortness of breath, cough and sputum production.

COPD affects an estimated 210 million people worldwide^{1,2} and is projected to be the fourth leading cause of death by 2030³. The market for drugs for the treatment of COPD in 2013 was valued at \$8.3bn in the US, Japan and the top 5 EU countries, according to Datamonitor⁴.

Current treatments for COPD include bronchodilators, which provide symptomatic relief, including the new combinations of bronchodilators such as long-acting beta agonists (LABAs) with long-acting anti-muscarinics (LAMAs). However, there is currently no recognised effective inhaled treatment for the underlying inflammation that characterises the disease as the anti-inflammatory effect of ICS and ICS/LABAs appears to be limited in COPD.

¹ WHO Fact Sheet Fact sheet N°315 October 2013

² Global Alliance Against Chronic Respiratory Diseases (GARD). Global surveillance, prevention and control of chronic respiratory diseases: a comprehensive approach. http://www.who.int/gard/publications/GARD_Manual/en/

³ Mathers C, Loncar D. Projections of global mortality and burden of disease from 2002 to 2030. PLoS Medicine, 2006, e442.

⁴ DataMonitor DMKC0047510, 19 August 2013.