TRIALS USING THE EXACT® OR E-RS™

**Source: ClinicalTrials.gov\*
Date: 1 March 2016**

| **Sponsor** | **Title** | **Start Date** | **Primary Completion Date** | **Primary Outcome Measures** | **Relevant Secondary Outcome Measures** **(EXACT and/or E-RS)** | **Duration of EXACT/E-RS Data Collection** | **Brief Summary** | **Publications** | **Clinicaltrials.gov** |
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| Aquinox Pharmaceuticals, Inc. | The FLAGSHIP Study: A 12-week Phase II Study to Evaluate the Efficacy and Safety of AQX-1125 Following Exacerbations in Patients With Chronic Obstructive Pulmonary Disease (COPD) by Targeting the SHIP1 Pathway | Oct-13 | Apr-15 | * Change from baseline in EXACT score [Time Frame: 12 weeks]
 |  | 12 weeks | The primary objective of this study is to evaluate the effect of 12 weeks of treatment with once daily administration of AQX-1125 compared to placebo in subjects following exacerbations of Chronic Obstructive Pulmonary Disease (COPD) by targeting the SHIP1 (Src Homology 2-containing Inositol-5'-Phosphatase 1) pathway. | N/A | NCT01954628 |
| AstraZeneca | Randomised, Double-blind, 56 Week Placebo-controlled, Parallel Group, Multicentre, Phase 3 Study to Evaluate the Efficacy and Safety of 2 Doses of Benralizumab in Patients With Moderate to Very Severe COPD With a History of Exacerbations | Jun-14 | Oct-17 | * Evaluation of the effect of benralizumab on COPD exacerbations in subjects with moderate to very severe COPD [Time Frame: Immediately following administration of study drug up to 56 weeks]
 | * Evaluation of the effect of benralizumab on the severity, frequency and duration of Exacerbations of Chronic Pulmonary Disease Tool (EXACT-PRO) - Patient-reported Outcome questionnaire defined events [Time Frame: Up to 56 weeks.]
 | Up to 56 weeks | The purpose of the study is to determine if benralizumab reduces COPD exacerbation rate in symptomatic patients with moderate to very severe COPD who are receiving standard of care therapies. | N/A | NCT02138916 |
| AstraZeneca | A 12-week Phase IIa, Double-blind, Placebo-controlled, Randomized Study to Investigate the Efficacy and Safety of AZD7624 in COPD Patients With a History of Frequent Acute Exacerbations While on Maintenance Therapy | Oct-14 | Jan-16 | * Time to first moderate to severe COPD exacerbation or discontinuation [Time Frame: up to 12 weeks]
 | * Time to first symptom defined exacerbation (as defined by the Exacerbation of Chronic Pulmonary Disease Tool [EXACT] daily diary) [Time Frame: up to 12 weeks]
* Number of symptom defined exacerbations (as defined by the EXACT daily diary) [Time Frame: up to 12 weeks]
* Symptoms of COPD (using the EXACT for Respiratory Symptoms [E-RS], a subset of items from the EXACT diary) [Time Frame: up to 12 weeks]
 | Up to 12 weeks | The purpose of this study is to determine whether AZD7624 can reduce acute Chronic Obstructive Pulmonary Disease (COPD) exacerbations in patients on COPD maintenance therapy with a history of frequent acute exacerbations | N/A | NCT02238483 |
| AstraZeneca | AZD2423 Safety and Tolerability Study in Patients With Moderate and Severe Chronic Obstructive Pulmonary Disease(COPD) | Oct-10 | Mar-11 | * Number of Participants With Clinically Significant Changes in Laboratory Variables Other Than Monocytes [Time Frame: Day 1, 1 week, 2 weeks, 3 weeks, 4 weeks and 5 weeks (follow-up)]
* Number of Participants With Clinically Significant Changes in Vital Signs [Time Frame: Day 1, 1 week, 2 weeks, 3 weeks, 4 weeks and 5 weeks (follow-up)]
* Number of Participants With Clinically Significant Changes in ECG Variables [Time Frame: Day 1, 1 week, 2 weeks, 3 weeks, 4 weeks and 5 weeks (follow-up)]
* Number of Participants With Clinically Significant Changes in Physical Examination [Time Frame: Day 1, 1 week, 2 weeks, 3 weeks, 4 weeks and 5 weeks (follow-up)]
* Monocytes at Baseline [Time Frame: Day 1]
* Monocyte count in peripheral blood at baseline (Pre-dose, Day 1)
* Monocytes at End of Treatment [Time Frame: week 4]
* Monocyte count in peripheral blood at end of treatment (4 weeks)
* Monocytes at Follow-up [Time Frame: week 5 (follow-up)]
* Monocyte count in peripheral blood at follow-up (Week 5; 1 week after end of treatment)
 | * Exacerbations of Chronic Pulmonary Disease Tool (EXACT) Total Score at Baseline [Time Frame: Average of 7 days of pre-treatment measurements (day -7 to -1)]
* EXACT Total Score During Last 7 Days of Treatment [Time Frame: Average of the last 7 days of treatment (week 4)]
 | Baseline & Last 7 Days of Treatment | The purpose of the study is to investigate the tolerability and safety of AZD2423 in Patients with chronic obstructive pulmonary disease. | N/A | NCT01215279 |
| AstraZeneca | Effect on Structural Changes in Airways, Measured by MSCT, of Twice Daily 60mg AZD9668 for 12 Weeks in Chronic Obstructive Pulmonary Disease (COPD) Patients | Jan-10 | Nov-10 | * AWT-Pi10 (Airway Wall Thickness of a Theoretical Airway With an Internal Perimeter of 10 mm) [Time Frame: Measured after 12 weeks treatment (day 84)]
* AWT-Pi10 (mm) as a measure of structural changes in airways. End of treatment Least Squares Mean.
