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Verona Pharma Completes Enrollment in Phase 2 Clinical Trial Evaluating Nebulized RPL554 as Add-on to Dual Bronchodilator Therapy for COPD Maintenance Treatment

Enrollment complete ahead of schedule

Top line data expected in January 2019

LONDON, Oct. 31, 2018 (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 that is has enrolled the last patient in its Phase 2 clinical trial evaluating the effect of nebulized RPL554 as an add-on to dual therapy using long-acting anti-muscarinic / long-acting beta2-agonists ("LAMA/LABA") and triple therapy (LAMA/LABA with an inhaled corticosteroid) in the maintenance treatment of patients with moderate to severe chronic obstructive pulmonary disease ("COPD"). A total of 79 patients with COPD have enrolled at sites in the U.S. and in the UK in this three way crossover study. It is anticipated that it will take several weeks to complete dosing. Following data analysis, top line data is expected to be available in January 2019.

This randomized, double-blind, three-way crossover trial is designed to investigate the efficacy and safety of nebulized RPL554 as an add-on to an inhaled LAMA/LABA, tiotropium/olodaterol (Stiolto® Respimat®), compared to placebo. Those patients already receiving inhaled corticosteroid ("ICS") anti-inflammatory therapy will continue a stable dose of ICS throughout the study, thus providing additional data on "triple therapy" use. Following a 7- to 14-day washout period in advance of dosing and between study arms, patients will receive three days of treatment with each of two dose strengths (1.5 mg or 6.0 mg) of nebulized RPL554 or placebo twice daily. The primary endpoint of this trial is improvement in lung function with RPL554 vs placebo (as add-on to tiotropium/olodaterol), as measured by peak forced expired volume in one second (FEV_1), a standard measure of exhaled breath volume to evaluate respiratory function.

"We are delighted that enrollment in this Phase 2 study has been completed ahead of schedule and now expect to report top line data in January following completion of dosing and data analysis," stated Jan-Anders Karlsson, PhD, CEO of Verona Pharma, "We have already demonstrated that RPL554, when administered as an add-on to a single bronchodilator, produces a large and sustained improvement in lung function. This study is expected to further inform the positioning of RPL554 as an add-on to dual bronchodilator therapy (with some patients also on inhaled corticosteroid as background treatment) for the treatment of more severe COPD patients, who continue to experience disease progression and worsening of symptoms despite being treated with currently available COPD therapies."

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

About COPD

Chronic obstructive pulmonary disease ("COPD") is a progressive and life-threatening respiratory disease for which there is no cure.[1] Although COPD is thought to be underdiagnosed, globally, around 384 million people suffer from the disease.[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] The condition damages the airways and the lungs, leading to persistent symptoms of 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] Many experience acute periods of worsening symptoms called 'exacerbations', often leading to emergency department visits or hospital admissions and are also associated with high mortality.[4] In the United States 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] About

30-40% of moderate to severe COPD patients on triple inhaled therapy (ICS/LAMA/LABA) remain uncontrolled and continue to experience airway obstruction (breathing difficulties), COPD symptoms and exacerbations.[6] There is an urgent need for drugs with novel mechanisms of action that can be used by these patients in addition to current therapies.

About Verona Pharma plc and RPL554

Verona Pharma is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies 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 previous clinical trials, RPL554 has been observed to result in bronchodilator effects when used alone or as an add-on treatment to other COPD bronchodilators. It has shown clinically meaningful and statistically significant improvements in lung function when administered in addition to frequently used short- and long-acting bronchodilators, such as tiotropium (Spiriva®), compared with such bronchodilators administered as a single agent. RPL554 improved FEV_1 over four weeks in patients with moderate-to-severe COPD when compared to placebo and improved COPD symptoms and Quality of Life in a Phase 2b multicenter European study performed in 403 patients. In addition, RPL554 has shown anti-inflammatory effects in a standard challenge study with COPD-like inflammation in human subjects. RPL554 has been well tolerated in these studies and has a favorable safety and tolerability profile, having been administered to more than 730 subjects in 12 clinical trials. Verona Pharma is developing RPL554 for the treatment of chronic obstructive pulmonary disease ("COPD"), cystic fibrosis ("CF"), 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 the design of the Phase 2 clinical trial of RPL554, the timing of availability of top-line data for the Phase 2 clinical trial, the importance of the Phase 2 clinical trial to our development plans for RPL554, the potential of RPL554 as a promising first-in-class treatment option for COPD, and the value of the data and insights that may be gathered from the Phase 2 clinical trial, including for the purpose of designing pivotal Phase 3 trials.

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 and the completion of our Phase 2 trial; we may not be successful in developing RPL554 for multiple indications; our ability to obtain regulatory approvals necessary to conduct later stage trials and to commercialize RPL554 in multiple major pharmaceutical markets; misconduct or other improper activities by our employees, 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 Annual Report on Form 20-F filed with the Securities and Exchange Commission ("SEC") on February 27, 2018 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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Source: Verona Pharma plc

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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 development of DPI and MDI formulations of RPL554 and the potential for these formulations to increase the market opportunity for the product, if approved.

These and other important factors 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.
