

Verona Pharma

Press release

7 September 2017

Verona Pharma Announces Positive Top-Line Data from Phase 2a Clinical Trial in COPD with RPL554 Dosed in Addition to Tiotropium (Spiriva®)

Achieved significant and clinically meaningful additional improvement in peak lung function and faster onset-of-action when added to tiotropium

Demonstrated statistical significance across all primary and secondary efficacy outcome measures, at 6 mg dose; a clear dose response compared to 1.5 mg dose

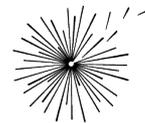
Management to hold conference call and webcast today at 8 am EDT time / 1 pm BST

LONDON, Sept. 07, 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 positive top-line results from its Phase 2a clinical trial, in which RPL554 was dosed in addition to tiotropium (Spiriva®), one of the most commonly used drugs to treat chronic obstructive pulmonary disease (COPD). In summary, despite the limited number of patients, the data from this Phase 2a trial demonstrated significantly improved peak lung function when RPL554 was added to tiotropium in patients with moderate-to-severe COPD.

This was a double blind, placebo-controlled, three way cross-over trial in 30 subjects with COPD and included two different doses of RPL554, 1.5 mg and 6 mg, or placebo, dosed twice-daily for three days, in addition to tiotropium, a long-acting anti-muscarinic (LAMA) bronchodilator, dosed once daily (ClinicalTrials.gov Identifier: NCT03028142). The primary outcome measures for the trial were peak forced expired volume in one second (FEV₁) on the third day of dosing and the average FEV₁ on the third day of dosing, representing measures of lung function and duration of effect. A number of secondary outcome measures were also recorded. Of note, the 6 mg dose of RPL554 achieved statistical significance, compared to placebo, on all primary and secondary outcome measures. The data confirmed dose dependency between the two RPL554 doses.

3 More London Riverside
London SE1 2RE
United Kingdom
T: +44 (0) 20 3283 4200
E: info@veronapharma.com

www.veronapharma.com



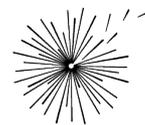
Highlights

- Primary outcome measures ¹ :
 - RPL554, compared to placebo, produced a statistically significant (1.5 mg, p=0.002; 6 mg, p<0.001) and a clinically meaningful (>100 ml) peak FEV₁ on the third day of dosing (additional bronchodilation) when administered on top of the standard bronchodilator tiotropium (Spiriva®).
 - Average FEV₁ on the third day of dosing (0 - 12 hours) of RPL554 when added on top of tiotropium was larger than that of tiotropium alone (1.5mg, p=0.099; 6 mg, p<0.001).
- Secondary outcome measures:
 - Both doses of RPL554 produced a statistically significant faster onset of action² (1.5 mg, 4.2 min; 6 mg, 4.6 min) when added to tiotropium compared to tiotropium alone (37.6 min; p<0.001)
 - The administration of RPL554 as an add-on treatment to tiotropium caused a marked reduction in Functional Residual Capacity (1.5 mg, p<0.01; 6 mg, p<0.05) and in Residual Volume (1.5 mg, p=0.07; 6 mg, p<0.01), both measures of trapped air in the lung, as compared to tiotropium alone
 - Suggesting that RPL554 treatment may reduce dyspnea, a major debilitating symptom of COPD³.
- Both doses of RPL554 were well tolerated as add-on treatments to tiotropium.
 - Adverse reactions were consistent with previous studies with RPL554 and tiotropium. No cardiovascular-related or gastrointestinal related adverse reactions were reported.

¹ In the study, a p-value<0.05 is regarded as statistically significant

² Defined as FEV₁ improvement by ≥10%

³ Dyspnea (shortness of breath) in COPD patients is often associated with hyperinflation of the lungs resulting from a higher residual volume of air



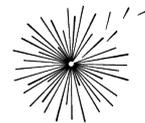
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Dave Singh, M.D., Professor of Clinical Pharmacology and Respiratory Medicine, Medicines Evaluation Unit, University of Manchester and Principal Investigator in this trial, commented, "Top-line results from this Phase 2a study demonstrate the very significant improvement in lung function that can be achieved in COPD patients using RPL554 in addition to tiotropium, the most widely used LAMA treatment. These encouraging results reinforce the potential for RPL554 to provide a meaningful difference in the treatment of COPD patients."

