ORLANDO, FL, September 28, 2013 /**24-7PressRelease**/ -- *To see if you qualify for this COPD Clinical Trial in Florida, visit Avail Clinical Research on the web (http://www.availclinical.com) or contact us directly at (386) 785-2404. There is no cost to participate, no insurance is required, and you may receive compensation for time and travel.

STUDY DESIGN

This study is designed to evaluate the effect of an experimental inhalation therapy administered once daily via a Novel Dry Powder Inhaler on arterial stiffness compared with placebo and vilanterol over a 24 - week treatment period in subjects with COPD. Vilanterol is included to help explain relative treatment effect of this experimental inhalation therapy in the new combination, however the comparison is not powered. Arterial stiffness will be measured as aPWV. This is a randomised, placebo-controlled, multicenter study. Subjects who meet the eligibility criteria at Screening and meeting the randomisation criteria at the end of a 2-week Run-In period will enter a 24-week treatment period. There will be an approximately 7-day Follow-Up period after the treatment period.

BACKGROUND & RATIONALE

Arterial stiffness is increasingly recognized as a surrogate marker for cardiovascular disease (CVD). In particular, arterial stiffness has been shown to be an independent predictor of future fatal and non-fatal CV events and all-cause mortality in hypertensive patients, apparently healthy elderly subjects and a general population. Arterial stiffness can be measured with non-invasive, reproducible and inexpensive techniques, which make it feasible to implement into clinical practice and large-scale clinical studies. Pharmacological treatments that have been shown to reduce arterial stiffness include antihypertensive treatment, such as beta-blockers, diuretics, calcium-channel antagonists, angiotensin II receptor blockers, and lipid-regulating agents such as statins and a combination of statin and ezetimibe.

PRIMARY OBJECTIVES

The primary objective of the study is to evaluate the effect of an experimental inhalation therapy administered once daily (QD) compared with placebo on aPWV in subjects with COPD and aPWV â‰¥ 11.0 m/s at baseline.

INCLUSION CRITERIA

1. Type of subject: outpatient

2. Informed consent: Subjects must give their signed and dated written informed consent to participate.

3. Gender: Male or female subjects

A female is eligible to enter and participate in the study if she is of:

-Non-child bearing potential (i.e., physiologically incapable of becoming pregnant, including any female who is post-menopausal or surgically sterile). Surgically sterile females are defined as those with a documented hysterectomy and/or bilateral oophorectomy or tubal ligation. Post-menopausal females are defined as being amenorrheic for greater than 1 year with an appropriate clinical profile, e.g., age appropriate, history of vasomotor symptoms. However in questionable cases, a blood sample with FSH _ 40MIU/ml and estradiol _40pg/ml (_140 pmol/L) is confirmatory.

-Child bearing potential, has a negative pregnancy test at screening, and agrees to one of the following acceptable contraceptive methods used consistently and correctly (i.e., in accordance with the approved product label and the instructions of the physician for the duration of the study âEUR" screening to follow-up contact):

-- Complete abstinence from intercourse from screening until the Follow-Up Phone Contact; or

-- Male partner is sterile (vasectomy with documentation of azoospermia) prior to female subject entry into the study, and this male partner is the sole partner for that subject; or

-- Implants of levonorgestrel inserted for at least 1 month prior to the study medication administration but not beyond the third successive year following insertion; or

-- Injectable progestogen administered for at least 1 month prior to study medication administration and administered until the Follow-Up Phone Contact; or

-- Oral contraceptive (combined or progestogen only) administered for at least one monthly cycle prior to study medication administration; or

-- Double barrier method: condom and occlusive cap (diaphragm or cervical/vault caps) with spermicidal agent (foam/gel/film/cream/suppository); or

-- An intrauterine device (IUD), inserted by a qualified physician, with published data showing that the highest expected failure rate is less than 1 per year; or

-- Estrogenic vaginal ring; or

-- Percutaneous contraceptive patches

4. Age: â‰¥ 40 years of age at Screening (Visit 1)

5. COPD diagnosis: Subjects with a clinical history of COPD in accordance with the following definition by the American Thoracic Society(ATS) /European Respiratory Society (ERS) [Celli, 2004]:

COPD is a preventable and treatable disease characterized by airflow limitation that is not fully reversible. The airflow limitation is usually progressive and is associated with an abnormal inflammatory response of the lungs to noxious particles or gases, primarily caused by cigarette

smoking. Although COPD affects the lungs, it also produces significant systemic consequences.

6. Tobacco use: Subjects with a current or prior history of â‰¥ 10 pack-years of cigarette smoking at Screening (Visit 1). Former smokers are defined as those who have stopped smoking for at least 6 months prior to Visit 1.

Note: Pipe and/or cigar use cannot be used to calculate pack-year history.

Number of pack years = (number of cigarettes per day/20) x number of years smoked

7. Severity of Disease:Subjects with a measured post-albuterol/salbutamol FEV1 â‰¤70% of predicted normal values calculated using NHANES III reference equations at Screening (Visit 1)Subject with a measured post-albuterol/salbutamol FEV1/FVC ratio of â‰¤0.70 at Screening (Visit 1)

Post-bronchodilator spirometry will be performed approximately 10-15 minutes afterthe subject has self-administered 4 inhalations (i.e., total 400mcg) of albuterol/salbutamol via an MDI with a valved-holding chamber.

8. Baseline aPWV: subjects with a measured aPWVâ‰¥ 11.0 m/s at Screening (Visit 1)

Avail Clinical Research conducts a variety of Clinical Trials in Florida. For more information about participating in an COPD Clinical Study, please visit our website or contact us directly at (386) 785-2404.