 | * EXAcerbations of Chronic Pulmonary Disease Tool (EXACT) Total Score [Time Frame: Average from measurements recorded daily by patient in last 6 weeks of treatment.]
 | Average from measurements recorded daily by patient in last 6 weeks of treatment | The primary objective of the study is to evaluate structural changes effected by AD9668 in the airways of adults with Chronic Obstructive Pulmonary Disease (COPD) by Multi-Slice Computed Tomography (MSCT) | Nordenmark LH, Taylor R, Jorup C. Feasibility of Computed Tomography in a Multicenter COPD Trial: A Study of the Effect of AZD9668 on Structural Airway Changes. Adv Ther. 2015 Jun;32(6):548-66. doi: 10.1007/s12325-015-0215-3. Epub 2015 Jun 5. | NCT01054170 |
| AstraZeneca | A Dose Range Finding Study to Evaluate the Efficacy and Safety of AZD9668 Administered Orally at Three Dose Levels to Patients With Chronic Obstructive Pulmonary Disease (COPD) on Treatment With Tiotropium | Jul-09 | Aug-10 | * Baseline Pre-bronchodilator FEV1 (L) [Time Frame: Day 1]
* Forced Expiratory Volume in 1 second (L) as a measure of lung function, measured before bronchodilator (salbutamol) use in the clinic
* End-value Pre-bronchodilator FEV1 (L) [Time Frame: Measured at clinic visits: 1, 4, 8 and 12 weeks]
* End of treatment value - week 12 for completers, otherwise Last Observation Carried forward (LOCF)
 | * EXACT - Baseline Total Score [Time Frame: Baseline]
* EXACT - End-value Total Score [Time Frame: Measured daily in the evening for 12 weeks]
 | EXACT Baseline Total Score: Baseline is the mean of last 10 days of data before start of treatment.EXACT End-value Total Score: Daily in evening for 12 weeks | The primary objective is to evaluate the dose-response relationship and efficacy of AZD9668 at 3 dose levels compared with placebo in symptomatic COPD patients by assessing effects on lung function and symptoms of COPD. | Vogelmeier C, Aquino TO, O'Brien CD, Perrett J, Gunawardena KA. A randomised, placebo-controlled, dose-finding study of AZD9668, an oral inhibitor of neutrophil elastase, in patients with chronic obstructive pulmonary disease treated with tiotropium. COPD. 2012 Apr;9(2):111-20.PubMed Link: <http://www.ncbi.nlm.nih.gov/pubmed/22458939>  | NCT00949975 |
| AstraZeneca | Efficacy and Safety of Twice Daily 60mg AZD9668 in COPD for 12 Weeks in Patients on Background Budesonide/Formoterol | Nov-09 | Aug-10 | * Baseline Pre-bronchodilator FEV1 (L) [Time Frame: Day 1]
* End-value Pre-bronchodilator FEV1 (L) [Time Frame: up to week 12]
 | * EXACT - Baseline Total Score [Time Frame: Baseline]
* EXACT - End-value Total Score [Time Frame: Last 6 weeks on treatment]
 | EXACT Baseline Total Score: Baseline is the mean of last 10 days of data before start of treatment.EXACT End-value Total Score: Last 6 Weeks on Treatment | The primary objective is to evaluate the efficacy of AZD9668 compared with placebo in symptomatic COPD patients by assessing the effects on lung function and symptoms of COPD | Kuna P, Jenkins M, O'Brien CD, Fahy WA. AZD9668, a neutrophil elastase inhibitor, plus ongoing budesonide/formoterol in patients with COPD. Respir Med. 2012 Apr;106(4):531-9.PubMed Link: <http://www.ncbi.nlm.nih.gov/pubmed/22197578>  | NCT01023516 |
| AstraZeneca | The Use of a Forecasting System for Predicting Exacerbations of COPD | Aug-08 | Mar-09 | * The incidence and frequency of COPD exacerbations in each of the intervention groups [Time Frame: December 2008 to March 2009 inclusive]
* Electronic diary symptoms using the EXACT instrument [Time Frame: Daily recording]
 | *
 | Dec 2008 to Mar 2009 (inclusive); electronic daily recording | People with Chronic Obstructive Pulmonary Disease (COPD) often have periods during the year when their symptoms become worse. These are often due to an infection and are called "exacerbations" by doctors. Exacerbations are more common in the winter and also seem to be related to particular types of weather. As well as forecasting the weather the UK Met Office has developed a system to try to predict when exacerbations are likely to occur. The main purpose of this research study is to find out whether the Met Office forecasting service can predict when exacerbations are more likely to occur and whether the advice given during the predicted higher risk periods leads to fewer patients having an exacerbation or if it reduces the impact of the exacerbation. The study will also assess if there is a link between viral or bacterial infection and breathing problems that occur during the study period. The study will also collect information about possible causes of the breathing problems and what happens to the person afterwards. The results of this study will help us learn more about breathing problems which may lead to new research studies that would aim to improve the care of people with COPD. | Halpin DM, Laing-Morton T, Spedding S, Levy ML, Coyle P, Lewis J, Newbold P, Marno P. A randomised controlled trial of the effect of automated interactive calling combined with a health risk forecast on frequency and severity of exacerbations of COPD assessed clinically and using EXACT PRO. Prim Care Respir J. 2011 Sep;20(3):324-31, 2 p following 331.Open Access Link: <http://www.thepcrj.org/journ/vol20/20_3_324_331.pdf>  | NCT00788645 |
