ARNASA

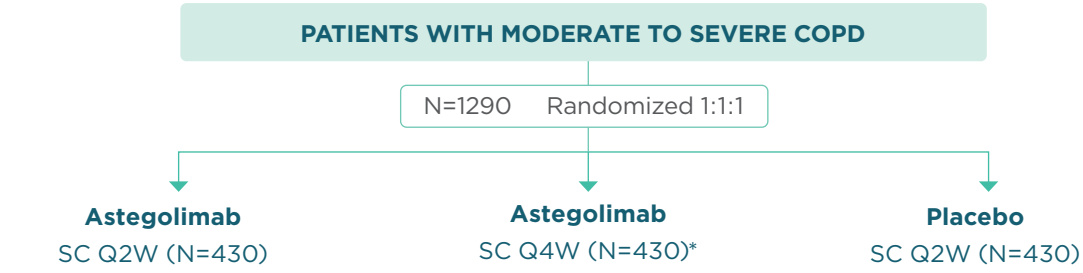
A STUDY TO EVALUATE ASTEGOLIMAB IN PARTICIPANTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

ARNASA (NCT05595642) This Phase 3 study will evaluate the efficacy and safety of astegolimab compared with placebo in participants with chronic obstructive pulmonary disease (COPD) who are former or current smokers and have a history of frequent exacerbations.

Trial Design: A randomized, double-blind, placebo-controlled study of astegolimab (2 dosing regimens) in a broad COPD population.

NOW ENROLLING
CLINICAL TRIAL IN COPD

Contact	Reference Study ID Number: GB44332 www.forpatients.roche.com or 888-662-6728
ClinicalTrials.gov	www.clinicaltrials.gov/study/NCT05595642
Email Roche Global Trials	Reference Study ID Number: GB44332 global-roche-genentech-trials@gene.com
Connect with your MSL	www.gene.com/medical-professionals/medinfo/connect-with-your-msl



*To ensure that all study participants undergo the same visit schedule, participants randomized to the Q4W dosing arm will alternate between injections of astegolimab and placebo Q2W.

SC=subcutaneous administration; Q2W=once every 2 weeks; Q4W=once every 4 weeks.

INCLUSION:

- Moderate to severe COPD (FEV_1 ≥20% and <80% predicted, FEV_1/FVC <0.7; GOLD classification 2-4)
- ≥2 exacerbations within the last 12 months
- Exertional dyspnea (mMRC ≥2)
- Smoking ≥10 pack-years
- Age 40-80 years
- Optimized standard of care maintenance therapy

EXCLUSION:

- NYHA III/IV heart failure
- Palliative treatment
- Current diagnosis of asthma or other significant pulmonary disease
- Corticosteroid treatment (>10 mg/day prednisolone equivalent)
- O_2 therapy >4 L/min

FEV_1=forced expiratory volume in 1 second; FVC=forced vital capacity; mMRC=modified Medical Research Council; NYHA=New York Heart Association.

PRIMARY ENDPOINT:

- Annualized rate of moderate to severe COPD exacerbations
  - Moderate exacerbations—new or increased symptoms leading to steroids and/or antibiotics
  - Severe exacerbations—hospitalization or death

OTHER SECONDARY AND EXPLORATORY ENDPOINTS:

- Safety
- Pharmacokinetic profiles
- Anti-drug antibodies
- Biomarkers

SECONDARY ENDPOINTS:

- Time to first exacerbation
- Change from baseline at 52 weeks in:
  - SGRQ-C (St. George's Respiratory Questionnaire, a validated COPD questionnaire)
  - Post-bronchodilator FEV_1
  - E-RS (Evaluating Respiratory Symptoms in COPD, part of the EXACT questionnaire)
- Annualized rate of severe COPD exacerbations (eg, hospitalization or death)

Product under investigation has not been approved for use outside the clinical trial setting. This information is presented only for the purpose of providing an overview of the clinical trials and should not be construed as a recommendation for use of any product for unapproved purposes.

For more information on trial inclusion and exclusion criteria, visit www.clinicaltrials.gov. Consistent with clinicaltrials.gov as of August 2023.

