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Verona Pharma Receives WHO Approval for “ensifentrine” as Recommended INN for RPL554

Assignment of the “-fentrine” stem in the INN attests to RPL554’s dual phosphodiesterase inhibitor mechanism of action

LONDON, Jan. 09, 2019 (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 that the World Health Organization (“WHO”) approved “ensifentrine” as the recommended International Non-proprietary Name (“INN”) for the company’s drug candidate, RPL554.

Ensifentrine 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 chronic obstructive pulmonary disease (“COPD”), cystic fibrosis (“CF”) and potentially asthma. The “-fentrine” stem indicates recognition from the WHO that RPL554 inhibits multiple phosphodiesterases, rather than a single phosphodiesterase, such as phosphodiesterase 3 or 4 alone.

“We are pleased to receive approval from the WHO for the use of ‘ensifentrine’, which to our knowledge, is the only molecule with an INN assignment using the ‘–fentrine’ stem currently in clinical development. We believe that this designation underlines our drug candidate’s position as a novel compound with a dual bronchodilator and anti-inflammatory mechanism of action,” said Jan-Anders Karlsson, PhD, CEO of Verona Pharma. “We are very encouraged by the positive data from our studies evaluating ensifentrine in COPD and CF, and look forward to advancing this novel drug candidate into late stage development as a potential new treatment for patients.”

“Ensifentrine is the only dual bronchodilator and anti-inflammatory drug candidate currently in development that I have come across in my research. This could be significant for patients and healthcare providers alike as there have been no new bronchodilator treatment classes over the last four decades,” said Gerard Criner, MD, FACP, FACCP, Chair and Professor of Thoracic Medicine and Surgery, Lewis Katz School of Medicine at Temple University.

In Phase 2 clinical trials completed to date, ensifentrine has been observed to result in bronchodilator effects when used alone or as an add-on treatment to other COPD bronchodilators, and has also shown anti-inflammatory effects in a standard challenge study with COPD-like inflammation in human subjects. Verona Pharma is currently conducting two further Phase 2 clinical trials: one to evaluate a nebulized formulation of ensifentrine as an add-on treatment to dual LAMA/LABA therapy and triple LAMA/LABA/ICS therapy, and the other to evaluate a dry powder inhaler (“DPI”) formulation of ensifentrine for the maintenance treatment of COPD. The company also plans to evaluate ensifentrine in a metered-dose inhaler (“MDI”) formulation as part of a comprehensive clinical program intended to fully demonstrate the clinical utility of ensifentrine in improving the standard of care for COPD. These data will be used to support the planning of the ensifentrine Phase 3 COPD program.

About Verona Pharma plc and ensifentrine
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, ensifentrine (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, the nebulized formulation of ensifentrine 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. Ensifentrine

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, ensifentrine has shown anti-inflammatory effects in a standard challenge study with COPD-like inflammation in human subjects. Ensifentrine has been well tolerated in these studies and has shown a favorable safety and tolerability profile, having been administered to more than 730 subjects in 12 clinical trials. Verona Pharma is developing ensifentrine for the treatment of COPD, 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 ensifentrine being the only molecule with an INN using the '–fentrine' stem currently in clinical development, the INN underlining ensifentrine's position as a novel compound with a dual mechanism of action, the advancement of ensifentrine into later stages of clinical development, including the use of data from the on-going Phase 2 studies in the planning of a Phase 3 program in COPD, ensifentrine's treatment potential and potential indications, the significance of ensifentrine for patients and healthcare providers, plans to evaluate ensifentrine in an MDI formulation, and demonstrating the clinical utility of ensifentrine.

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 ensifentrine, 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 ensifentrine, 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 ensifentrine which could adversely affect our ability to develop or commercialize ensifentrine; potential delays in enrolling patients, which could adversely affect our research and development efforts; we may not be successful in developing ensifentrine for multiple indications; our ability to obtain approval for and commercialize ensifentrine 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 ensifentrine; and lawsuits related to patents covering ensifentrine 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, 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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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.

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