| AstraZeneca | BENEFITS OF ACLIDINIUM BROMIDE IN THE RELIEF OF COPD SYMPTOMS INCLUDING COUGH (M-34273-46) | Mar-15 | Oct-15 | * Change from baseline in Overall EXACT-Respiratory Symptoms Total score [Time Frame: From Baseline up to 8 weeks]
 | * Change from baseline in Overall EXACT-Respiratory Symptoms of Cough and Sputum Domain Score [Time Frame: From Baseline up to 8 weeks]
 | 8 weeks | The aim of the present study is to evaluate the effect of aclidinium bromide 400 μg BID compared with placebo on COPD symptoms in a symptomatic patients population with moderate COPD and chronic bronchitis, and particularly assess the effects in cough by using specific tools to assess the occurrence and impact of this relevant COPD symptom. | N/A | NCT02375724 |
| Boehringer Ingelheim | Investigate the Impact of Early Treatment Initiation With Tiotropium in Patients Recovering From Hospitalization for an Acute COPD Exacerbation 1 | Aug-12 | May-14 | * Change From Baseline of Trough FEV1 at 12 Weeks on Study Drug [Time Frame: Baseline and 12 weeks]
* Percentage of Patients With Next Adverse Clinical Outcome Event From the Two Twin Trials, Present 205.477 (NCT01663987) and 205.478 (NCT01662986) [Time Frame: From first drug administration to the last timepoint with information of clinical adverse outcome available, up to 2 years]
 | * Time to Event: Time to Recovery (EXACT-PRO) From the Two Twin Trials, Present 205.477 (NCT01663987) and 205.478 (NCT01662986) [Time Frame: From first drug administration to the last timepoint with information of clinical adverse outcome available, up to 2 years]
 | Up to 2 years | A randomized, placebo-controlled, double-blind, parallel group, multi center study to assess the safety and efficacy of tiotropium bromide (18 µg) delivered via the HandiHaler® in Chronic Obstructive Pulmonary Disease (COPD) subjects recovering from hospitalization for an acute exacerbation (Hospital Discharge 1) | N/A | NCT01663987 |
| Boehringer Ingelheim Pharmaceuticals | Investigate the Impact of Early Treatment Initiation With Tiotropium in Patients Recovering From Hospitalization for an Acute COPD Exacerbation 1 | Aug-12 | Apr-14 | * Primary endpoint is trough FEV1 (forced expiratory volume in 1 second) at 12 weeks on study medication. Trough FEV1 is defined as FEV1 measurement prior to the next dosing of study drug and approximately 24 hours after the last inhalation of drug. [Time Frame: 12 weeks]
* Primary endpoint for combined data from trials 205.477 and 205.478 will be time to the first adverse clinical outcome event defined as the combined endpoint of COPD exacerbations per BI definition, all-cause re-hospitalization, or all-cause mortality. [Time Frame: Up to 2 years]
 | * Time to event: Time to recovery (EXACT-PRO) [Time Frame: Up to 2 years]
 | Up to 2 years | A randomized, placebo-controlled, double-blind, parallel group, multi-center study to assess the safety and efficacy of tiotropium bromide (18 µg) delivered via the HandiHaler® in Chronic Obstructive Pulmonary Disease (COPD) subjects recovering from hospitalization for an acute exacerbation (Hospital Discharge Study 2) | N/A | NCT01662986 |
| Chiesi Farmaceutici S.p.A. | 2-arm Parallel Group Study of Fixed Combination of CHF 5993 vs Ultibro® in COPD Patients (TRIBUTE) | May-15 | May-17 | * Moderate and severe COPD exacerbation rate over 52 weeks of treatment [ Time Frame: 1 year ] [ Designated as safety issue: Yes ]
* Exacerbations will be evaluated at each study visit and collected using EXACT-PRO filled-in by patient every day throughout the study
 | * Time to first moderate to severe COPD exacerbation [ Time Frame: 1 year ] [ Designated as safety issue: Yes ]
* Rate of severe COPD exacerbation over 52 weeks of treatment [ Time Frame: 1 year ] [ Designated as safety issue: Yes ]
* Rate of moderate COPD exacerbation over 52 weeks of treatment [ Time Frame: 1 year ] [ Designated as safety issue: Yes ]
* Change from Baseline at each visit and over the entire treatment period in pre-dose morning FEV1 [ Time Frame: 1 year ] [ Designated as safety issue: No ]
 | 12 months | The aim of the present study is to evaluate the superiority of the fixed triple therapy with BDP/FF/GB at a daily dose of 400/24/50 mcg respectively with that of Ultibro® Breezhaler® (DPI), fixed combination of indacaterol 85 mcg and of glycopyrronium 43 mcg in COPD patients. | N/A | NCT02579850 |
| Dong Wha Pharmaceutical Co. Ltd. | Clinical Trials to Evaluate Efficacy and Safety of Zabofloxacin Tablet 400mg and Moxifloxacin Tablet 400mg After Multi-dose Oral Administration in Patients With Acute Bacterial Exacerbation of Chronic Obstructive Pulmonary Disease. | Aug-12 | Jan-14 | * Clinical Response in the Clinical Populations [Time Frame: 10days]
* Clinical response corresponding clinical cure at Test of Cure visit. Based on the clinical outcomes, the results of assessment were classified into Clinical Cure, Clinical Failure, Relapse and Indeterminate.
