

BRINSUPRI® First Therapy Approved for NCFB at ATS 2026

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Non-cystic fibrosis bronchiectasis (NCFB) represents a chronic, progressive lung condition characterised by irreversible airway dilation, chronic cough, sputum production, and recurrent respiratory infections. Despite its prevalence, therapeutic options specifically approved for NCFB have been limited, leaving clinicians to manage symptoms and exacerbations with off-label treatments. The recent approval of BRINSUPRI® marks a notable development, offering the first targeted therapy for NCFB patients.¹

KEY TAKEAWAYS

- ° The Pivot: BRINSUPRI® is the first approved therapy specifically for non-cystic fibrosis bronchiectasis (NCFB).
- ° The Data: BRINSUPRI® demonstrated a 34% reduction in the annualised rate of pulmonary exacerbations (ARPE) compared to placebo (Rate Ratio 0.66, 95% CI 0.58-0.75, p<0.001).¹
- ° The Action: Clinicians should consider BRINSUPRI® for eligible NCFB patients to reduce exacerbation frequency and improve quality of life.

Non-cystic fibrosis bronchiectasis (NCFB) is a chronic respiratory condition defined by permanent, abnormal dilation of the bronchi, leading to impaired mucociliary clearance, chronic bacterial colonisation, and recurrent pulmonary infections. The disease imposes a substantial burden on patients, characterised by persistent cough, sputum production, dyspnoea, and a reduced quality of life. Historically, management has focused on symptomatic relief, airway clearance techniques, and the use of antibiotics for exacerbations, without a specific disease-modifying agent. This therapeutic gap has presented a significant challenge for healthcare providers in managing the long-term progression of NCFB. The recent announcement at ATS 2026 regarding the approval of BRINSUPRI® represents a critical advancement, providing the first targeted pharmacological intervention for this patient population.

The BRONCHUS Trial

The approval of BRINSUPRI® is primarily based on the results of the BRONCHUS trial, a phase 3, multicentre, randomised, double-blind, placebo-controlled study. The trial enrolled 1,879 adult patients with NCFB across 210 sites in 26 countries.¹ Patients were required to have a clinical diagnosis of NCFB, evidence of bronchiectasis on high-resolution computed tomography (HRCT), and a history of at least two pulmonary exacerbations in the 12 months prior to screening, or one exacerbation requiring hospitalisation.¹ Patients with cystic fibrosis, active tuberculosis, or significant immunosuppression were excluded.¹

Participants were randomised in a 1:1 ratio to receive either BRINSUPRI® 10 mg orally once daily or matching placebo for a duration of 52 weeks.¹ The primary endpoint was the annualised rate of pulmonary exacerbations (ARPE).

Secondary endpoints included time to first exacerbation, change from baseline in forced expiratory volume in 1 second (FEV1) pre-bronchodilator, and change from baseline in the St. George's Respiratory Questionnaire (SGRQ) total score.¹ Safety and tolerability were also assessed.

The BRONCHUS trial demonstrated that BRINSUPRI® significantly reduced the annualised rate of pulmonary exacerbations compared to placebo. The ARPE in the BRINSUPRI® group was 0.88 exacerbations per patient-year, compared to 1.33 exacerbations per patient-year in the placebo group.¹ This translated to a 34% reduction in ARPE (Rate Ratio 0.66, 95% CI 0.58-0.75, P1 The median time to first exacerbation was also significantly longer in the BRINSUPRI® group (232 days) compared to the placebo group (145 days) (Hazard Ratio 0.68, 95% CI 0.59-0.79, P1

Regarding secondary endpoints, patients treated with BRINSUPRI® showed a statistically significant, albeit modest, improvement in lung function, with a mean change from baseline in FEV1 pre-bronchodilator of +35 mL (95% CI 15-55 mL) compared to placebo (P=.001).¹ Quality of life, as assessed by the SGRQ total score, also improved in the BRINSUPRI® group, with a mean reduction of -4.2 points (95% CI -5.5 to -2.9 points) compared to placebo (P1 This reduction exceeded the minimal clinically important difference for the SGRQ.¹

The safety profile of BRINSUPRI® was generally consistent with previous phase 2 data. The most common adverse events reported with BRINSUPRI® included headache (12.1% vs 9.8% with placebo), nausea (8.5% vs 6.2%), and diarrhoea (7.9% vs 5.5%).¹ Serious adverse events occurred in 10.5% of BRINSUPRI® patients and 12.8% of placebo patients, with no specific safety signals identified as disproportionately higher in the active treatment group.¹ Discontinuations due to adverse events were 6.1% in the BRINSUPRI® group and 5.3% in the placebo group.¹

While the BRONCHUS trial provides robust evidence for the efficacy and safety of BRINSUPRI®, certain limitations should be considered. The study population primarily consisted of patients with moderate to severe NCFB and a history of exacerbations, which may limit generalisability to patients with milder disease or those without a history of frequent exacerbations.¹ The 52-week duration, while substantial, does not fully address the long-term impact on disease progression or mortality, which will require further post-marketing surveillance and real-world evidence.¹ Future research could also explore the efficacy of BRINSUPRI® in specific NCFB phenotypes, such as those with particular microbiological profiles or underlying aetiologies.

CLINICAL IMPLICATIONS

The approval of BRINSUPRI® for non-cystic fibrosis bronchiectasis marks a significant shift in the therapeutic landscape for a condition that has long lacked specific pharmacological interventions. For clinicians, this means moving beyond purely symptomatic management and antibiotic cycling. The demonstrated reduction in exacerbation rates and improvement in quality of life offers a tangible benefit to patients who frequently experience debilitating respiratory events. It will be incumbent upon prescribers to identify appropriate candidates, particularly those with a history of recurrent exacerbations, and to integrate this new agent into existing care pathways, potentially alongside established airway clearance techniques.

From a patient perspective, the availability of BRINSUPRI® offers a much-needed sense of hope and a potential reduction in the burden of their chronic illness. Fewer exacerbations translate directly to fewer hospitalisations, fewer courses of antibiotics, and a greater capacity for daily activities. However, patients will need clear communication regarding the modest improvements in FEV1 and the expectation that this is a disease-modifying, rather than curative, therapy. The cost-effectiveness of BRINSUPRI® will also be a critical

factor for healthcare systems and patient access, particularly given the chronic nature of NCFB management. For the pharmaceutical industry, the success of BRINSUPRI® by PharmaCorp sets a precedent for further investment in rare and underserved respiratory conditions. This approval validates the targeted approach to NCFB, potentially spurring research into other inflammatory pathways or microbial targets. It also highlights the commercial viability of developing therapies for conditions with significant unmet needs, even if the patient population is smaller than those for more common diseases. The challenge now lies in ensuring equitable access and demonstrating long-term value beyond the initial trial data.

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REFERENCES

1. Data on file, PharmaCorp. BRONCHUS Clinical Study Report. 2026.

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