Verona Pharma

Press release

27 September 2017

Verona Pharma Reports Positive Top-Line Data from U.S. Pharmacokinetic Trial Demonstrating Nebulized RPL554 Delivers Optimal Clinical Dose to Patients

Earlier than expected results demonstrate absorption occurs primarily in the lungs following inhaled administration

LONDON, Sept. 27, 2017 (GLOBE NEWSWIRE) -- Verona Pharma plc (AIM:VRP) (NASDAQ:VRNA) ("Verona Pharma"), a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for respiratory diseases, announces today top-line results from its clinical pharmacokinetic (PK) trial in the United States demonstrating that inhaled RPL554 is an appropriate form of administration for patients with chronic obstructive pulmonary disease (COPD) and other respiratory disorders.

With any inhaled or nebulized medication, a portion of the substance is deposited in the mouth and then swallowed by the patient. These results show that in the study subjects only 10.4 percent of the inhaled dose entered the bloodstream via the gastrointestinal tract. The low oral bioavailability of nebulized RPL554, as demonstrated in the study, is consistent with optimal inhaled delivery of medications for the treatment of COPD and asthma. Therefore, the results from this study confirm that inhaled RPL554 is an appropriate form of administration for patients.

This complete block two-way crossover trial evaluated a single dose of RPL554 in 12 healthy volunteers to determine the process of bodily absorption, distribution, metabolism and excretion of this novel therapy, including the swallowed portion of the nebulized dose. The trial was conducted under an Investigational New Drug application accepted by the U.S. Food and Drug Administration in June 2017, and Verona Pharma is reporting top-line results earlier than expected.

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Highlights

• Primary outcome measures:

- 10.4 percent of nebulized RPL554 reached the bloodstream via the gastrointestinal tract demonstrating suitability for inhaled administration.
- 11.9 hour half-life in blood is consistent with earlier data and supports twice-daily dosing of RPL554.

• Secondary outcome measures:

- Low oral bioavailability and blood levels of RPL554, as a result of swallowed medication, suggest limited contribution to systemic effects of inhaled medication in the lungs.
- RPL554 was well tolerated by all subjects without any evidence of safety concerns.

"These data demonstrate that inhalation of RPL554 is an appropriate route of administration for people with COPD and other respiratory diseases. The low oral bioavailability seen in this PK trial reinforces that the swallowed portion of the medication contributes very little to the effects of RPL554. The inhaled portion provides novel bronchodilator and anti-inflammatory effects, and has limited systemic exposure," said Jan-Anders Karlsson, PhD, CEO of Verona Pharma. "We believe that our ability to consistently deliver higher doses of RPL554 directly to the lungs, while at the same time having only low levels in the bloodstream, is consistent with a promising therapeutic effect, and we continue to see good tolerability of the compound across our clinical trials."

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RPL554 is a first-in-class, inhaled, dual inhibitor of the enzymes phosphodiesterase 3 and 4 designed to have anti-inflammatory as well as bronchodilator properties, and is currently in development for the maintenance treatment of COPD patients and for the treatment of patients with cystic fibrosis.

In previous clinical trials, RPL554 has been observed to result in bronchodilatory effects when used alone or in combination with other COPD bronchodilators. These trials have shown clinically meaningful and statistically significant improvements in lung function when RPL554 is added to two commonly used bronchodilators, as compared to the improvements in lung function when either bronchodilator is administered as a single agent. RPL554 has also shown anti-inflammatory effects in a standard challenge study with COPD-like inflammation in human subjects. In these studies, RPL554 has been well tolerated.

About Chronic Obstructive Pulmonary Disease

Chronic obstructive pulmonary disease (COPD) is a progressive and life-threatening respiratory disease for which there is no cure.[1] The condition damages the airways and the lungs, leading to persistent breathlessness, impacting a person's daily life and their ability to perform simple activities such as walking a short flight of stairs or carrying a suitcase.[1] Although COPD is thought to be underdiagnosed, globally, around 384 million people suffer from the disease.[1,[2]] This number, according to the World Health Organization (WHO), is likely to increase in coming years, with estimates that COPD will become the third leading cause of death worldwide by 2030.[1,[3]] Current COPD therapies focus on reducing and controlling symptoms. Yet, despite the wide availability of these treatments, many patients continue to suffer acute periods of worsening symptoms known as exacerbations. These exacerbations often lead to emergency department visits or hospital admissions, and are also associated with high mortality.[4] In the U.S. alone, the 2010 total annual medical costs related to COPD were estimated to be $32 billion, and are projected to rise to $49 billion in 2020.[5]

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About Verona Pharma plc

Verona Pharma is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapeutics for the treatment of respiratory diseases with significant unmet medical needs.

Verona Pharma's product candidate, RPL554, is a first-in-class, inhaled, dual inhibitor of the enzymes phosphodiesterase 3 and 4 that acts as both a bronchodilator and an anti-inflammatory agent in a single compound. In clinical trials, treatment with RPL554 has been observed to result in statistically significant improvements in lung function as compared to placebo and has shown clinically meaningful and statistically significant improvements in lung function when added to two commonly used bronchodilators as compared to either bronchodilator administered as a single agent. Verona Pharma is developing RPL554 for the treatment of chronic obstructive pulmonary disease (COPD), cystic fibrosis, and potentially asthma.

Forward-Looking Statements

This press release contains forward-looking statements. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding delivery of higher doses of RPL554 to the lungs having a promising therapeutic effect, estimates that COPD will be the third leading cause of death worldwide by 2030, and the treatment potential for RPL554.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from our expectations expressed or implied by the forward-looking statements, including, but not limited to, the following: our limited operating history; our need for additional funding to complete development and commercialization of RPL554, which may not be available and which may force us to delay, reduce or eliminate our development or commercialization efforts; the reliance of our business on the success of RPL554, our only product candidate under development; economic, political, regulatory and other risks involved with international operations; the lengthy and expensive process of clinical drug development, which has an uncertain outcome; serious adverse, undesirable or unacceptable side effects associated with RPL554, which could adversely affect our ability to develop or commercialize RPL554; potential delays in enrolling patients, which could adversely affect our research and development efforts; we may not be successful in developing RPL554 for multiple indications; our ability to obtain approval for and commercialize RPL554 in multiple major pharmaceutical markets; misconduct or other improper activities by our employees,

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consultants, principal investigators, and third-party service providers; material differences between our "top-line" data and final data; our reliance on third parties, including clinical investigators, manufacturers and suppliers, and the risks related to these parties' ability to successfully develop and commercialize RPL554; and lawsuits related to patents covering RPL554 and the potential for our patents to be found invalid or unenforceable. These and other important factors under the caption "Risk Factors" in our final prospectus filed with the Securities and Exchange Commission ("SEC") on April 28, 2017 relating to our Registration Statement on Form F-1, and our other reports filed with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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[1]World Health Organization. *Chronic Obstructive Pulmonary Disease.* http://www.who.int/mediacentre/factsheets/fs315/en/. *Accessed September 2017.*
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