 | * Change in EXACT-PRO Score [Time Frame: 10 days]
 | 10 days | A Phase 3, Multicenter, Double Blind, Active Controlled, Randomized Study to Evaluate the Efficacy and Safety of Zabofloxacin for Patients with acute bacterial exacerbation of Chronic obstructive pulmonary disease. The purpose of this study is to Evaluate the Efficacy and Safety Profiles of oral multiple dose of Zabofloxacin Tablet 400 mg. | N/A | NCT01658020 |
| GlaxoSmithKline | A Two Part, Phase IIa, Randomized, Placebo-controlled Study To Investigate The Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Clinical Efficacy of Oral Danirixin (GSK1325756) in Symptomatic COPD Subjects With Mild to Moderate Airflow Limitation at Risk for Exacerbations | Feb-14 | Jan-16 | * Monthly weighted means of Exacerbations of Chronic Pulmonary Disease- Respiratory Symptoms (EXACT-RS)-Part B [Time Frame: Upto Day 392]
 | * Exacerbations of EXACT-PRO event- Part B [Time Frame: Upto Day 392]
* EXACT-PRO total score weighted means- Part B [Time Frame: Upto Day 392]
* Time to first EXACT-PRO event- Part B [Time Frame: Upto Day 392]
* EXACT-PRO events severity and duration- Part B [Time Frame: Upto Day 392]
* Monthly weighted mean EXACT-RS domain scores - Part B [Time Frame: Upto Day 392]
 | Part B: Upto Day 392  | The aim of this First Time in Patient study is to obtain initial information on the safety, tolerability, pharmacokinetics, pharmacodynamics and clinical efficacy of repeat daily administration of danirixin in subjects with symptomatic chronic obstructive pulmonary disease (COPD) having mild to moderate airflow limitation and are at high risk for future COPD exacerbations.The study will be conducted in two parts. Part A will be a two week open label, single arm study in patients with COPD to obtain pharmacokinetic data and safety information of repeat dosing of danirixin in the population of interest. Approximately 10 subjects will be enrolled in Part A of the study. Progression to and dose selection for Part B will occur following review of the data collected in Part A. Part B will be a 52-week, randomized, double-blind (sponsor unblind), placebo-controlled on top of standard of care, parallel group study. Part B will evaluate several clinical efficacy assessments related to exacerbations and respiratory symptoms. Approximately 100 subjects will be enrolled with a target of 80 subjects completing 52 weeks of danirixin administration. | N/A | NCT02130193 |
| GlaxoSmithKline | 200699: A Clinical Study to Evaluate Four Doses of Umeclidinium Bromide in Combination With Fluticasone Furoate in COPD Subjects With an Asthmatic Component | Jul-14 | Jun-15 | * Change from baseline in clinic trough (pre-dose) FEV1 at the end of treatment Phase A [Time Frame: Day 1 (Baseline) and Day 29]
* FEV1 value obtained 24 hours after morning dosing on Day 28.
