Navigator

The Navigator Study is recruiting!

A Phase 2, randomized, double-blind, placebo-controlled, 52-week study to assess efficacy, safety, tolerability, and pharmacokinetics of 2 doses of EXPD-101 in participants with chronic obstructive pulmonary disease (COPD) with frequent exacerbations **and** chronic bronchitis. The study will include about 600 patients globally.

COPD is the third leading cause of death worldwide.[1] Acute COPD exacerbations are common, carrying significant health risks.[2, 3]

Most current treatments aim to reduce the frequency and severity of acute exacerbations. These treatments do not work for 30–40% of COPD patients.[3] Additionally, add-on treatments have meaningful safety concerns.[4]

Participation (up to 60 weeks) involves:

- Up to 11 study visits
- Study treatment period for 52 weeks
- Randomization 1:1:1 to take orally once a day:
  - EXPD-101 Dose 1
  - EXPD-101 Dose 2
  - Placebo
- Regular assessments: Blood tests, spirometry, computed tomography (CT) scan, skin and dental checks, questionnaires, and daily eDiary
- Sub-studies: Sputum for inflammatory markers, chest CT for mucus plugging, dental safety, pharmacogenomics (PGx), and optional pharmacokinetics (PK)

Expedition THERAPEUTICS

Inclusion criteria:

✔ ≥40 and ≤85 years of age

✔ Diagnosed with COPD (≥1 year) **and** chronic bronchitis (≥3 months in past year)

✔ ≥2 moderate or ≥1 severe COPD exacerbations within 12 months prior to screening

✔ Current or ex-tobacco smoker (≥10 pack-years)

✔ Stable on maintenance therapy with dual or triple inhaled therapy for ≥3 months

Exclusion criteria:

✘ COPD exacerbation within the 4 weeks prior to randomization

✘ Clinically important pulmonary disease other than COPD

✘ Significant renal impairment (eGFR <60 mL/min/1.73 m^2) or hepatic impairment (ALT/AST >2× ULN or bilirubin >1.5× ULN)

✘ History or active conditions associated with non-hereditary palmoplantar keratosis

✘ Active periodontal disease

There are additional requirements for participating.

Please refer any patients (with their permission) who may be eligible for the Navigator Study.

Diversity among our clinical trial participants is important to assess risk/benefit ratios for different groups. Please consider referring patients who reflect the COPD population.

Any questions, or to discuss a patient referral, please contact us.

Toni Tedesco
Clinical Trial Associate | Expedition Therapeutics
toni.tedesco@expeditiontx.com

The Navigator Study Team

References

1. Global Initiative for Chronic Obstructive Lung Disease (GOLD). 2024; Available at: https://goldcopd.org/2025-gold-report/
2. Hopkinson NS. *Lancet Resp Med*. 2025;13;3:193-194
3. Christenson SA, et al. *Lancet*. 2022;399(10342):2227-2242
4. Chong J, et al. *Coch Database Sys Rev*. 2017;9;CD002309