"We are pleased that RPL554 demonstrated a significant and clinically meaningful improvement in lung function of COPD patients and speeds up onset of action when it is administered as an add-on treatment to one of the most widely prescribed LAMA bronchodilators in these patients. LAMAs are the mainstay of all regimens under the GOLD⁴ treatment guidelines. We observed a clear dose response with the 6 mg dose, achieving statistical significance on all of the primary and secondary endpoints," said Jan-Anders Karlsson, PhD, CEO of Verona Pharma. "These findings extend our previous data and show that RPL554 has the potential to further improve lung function when administered as an add-on treatment to both short-acting and long-acting bronchodilators. We continue to enroll patients in our Phase 2b study to assess nebulized RPL554 for the maintenance treatment of COPD, and the data from the current study further affirms our belief that RPL554 can become a valuable addition to drugs commonly used by patients with COPD."

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 as an add-on treatment to 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.



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⁴ GOLD (Global initiative for Obstructive Lung Disease) treatment guidelines - standardized treatment guidelines for COPD based on an assessment of severity of symptoms

Conference Call

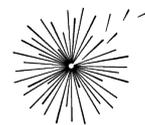
Verona Pharma will host an investment community conference call at today 8:00 a.m. Eastern Daylight Time (1:00 p.m. British Summer Time) to discuss the positive top-line data from the Phase 2a clinical trial in COPD disclosed in this press release.

Analysts and investors may participate in the conference call by utilizing the conference ID: 4242325 and dialing the following numbers:

- 1-877-280-2342 or +1-718-354-1359 for callers in the United States
- 0800 279 4841 or +44(0)20 3427 1911 for callers in the United Kingdom
- 0800 589 2674 or +49(0)69 2222 2221 for callers in Germany

Those interested in listening to the conference call live via the internet may do so by visiting the “Investors” page of Verona Pharma’s website at www.veronapharma.com and clicking on the webcast link. Slides highlighting the top-line data are posted to “Events and Presentations” page on the “Investors” section of Verona Pharma’s website at <http://investors.veronapharma.com/events-and-presentations/events>.

The information contained within this announcement is inside information as stipulated under the MAR. The person responsible for this announcement on behalf of Verona Pharma is Jan-Anders Karlsson, Chief Executive Officer.



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About Chronic Obstructive Pulmonary Disease

Chronic obstructive pulmonary disease (COPD) is a progressive respiratory disease for which there is no cure. The condition damages the airways and the lungs, leading to cough, mucus secretion and shortness of breath, impacting a person's ability to perform daily activities. According to the World Health Organization, COPD is the third leading cause of death globally, with 210 million people worldwide suffering from the disease. Current therapies to treat COPD are aimed at reducing and controlling symptoms. Despite the wide availability of these therapies, many COPD patients continue to suffer acute periods of worsening symptoms known as exacerbations. In the U.S. alone, these exacerbations are associated with approximately 1.5 million emergency department visits, 687,000 hospitalizations, and 129,000 deaths per year. The total annual medical costs related to COPD in the U.S. were estimated to be \$32 billion in 2010, and are projected to rise to \$49 billion in 2020.

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 RPL554's ability to treat dyspnea, RPL554's potential to make a meaningful difference in and be a valuable addition to the treatment of COPD patients, and RPL554's potential to improve lung function when administered as an add-on treatment with bronchodilators..

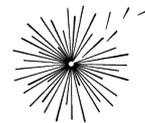
3 More London Riverside
London SE1 2RE
United Kingdom
T: +44 (0) 20 3283 4200
E: info@veronapharma.com

www.veronapharma.com



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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 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, 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.



Verona Pharma

For further information, please contact:

Verona Pharma plc
Jan-Anders Karlsson, Chief Executive Officer
Tel: +44 (0)20 3283 4200
info@veronapharma.com

Stifel Nicolaus Europe Limited (Nominated Adviser and UK Broker)
Stewart Wallace / Jonathan Senior / Ben Maddison
Tel: +44 (0) 20 7710 7600
SNELVeronaPharma@stifel.com

FTI Consulting (UK Media and Investor enquiries)
Simon Conway / Natalie Garland-Collins
Tel: +44 (0)20 3727 1000
veronapharma@fticonsulting.com

ICR, Inc. (US Media and Investor enquiries)
James Heins
Tel: +1 203-682-8251
James.Heins@icrinc.com

Stephanie Carrington
Tel. +1 646-277-1282
Stephanie.Carrington@icrinc.com

**THIS ANNOUNCEMENT CONTAINS INSIDE INFORMATION FOR THE
PURPOSES OF ARTICLE 7 OF REGULATION (EU) NO 596/2014.**