Chronic Obstructive Pulmonary Diseases:
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The COPD Pipeline XXXX

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Abbreviations: chronic obstructive pulmonary disease, **COPD**; phosphodiesterase, **PDE**; forced expiratory volume in 1 second, **FEV_1**; non-typeable Haemophilus influenza, **NTHi**; Moraxella catarrhalis, **MCat**; long-acting beta2-agonist, **LABA**; long-acting muscarinic antagonist, **LAMA**

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Keywords

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The Gala Airway

The Gala Airway treatment system, RheOx™, is a device for the treatment of chronic bronchitis that is based on the delivery of high frequency, short duration energy to the epithelium and sub-mucosal layers of the airways, targeting abnormal, mucus-producing cells. The treatment is delivered during a bronchoscopic procedure with the patient under general anesthesia, in 2 sessions of treatment 1 month apart. The bronchoscopic procedure lasts less than 60 minutes in total. A single group of 15 participants who have been diagnosed with chronic bronchitis for at least 2 years, have a cigarette smoking history of at least 10 pack years and 1 or more exacerbations in the previous 12 months will be enrolled.[1] The first 2 participants were successfully treated in November 2018.[2] The primary outcome measure is safety with secondary outcomes of clinical utility and quality of life improvement as measured by the St George's Respiratory Questionnaire and the COPD Assessment Test (CAT) at 6 and 12 months (NCT03631472).[1,2]

MyCOPD

There are over 300 studies on Clinical Trials.gov that report on "self-care" in some way. As stated on one trial that is introducing a new digital tool for helping patients manage their chronic obstructive pulmonary disease (COPD), "Involvement of patients in the management of their own medical conditions (self-care) has been shown to improve how individuals feel, reduce the frequency of medical emergencies and reduce the costs of health care. In order to self-care successfully patients require the correct knowledge, skills and the confidence to make the right decisions; about their treatments, use of health care services and lifestyle choices."[3]

The trial is being conducted by MyMHealth (short for "My Mobile Health) a United Kingdom company focused on providing digital tools—phones, tablets and even smart TVs—to assist patients in recording symptoms, accessing information and learning about treatments.

MyMHealth has produced an app called MyCOPD and in their clinical trial investigators will explore whether the app helps 60 patient enrollees (former or current smokers with a forced expiratory volume in 1 second [FEV_1] to forced vital capacity [FVC] ratio of <70%) self-manage their COPD and engage in appropriate decision making regarding their disease. As a primary outcome measurement, investigators will use the CAT to measure the impact of COPD on each patient's health status before, during and after using the MyCOPD app for 3 months. In addition, patient engagement, quality of life, inhaler technique, medication adherence and change in activity will also be assessed (NCT03620630).[3]

ACT-541468

ACT-541486 is a dual orexin receptor antagonist, that is being evaluated for its effect on nighttime respiration in patients with moderate COPD. The program is comprised of 2 placebo-controlled dose-response studies. Participants will be required to have moderate COPD, an FEV_1 less than 80% of predicted, and a FEV_1/FVC ratio less than 70%. The primary outcome will be the mean oxygen saturation (SaO2), as measured by finger pulse oximetry during total sleep time, after a once a day evening dose for 5 nights. A total of 28 patients will be enrolled in the trial. (NCT03646864)[4]

Efficacy of Triple Therapy in COPD

A new 4,000-patient study, completed in November of 2018, included patients with COPD and the random new use of either a fixed-dose long-acting beta2-agonist (LABA)/long-acting muscarinic antagonist (LAMA) combination or the same combination plus an inhaled corticosteroid (ICS).[5] All participants were above 55 years of age, new to LABA/LAMA combinations and inhaled ICS and without a diagnosis of asthma. The 3 primary outcomes were the number of participants hospitalized with a *severe* exacerbation and the number hospitalized with a *moderate* exacerbation and the number of participants hospitalized with community-acquired (severe) pneumonia. No results have been posted for the study at the time this column went to press. The trend in COPD therapy has been to add and combine agents with complementary actions to maximize therapy while minimizing the undesirable actions of the therapy where possible. Further, the use of long-acting agents (meaning: 12-or 24-hour actions) is likely to be considered to be desirable by many patients and prescribers. The "cocktail" approach in the present triple-therapy drug, if it can be used with benefit and without harm, will be considered to be a success by many . (NCT 03724877)[5]

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References

1. National Institutes of Health. Gala early feasibility study for the treatment of chronic bronchitis in the United States (Gala_EFS). ClinicalTrials.gov website. https://clinicaltrials.gov/ct2/show/NCT03631472 Published August 2018. Accessed January 2019.

2. Gala enrolls first subjects in an early feasibility study of RheOx™ for chronic bronchitis in the United States [news release]. Menlo Park, CA: Gala Therapeutics; November 5, 2018. https://www.prnewswire.com/news-releases/gala-enrolls-first-subjects-in-an-early-feasibility-study-of-rheox-for-chronic-bronchitis-in-the-united-states-300743610.html Accessed January 2019.

3. National Institutes of Health. Clinical efficacy and cost effectiveness of MYCOPD in patients with mild and moderate newly diagnosed COPD (EARLY). ClinicalTrials.gov website. https://clinicaltrials.gov/ct2/show/NCT03620630 Published August 2018. Updated November 2018. Accessed January 2019.

4. National Institutes of Health. A study to evaluate the effects of ACT-541468 on respiration in patients with moderate chronic obstructive pulmonary disease. ClinicalTrials.gov website. https://clinicaltrials.gov/ct2/show/NCT03646864 Published August 2018.Updated November 2018. Accessed January 2019.

5. National Institutes of Health. Effectiveness of triple therapy in COPD. ClinicalTrials.gov website. https://clinicaltrials.gov/ct2/show/NCT03724877 Published October 2018. Updated November 2018. Accessed January 2019.