11 June 2015

RPL554 Phase 2a trial started; headline data expected Q1 2016

First asthma patients dosed with RPL554 in new proprietary nebulised formulation

11 June 2015, Cardiff – Verona Pharma plc (AIM: VRP.L), the drug development company focused on first-in-class medicines to treat respiratory diseases, today announces that the first patients have been dosed with RPL554 in a Phase 2a dose-finding trial in asthma patients using the Company's new proprietary nebulised formulation. RPL554 is a novel inhaled PDE3/PDE4 inhibitor, currently in development as a nebulised treatment for acute exacerbations in chronic obstructive pulmonary disorder (COPD) patients in a hospital or home-care setting. The nebulised bronchodilator market was worth approximately $1 billion in 2014 in the US.1

The study is being carried out in asthmatics as typically a dose response relationship to bronchodilators can be more accurately established in this group of patients, compared to COPD patients. In this trial, up to 30 patients with mild to moderate chronic asthma will each receive single doses of nebulised RPL554, from the very low dose to the highest dose previously tested in the Phase 1b single ascending and multiple ascending dose (SAD and MAD) studies of the same drug in healthy subjects. In this double-blind, placebo-controlled, crossover study each patient will also receive two different doses of nebulised salbutamol, a commonly used bronchodilator in these patients, and placebo. The primary objective of the trial is to establish the bronchodilator effect and duration of action of RPL554 in asthma patients. The study is being performed at Celerion (Belfast, Ireland) and Skane University Hospital (Lund, Sweden).

As reported on 23 March 2015 and 8 June 2015, Phase 1b results in SAD and MAD studies of nebulised RPL554 with this new formulation in healthy volunteers, have demonstrated that the drug is well tolerated in doses up to 16 times larger than those previously demonstrated to produce bronchodilation using the prior formulation. Given that this new formulation is better tolerated and higher doses can be administered, this latest trial is likely to provide useful data for further development work on RPL554 and also its potential as a future treatment for asthma sufferers.

Dr Jan-Anders Karlsson, the CEO of Verona Pharma, said:

"We have demonstrated in our previous studies in healthy volunteers with RPL554 in its new formulation that the drug is well tolerated at significantly higher doses than have previously been shown to produce bronchodilation. We have now begun examining the safety and bronchodilator responses to RPL554 in COPD, in the ongoing Phase 1b study, and in asthma patients using our new formulation.

Given that constriction of the airways is a key feature of different lung diseases, including asthma, a novel drug that produces potent bronchodilation but has a novel mechanism of action, would also be of potential value in these patients, especially when presenting with an acute exacerbation whilst on the maximum tolerated doses of their current asthma medicine. The data from this latest study should inform our further development plans for RPL554 when it reports initial data in Q1 2016."

For further information please contact: Verona Pharma plc

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

N+1 Singer (Nominated Adviser and UK Broker)
Aubrey Powell / James White
Tel: +44 (0)20 7496 3000

FTI Consulting
Simon Conway / Stephanie Cuthbert / 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

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. RPL554 has also shown anti-inflammatory effects and been well tolerated in clinical trials. 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.

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.