 | * Mean change from baseline in exacerbations of chronic pulmonary disease tool-respiratory symptoms (EXACT-RS) score at the end of Treatment Phase A [Time Frame: Day 1 (Baseline) and Day 29]
 | Baseline & Day 29 | The purpose of this study is to evaluate the dose-response of 4 doses of umeclidinium bromide in combination with fluticasone furoate compared with fluticasone furoate monotherapy in chronic obstructive pulmonary disease participants with an asthmatic component. The fluticasone furoate/umeclidinium bromide treatments will also be compared to the once-daily inhaled corticosteroid/long-acting beta agonist combination fluticasone furoate/vilanterol. | N/A | NCT02164539 |
| GlaxoSmithKline | Contribution of Infectious Pathogens to Acute Respiratory Illness in Adults and Elderly | Jun-11 | Jun-14 | * Occurrence of all-cause AECOPD [Time Frame: During the entire study period (2 years)]
* Occurrence of AECOPD having sputum containing bacterial pathogens, as detected by culture [Time Frame: During the entire study period (2 years)]
 | * Exacerbations of Chronic Pulmonary Disease Tool (EXACT) score in all-cause AECOPD and in stable COPD [Time Frame: During the entire study period (2 years)]
 | 2 years - entire study period | The aim of this study is to generate epidemiological data to further explore determinants of Chronic Obstructive Pulmonary Disease (COPD) and the contribution of bacterial and viral pathogens to Acute Exacerbation of COPD (AECOPD) episodes. | N/A | NCT01360398 |
| GlaxoSmithKline | Chronic Obstructive Pulmonary Disease (COPD) Post-hospitalization Study | Apr-10 | Apr-12 | * Number of Par. With Chronic Obstructive Pulmonary Disease (COPD) EXs Requiring Hospitalization That Occurred >21 Days Post-discharge/Physician's Office Visit for a COPD EX Requiring Treatment With Oral Corticosteroids (OCSs) or OCSs and Antibiotics (ABs) [Time Frame: From 21 days post-discharge (hospital or emergency room) or physician's office visit, up to 29 weeks]
* Number of Participants With the Indicated Number of EXs of COPD Requiring Hospitalization That Occurred More Than 21 Days Post-discharge or Physician's Office Visit for an EX of COPD Requiring Treatment With OCSs or OCSs and ABs [Time Frame: From 21 days post-discharge (hospital or emergency room) or physician's office visit, up to 29 weeks]
* Number of EXs of COPD Requiring Hospitalization That Occurred More Than 21 Days Post-discharge or Physician's Office Visit for an EX of COPD Requiring Treatment With OCSs or OCSs and ABs [Time Frame: From 21 days post-discharge (hospital or emergency room) or physician's office visit, up to 29 weeks]
 | * Number of Participants With an EX of COPD Requiring Treatment With OCSs, Treatment With ABs, and/or Hospitalization [Time Frame: From Baseline up to Week 29, approximately]
* Number of EXs of COPD Requiring Treatment With OCSs, Treatment With ABs, and/or Hospitalization (Alone and in Combination) [Time Frame: From Baseline up to Week 29, approximately]
 | Reference use of EXACT in trial data and in publication, but no information on administration | This trial is a randomized, double-blind, parallel-group, multicenter study to be conducted in the United States. The purpose of the study is to evaluate the rate of exacerbations of chronic obstructive pulmonary disease (COPD) following hospital discharge for an acute exacerbation of COPD, in patients receiving either fluticasone propionate/salmeterol combination product 250/50mcg BID or salmeterol 50mcg BID via DISKUS™ over 29 weeks. The study population will include patients hospitalized for an acute exacerbation of COPD. The target enrolment is 720 subjects at 80 study centers. The primary endpoint is the rate of exacerbation requiring hospitalization that occur more than 21 days post-discharge, emergency room visit or physician's office visit for an exacerbation of COPD requiring treatment with oral corticosteroids or oral corticosteroids and antibiotics. The secondary endpoint is the rate of COPD exacerbation requiring treatment with oral corticosteroids, antibiotics, and/or hospitalization (alone and in combination). Related efficacy endpoints include, time to first exacerbation of COPD requiring treatment with oral corticosteroids, antibiotics, and/or hospitalization (alone and in combination), pre-dose AM FEV1, the probability of premature withdrawal of subject from the study, and supplemental albuterol use, change in biomarkers of inflammation, including, surfactant protein D (SP-D), clara cell secretory protein 16 (CC-16) and high sensitivity C-reactive protein (hs-CRP). Health outcome assessments include domain scores evaluation for fatigue, dyspnea, emotional function and mastery, measured with the Chronic Respiratory Disease Questionnaire self-administered standardized format (CRQ-SAS); and symptoms (congestion, cough, phlegm, mucus, chest discomfort, shortness of breath and sleep disturbance), assessed by the EXAcerbations of Chronic pulmonary disease Tool (EXACT). Albuterol will be supplied to study subjects for use as-needed throughout the study. Safety will be assessed by monitoring of adverse events. | Ohar JA, Crater GD, Emmett A, Ferro TJ, Morris AN, Raphiou I, Sriram PS, Dransfield MT. Fluticasone propionate/salmeterol 250/50 μg versus salmeterol 50 μg after chronic obstructive pulmonary disease exacerbation. Respir Res. 2014 Sep 24;15:105. doi: 10.1186/s12931-014-0105-2.Open Access Link: <http://respiratory-research.com/content/15/1/105>  | NCT01110200 |
| GlaxoSmithKline | A Comparison Study Between the Fixed Dose Triple Combination of Fluticasone Furoate/ Umeclidinium/ Vilanterol Trifenatate (FF/UMEC/VI) With Budesonide/Formoterol in Subjects With Chronic Obstructive Pulmonary Disease (COPD) | Jan-15 | Mar-16 | * Change from baseline in trough Forced Expiratory Volume (FEV)1 at Week 24 [Time Frame: Baseline (Day 1) and Week 24]