To see full clinical trial details, scan QR code or visit **www.clinicaltrials.gov/study/NCT05595642**

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ALIENTO

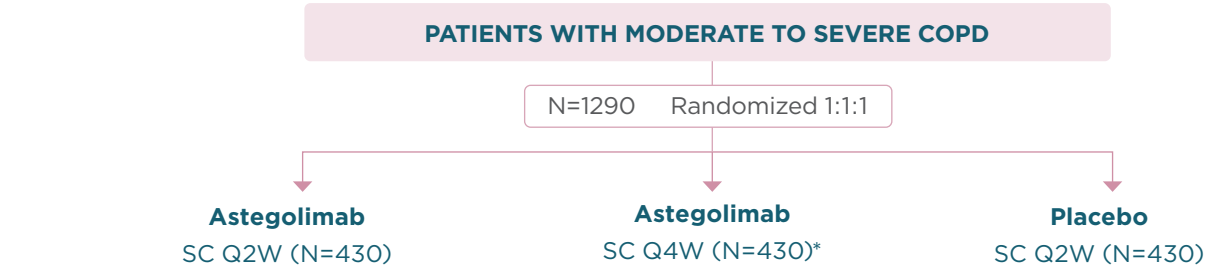
A STUDY TO EVALUATE ASTEGOLIMAB IN PARTICIPANTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

ALIENTO (NCT05037929) This Phase 2b study will evaluate the efficacy, safety, and pharmacokinetics of astegolimab in combination with standard of care chronic obstructive pulmonary disease (COPD) maintenance therapy in patients with COPD who are former or current smokers and have a history of frequent exacerbations.

Trial Design: A randomized, double-blind, placebo-controlled study of astegolimab (2 dosing regimens) in a broad COPD population.

NOW ENROLLING
CLINICAL TRIAL IN COPD

Contact	Reference Study ID Number: GB43311 www.forpatients.roche.com or 888-662-6728
ClinicalTrials.gov	www.clinicaltrials.gov/study/NCT05037929
Email Roche Global Trials	Reference Study ID Number: GB43311 global-roche-genentech-trials@gene.com
Connect with your MSL	www.gene.com/medical-professionals/medinfo/connect-with-your-msl



*To ensure that all study participants undergo the same visit schedule, participants randomized to the Q4W dosing arm will alternate between injections of astegolimab and placebo Q2W.

SC=subcutaneous administration; Q2W=once every 2 weeks; Q4W=once every 4 weeks.

INCLUSION:

- Moderate to severe COPD (FEV_1 ≥20% and <80% of predicted normal value at screening)
- ≥2 exacerbations within the last 12 months
- Exertional dyspnea (mMRC ≥2)
- Smoking ≥10 pack-years
- Age 40-90 years
- Optimized standard of care maintenance therapy

EXCLUSION:

- NYHA III/IV heart failure
- Palliative treatment
- Current diagnosis of asthma or other significant pulmonary disease
- Corticosteroid treatment (>10 mg/day prednisolone equivalent)
- O_2 therapy >4 L/min

FEV_1=forced expiratory volume in 1 second; mMRC=modified Medical Research Council; NYHA=New York Heart Association.

PRIMARY ENDPOINT:

- Annualized rate of moderate to severe COPD exacerbations
  - Moderate exacerbations—new or increased symptoms leading to steroids and/or antibiotics
  - Severe exacerbations—hospitalization or death

OTHER SECONDARY AND EXPLORATORY ENDPOINTS:

- Safety
- Pharmacokinetic profiles
- Anti-drug antibodies
- Biomarkers

SECONDARY ENDPOINTS:

- Time to first exacerbation
- Change from baseline at 52 weeks in:
  - Quality of Life assessed through St. George's Respiratory Questionnaire-COPD (SGRQ-C)
  - Post-bronchodilator FEV_1
  - Evaluating Respiratory Symptoms in COPD
- Proportion of SGRQ-C responders
- Annualized rate of severe COPD exacerbations
- Change in five-repetition sit-to-stand time

Product under investigation has not been approved for use outside the clinical trial setting. This information is presented only for the purpose of providing an overview of the clinical trials and should not be construed as a recommendation for use of any product for unapproved purposes.

For more information on trial inclusion and exclusion criteria, visit www.clinicaltrials.gov. Consistent with clinicaltrials.gov as of September 2023.

To see full clinical trial details, scan QR code or visit
www.clinicaltrials.gov/study/NCT05037929

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