FOR IMMEDIATE RELEASE

Respira to Present Clinical Data on RT234-PAH Patient-Controlled Treatment to Acutely Improve Episodic Symptoms in Pulmonary Arterial Hypertension (PAH) Patients

- RT234 is a potential first-in-class, as-needed treatment for symptoms of PAH –
- RT234 is well tolerated when administered to both healthy individuals and to PAH patients on top of maintenance therapies –

ALBUQUERQUE, N.M., October 16, 2020— Respira Therapeutics, Inc., a clinical-stage company developing inhaled therapeutics for cardiopulmonary diseases that improve patient outcomes through enhanced drug targeting to the small airways of the lung, announced today clinical data from Phase 1 and Phase 2a clinical studies of its lead product candidate, RT234-PAH (vardenafil administered as a dry powder inhaled treatment), that support its further development as an as-needed (PRN) treatment that will allow patient-controlled dosing to acutely improve episodic symptoms and exercise capacity in pulmonary arterial hypertension (PAH) patients. The data will be presented at the American College of Chest Physicians virtual CHEST Annual Meeting 2020 taking place October 18–21, 2020.

“Despite being on multiple PAH maintenance therapies, patients with PAH live with daily acute episodes of shortness of breath, tiredness, racing heart, and lack of exercise capacity that substantially curtail their ability to perform daily functions,” said Bob Curtis, President and CEO of Respira. “Results of our initial clinical studies demonstrate that RT234-PAH, based on its rapid onset of action, extended duration of action, and minimal safety and tolerability issues when used in addition to PAH maintenance therapies, has the potential to be a first-in-class, as-needed treatment that may allow patients to acutely relieve their episodic symptoms of PAH and improve their quality of life. The very positive results of these two clinical studies support the continued development of RT234-PAH as an as-needed, preemptive treatment for PAH patients.”


Recorded Presentation and Live Q&A: “Acute Hemodynamic Improvement in Chronic Pulmonary Arterial Hypertension on Dual Therapy Following RT234-PAH Inhalation”

Presenter: Nathan Dwyer, MBBS

Date & Time: Sunday, October 18, 2020 | 12:30 p.m.–1:30 p.m. CT

Summary & Key Findings:
The Phase 2a multi-center, open-label, escalating-dose clinical trial was designed to evaluate acute changes in pulmonary vascular resistance (PVR) and other hemodynamic (HD) parameters in PAH patients on stable maintenance dual therapy. Three cohorts of five subjects each received 0.2, 0.6, and 1.2 mg RT234 during right heart catheterization. HD parameters were recorded at 5, 15, 30, 45, and 60 minutes post-inhalation. Summary of data:

- RT234 inhalation of the middle (0.6 mg) and high (1.2 mg) doses resulted in rapid reduction in PVR that was sustained for at least 60 minutes post-administration and was well tolerated
- The study demonstrated that RT234 possesses the critical design features of an as-needed treatment to acutely improve episodic symptoms and exercise capacity in PAH:
  - A rapid onset of action (PVR reduction within 5 minutes of administration), with acute improvements noted in exercise tolerance
• An acceptable duration of post-administration pulmonary hemodynamic action for a PRN medication
• Minimal local and systemic safety and tolerability issues when administered in addition to maintenance therapies
• Noninvasive delivery system with administration of less than one minute

e-Poster #P1912: “Safety and Pharmacokinetics of Vardenafil Inhalation Powder (RT234-PAH) Following Oral Inhalation in Healthy Adult Volunteers”
**Presenter:** Edwin Parsley, DO
**Date & Time:** Available throughout the conference

**Summary & Key Findings:**
The Phase 1 study designed to evaluate safety and pharmacokinetics of RT234 encompassed a single ascending dose study (SAD) followed by a multiple ascending dose (MAD) study that used the maximum tolerated dose from the SAD. In the MAD, subjects received a 2.4 mg dose every four hours for up to four doses (i.e., 9.6 mg/day) for seven consecutive days. RT234 was well tolerated, with no dose-limiting toxicity observed and low incidence of cough and local airway irritation.

**About RT234**
Respira’s lead drug-device product candidate, RT234-PAH, is a first-in-class inhaled therapy intended for as-needed (PRN) use to improve exercise tolerance and provide acute relief from breathlessness and fatigue, the most commonly reported symptoms in WHO Group 1 pulmonary arterial hypertension (PAH) patients. This contrasts with all current PAH treatments, which are taken according to a specific treatment regimen and monitored for chronic improvements in outcome measures. RT234 demonstrated significant safety margins in preclinical testing and was well tolerated in Phase 1 clinical studies, with PK consistent with expectations for a PRN medication. Respira has received FDA Orphan Drug designation for the active ingredient in RT234, vardenafil, a potent PDE5i vasodilator that is FDA-approved in an oral form for a non-PAH indication. RT234 is currently in Phase 2 clinical testing for this indication. Respira is pursuing the 505(b)(2) FDA approval pathway, which will allow the company to reference previous findings of safety and efficacy of vardenafil to supplement the company’s safety and efficacy data on its proprietary vardenafil inhalation powder drug formulation. Respira intends to pursue additional indications for RT234 in other WHO pulmonary hypertension patient groups.

**About Respira Therapeutics**
Respira Therapeutics is a clinical-stage company developing inhaled therapeutics for cardiopulmonary diseases that improve patient outcomes through enhanced drug targeting to the small airways of the lung. Respira’s approach combines state-of-the-art, proprietary inhaled drug formulations with dry powder inhaler device technologies to create novel therapeutic products designed to improve dose consistency while enhancing delivery to the lung periphery. Respira’s lead product candidate, RT234-PAH, has received FDA Orphan Drug Designation for Pulmonary Arterial Hypertension and is in Phase 2 clinical trials as a first-in-class inhaled therapeutic for as-needed use to provide acute relief for the most commonly reported symptoms in PAH patients. Learn more at [www.respiratherapeutics.com](http://www.respiratherapeutics.com).

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