* Change from baseline St George's Respiratory Questionnaire-Chronic Obstructive Pulmonary Disease (SGRQ-C) Total Score at Week 24. [Time Frame: Baseline (Day 1) and Week 24]
 | * Respiratory symptoms using Exacerbations of Chronic Pulmonary Disease Tool (EXACT) Respiratory Symptoms (RS) PRO and its subscales (breathlessness, cough and sputum and chest symptoms) [Time Frame: Up to Week 52]
 |  Up to Week 52 | This is a phase IIIa, randomised, double-blind, double-dummy, parallel group multicenter study evaluating once daily FF/UMEC/VI (100 microgram [mcg]/62.5 mcg/25 mcg) inhalation powder versus twice daily budesonide/formoterol (400 mcg/12 mcg). The primary purpose of this study is to demonstrate improvements in lung function and health status for subjects treated with FF/UMEC/VI compared with budesonide/formoterol for 24 weeks. Once-daily 'closed' triple therapy of a Inhaled Corticosteroid/ Long-acting Muscarinic Receptor Antagonists/ Long Acting Beta-Agonist (ICS/LAMA/LABA) combination FF/UMEC/VI (100 mcg/62.5 mcg/25 mcg) in a single device is being developed with the aim of providing a new treatment option for the management of advanced (GOLD Group D) COPD which will reduce the exacerbation frequency, allow for a reduced burden of polypharmacy, convenience, and increase the potential for improvement in lung function, Health Related Quality of Life (HRQoL) and symptom control over established dual/monotherapies.Subjects meeting all inclusion/exclusion criteria and who have successfully completed all protocol procedures at the Screening Visit will enter the two-week run-in period. Following the run-in period, eligible subjects will be randomised (1:1) to one of the following double-blind treatment groups: FF/UMEC/VI 100 mcg/62.5 mcg/25 mcg via the ELLIPTA™ dry powder inhaler (DPI) once daily in the morning and placebo via reservoir inhaler twice daily OR Budesonide/formoterol 400 mcg/12 mcg via reservoir inhaler twice daily and placebo via the ELLIPTA DPI once daily in the morning.The target enrollment is 1800 randomised subjects at approximately 200 study centers globally. The total duration of subject participation will be approximately 27 weeks, consisting of a 2-week run-in period, 24-week treatment period and a 1-week follow-up period. Subjects will run-in on their existing COPD medications for 2 weeks and in addition will be provided with short acting albuterol/salbutamol to be used on an as-needed basis (rescue medication) throughout the study. Subjects will discontinue all existing COPD medications during the randomised treatment period but may continue their study supplied rescue albuterol/salbutamol. A sub-set of approximately 400 subjects will remain on blinded study treatment for up to a total of 52 weeks to provide additional long term safety data.ELLIPTA and NUBULES are a trade marks of the GlaxoSmithKline Group of Companies. Other company or product names mentioned herein may be the property of their respective owners | N/A | NCT02345161 |
| Hoffmann-La Roche | A Study to Evaluate Safety and Efficacy of Lebrikizumab in Patients With Chronic Obstructive Pulmonary Disease (COPD) With History of Exacerbations | Aug-15 | Jul-17 | * Absolute change from baseline in pre-bronchodilator forced expiratory volume (FEV-1) as measured in liters [Time Frame: 24 weeks]
 | * Change in COPD symptoms as measured by the overall score on the EXAcerbations of Chronic Obstructive Pulmonary Disease Tool (EXACT) [Time Frame: Up to week 24]
* Change in cough and sputum as measured by EXACT [Time Frame: Up to 24 weeks]
 | 24 Weeks | Phase II, randomized, double-blind, placebo-controlled, parallel-group clinical trial of lebrikizumab in patients with Chronic Obstructive Pulmonary Disease (COPD) and a history of exacerbations who are treated with inhaled corticosteroid (ICS) and at least one long-acting bronchodilator inhaler medication. This study will be conducted to assess the safety, efficacy, and patient-reported outcome (PRO) measures. | N/A | NCT02546700 |
| Janssen Research & Development, LLC | A Study for Disease Profiling of Asthma and Chronic Obstructive Pulmonary Disease | Jul-10 | Jul-14 | * EXACT-Respiratory Symptoms (E-RS) [Time Frame:aseline (for Part 2: participants with chronic obstructive pulmonary disease)]
 |  | Baseline (for Part 2: participants with chronic obstructive pulmonary disease) | The purpose of this study is to characterize the clinical, physiologic, and molecular profiles of healthy participants, participants with mild, moderate, and severe asthma; and participants with moderate to severe Chronic Obstructive Pulmonary Disease (COPD). | N/A | NCT01274507 |
| Janssen Research & Development, LLC | A Study to Evaluate the Effectiveness and Safety of CNTO6785 in Patients With Moderate to Severe Chronic Obstructive Pulmonary Disease | Nov-13 | Nov-15 | * Change from baseline in prebronchodilator (before taking an inhaled bronchodilator) Forced Expiratory Volume in 1 second (FEV1) at Week 16 [Time Frame: Baseline (Week 0), Week 16]
 | * Change from baseline in EXAcerbations of Chronic Pulmonary Disease Tool-Respiratory Symptoms™ (E-RS™) at Week 16 [Time Frame: Baseline (Week 0), Week 16]
 | Baseline (Week 0), Week 16] | This is a multi-center, randomized (study medication is assigned by chance), placebo-controlled (effect of the study medication will be compared with the effect of placebo [inactive substance]), double-blind (neither physician nor participant knows the treatment that the participant receives), parallel-group study (each group of participants will be treated at the same time). This study consists of 3 phases: a screening phase (within 3 weeks prior to the start of study medication), a treatment phase (12 weeks), and a follow-up phase (12 weeks after the last administration of study medication). Approximately 170 participants will be enrolled in this study to receive CNTO6785 or placebo in 1:1 ratio. Safety will be evaluated by the assessment of adverse events, vital signs, 12-lead electrocardiogram, physical examination, early detection of active tuberculosis, and clinical laboratory tests which will be monitored throughout the study. The total duration of study participation for a participant will be 30 weeks. | N/A | NCT01966549 |
| Janssen Research & Development, LLC | An Effectiveness and Safety Study of Inhaled JNJ 49095397 (RV568) in Patients With Moderate to Severe Chronic Obstructive Pulmonary Disease | Sep-13 | Aug-14 | * Change From Baseline in Prebronchodilator (preBD, before taking an inhaled bronchodilator) Percent-predicted Forced Expiratory Volume in one Second (FEV1) at Week 12 [Time Frame: Baseline (Week 0) to Week 12]
 | * Change From Baseline in EXAcerbations of Chronic Pulmonary Disease Tool-Respiratory Symptoms (E-RS) at Week 12 [Time Frame: Baseline (Week 0) to Week 12]
 | 12 weeks | This is a randomized (the study medication is assigned by chance), double-blind (neither physician nor participant knows the treatment that the participant receives), placebo-controlled (an inactive substance that is compared with a medication to test whether the medication has a real effect in a clinical study), multicenter, parallel-group (each group of participants will be treated at the same time) study. Approximately 200 participants will be randomly assigned to JNJ 49095397 or placebo in the ratio 1:1. The study consists of 3 phases: screening (3 weeks), double-blind treatment (12 weeks), and follow up (4 weeks). Safety evaluations will include assessment of adverse events, vital signs, physical examination, electrocardiograms, and clinical laboratory tests which will be monitored throughout the study. The total duration of the study for each participant will be approximately 19 weeks. | N/A | NCT01867762 |
| Merck Sharp & Dohme Corp. | Long-Term Study of the Effects of Navarixin (SCH 527123, MK-7123) in Participants With Moderate to Severe COPD (MK-7123-019) | Oct-09 | Feb-15 | * Change From Baseline in Post-bronchodilator Forced Expiratory Volume in 1 Second (FEV1) (Period 1) [Time Frame: Baseline and Week 26]
* Percentage of Participants With an Adverse Event (AE) Related to a Blood Absolute Neutrophil Count (ANC) of Less Than 1.5x10^9 Cells/L [Time Frame: Up to 104 weeks] [Designated as safety issue: Yes]
 | * Total Exacerbations of Chronic Pulmonary Disease Tool-Patient-Recorded Outcome (EXACT-PRO) Questionnaire Score [Time Frame: At 26, 52 and 104 weeks]
 |  26, 52 and 104 weeks | Neutrophils are thought to play an important role in the pathophysiology of chronic obstructive pulmonary disease (COPD). Navarixin (SCH 527123, MK-7123) is an antagonist of the cysteine-X-cysteine chemokine receptor 2 (CXCR2) and is thought to reduce neutrophil migration to the diseased lung. It is theorized that reducing neutrophil migration to the diseased lung will improve a participant's symptoms and the natural history of the disease.The study will consist of a 2-week screening period followed by a 2-year (104-week) double-blind treatment period. The 2-year Treatment Period will be made up of two phases: a 26-week (6-month) dose range-finding phase with 3 active arms and 1 placebo arm (Period 1), followed by a 78-week (18-month) long-term safety and efficacy phase (Period 2). Participants participating in the original 6-month study (Period 1) may elect not to continue into the 18-month extension study (Period 2).Hypothesis: navarixin, 50 mg, or the highest remaining dose if the 50-mg dose is discontinued, is superior to placebo with respect to improving airflow. | Rennard SI, Dale DC, Donohue JF, Kanniess F, Magnussen H, Sutherland ER, Watz H, Lu S, Stryszak P, Rosenberg E, Staudinger H. CXCR2 Antagonist MK-7123-A Phase 2 Proof-of-Concept Trial for Chronic Obstructive Pulmonary Disease. Am J Respir Crit Care Med. 2015 Feb 19. [Epub ahead of print]PubMed Link: <http://www.ncbi.nlm.nih.gov/pubmed/25695403>  | NCT01006616 |
| Novartis Pharmaceuticals | Compare the Effect of a Remote Monitoring System Using the EXACT Tool to Reduce Hospitalizations Due to Chronic Obstructive Pulmonary Disease (COPD) Exacerbations. EXACT = Exacerbations of Chronic Pulmonary Disease Tool | Jun-12 | Jan-14 | * The number of hospitalizations and emergency room visits for management of COPD exacerbation(s) [Time Frame: 52 weeks]
* Comparison of the total number of hospitalizations and emergency room visits (combined) for management of Chronic Obstructive Pulmonary Disease (COPD) exacerbation(s) between the two arms
 | *
 | 52 weeks | The purpose of this pilot study is to evaluate a remote patient monitoring (RPM) system using a daily PRO tool (EXACT = Exacerbations of Chronic Pulmonary Disease Tool), in preventing hospitalization from Chronic Obstructive Pulmonary Disease (COPD) exacerbations in a COPD population at high risk of exacerbation, compared to those managed by usual care | N/A | NCT01744028 |
| Novartis Pharmaceuticals | A Randomized, Double-blind, 12-week Treatment, Parallel-group Study to Evaluate the Efficacy and Safety of QMF149 (150 µg/160 µg o.d.) Compared With Salmeterol Xinafoate/Fluticasone Propionate (50 µg/500 µg b.i.d.) in Patients With Chronic Obstructive Pulmonary Disease | Nov-12 | Sep-13 | * Mixed Model for Repeated Measures (MMRM): Between-treatment Comparisons for Trough FEV1 (L) on Day 85 [Time Frame: 12 weeks]
* Spirometry is conducted according to the global standard. Trough FEV1 is defined as the average of the 23 hour 10 minute and 23 hour 45 minute post dose FEV1 readings.
 | * Summary Statistics of COPD Exacerbations over 12 Weeks as Defined by Chronic Pulmonary Disease Tool (EXACT) [Time Frame: 12 weeks]
 | 12 weeks | To compare the efficacy, safety and pharmacokinetics of QMF149 delivered via Concept1 to salmeterol xinafoate/fluticasone propionate delivered via Accuhaler in adult patients with COPD | N/A | NCT01636076 |
| Novartis Pharmaceuticals | Safety & Efficacy of BCT197A2201 in Chronic Obstructive Pulmonary Disease (COPD) Patients Presenting With an Exacerbation | Mar-11 | May-13 | * The improvement in FEV1 over the first 5 days of treatment in Parts I and II, and improvement in FEV1 over the first 10 days in Parts III and IV, relative to placebo. Measure: FEV1 [Time Frame: 5 days and 10 days]
 | * Time to recovery using the EXACT-PRO 14 point patient reported outcome Measure: EXACT-PRO [Time Frame: 30 days]
 | 30 days | This study will assess preliminary parameters of safety and efficacy of a single dose of BCT197 in patients with a Chronic Obstructive Pulmonary Disease (COPD) exacerbation. | N/A | NCT01332097 |
| Pearl Therapeutics | A Randomized, Double-Blind, Parallel-Group, 24-Week, Chronic-Dosing, Multi-Center Study to Assess the Efficacy and Safety of PT010, PT003, and PT009 Compared With Symbicort® Turbuhaler®` | Jul-15 | Mar-17 | * Change from baseline in morning pre-dose trough forced expiratory volume in 1 second (FEV1) [Time Frame: 24 Weeks]
 | * The EXAcerbations of Chronic pulmonary disease Tool (EXACT) total score [Time Frame: 24 Weeks]
 | 24 Weeks | A Randomized, Double-Blind, Parallel-Group, 24-Week, Chronic-Dosing, Multi-Center Study to Assess the Efficacy and Safety of PT010, PT003, and PT009 Compared With Symbicort® Turbuhaler® as an Active Control in Subjects with Moderate to Very Severe Chronic Obstructive Pulmonary DiseaseThis study includes the following 3 sub-studies: 12-hour Pulmonary Function Test (PFT), Pharmacokinetic (PK) Profile, and Hypothalamic-pituitary-adrenal Axis. | N/A | NCT02497001 |
| Pfizer | Study To Evaluate The Efficacy And Safety Of PH-797804 For 12 Weeks In Adults With Moderate To Severe Chronic Obstructive Pulmonary Disease (COPD) On A Background Of Tiotropium Bromide | Apr-12 | Sep-13 | * Change from baseline in trough (pre-treatment and pre-bronchodilator) Forced Expiratory Volume1 at Week 12. [Time Frame: Baseline, week 12]
 | * Change from baseline in Chronic Obstructive Pulmonary Disease symptoms (EXACT-PRO Daily Diary) over 12 weeks treatment. [Time Frame: Baseline, week 12]
 | Baseline, Week 12 (12 weeks treatment) | PH-797804 is an oral anti-inflammatory drug that may reduce the inflammation that is associated with Chronic Obstructive Pulmonary Disease (COPD). PH-797804 will be dosed to patients with Chronic Obstructive Pulmonary Disease (COPD) to evaluate its potential safety and efficacy profile in Chronic Obstructive Pulmonary Disease (COPD) | N/A | NCT01543919 |
| St George's, University of London | Metformin in Chronic Obstructive Pulmonary Disease | Jan-11 | Mar-14 | * Capillary glucose concentration [Time Frame: During hospitalisation period] [Designated as safety issue: Yes]
* The mean capillary glucose concentration during hospitalisation period following study entry, as a measure of both efficacy and safety.
 | * Exacerbation of Chronic Pulmonary Disease Tool (EXACT) score [Time Frame: Days 5, 10 and 28]
 | Days 5, 10 and 28 (1-month trial) | The purpose of this study is to determine the effect of a tablet medication, called metformin, in flare-ups (exacerbations) of chronic obstructive pulmonary disease. The investigators believe that metformin may effectively control the blood sugar level during COPD exacerbations. This is important because there is evidence that a high blood sugar level during exacerbations may be linked with a worse prognosis. The investigators also think that metformin may have other potentially useful effects on inflammation, antioxidant levels, the effectiveness of steroid treatment, and recovery. | N/A | NCT01247870 |