AIRSUPRA® Reduces Asthma Exacerbations in ATS 2026 Data

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Managing asthma exacerbations remains a critical challenge, with current short-acting beta-agonist (SABA) monotherapy often failing to adequately control inflammation. New data presented at ATS 2026 for AIRSUPRA® (albuterol 90 mcg/budesonide 80 mcg) indicates a potential shift in rescue therapy, showing a reduction in severe asthma events compared to albuterol alone.

KEY TAKEAWAYS

- The Pivot: AIRSUPRA® offers a corticosteroid component in a rescue inhaler, moving beyond SABA monotherapy for acute symptoms.
- The Data: The trial demonstrated a 27% reduction (HR 0.73, 95% CI 0.65-0.82, pThe Action: Clinicians should consider AIRSUPRA® as an alternative to SABA monotherapy for patients requiring rescue medication, particularly those at risk of exacerbations.

Asthma management guidelines have long emphasized the role of inhaled corticosteroids (ICS) for maintenance therapy and SABAs for symptom relief. However, reliance on SABA monotherapy for rescue has been associated with increased risk of severe exacerbations and adverse outcomes.1 The rationale for combining a SABA with an ICS in a single rescue inhaler is to address both bronchoconstriction and underlying airway inflammation during acute episodes. This approach aims to provide immediate symptom relief while simultaneously delivering anti-inflammatory treatment, potentially mitigating the progression of an exacerbation.2

Asthma affects millions globally, with varying degrees of severity and significant healthcare burden due to exacerbations. These acute worsening episodes often require emergency department visits or hospitalization, impacting patient quality of life and increasing costs. Current guidelines recommend a stepwise approach to asthma management, with ICS as the cornerstone of controller therapy. Despite these recommendations, many patients continue to experience exacerbations, highlighting an unmet need for more effective rescue strategies. The development of anti-inflammatory reliever therapies (AIRT) represents a shift from traditional SABA-only rescue, aiming to provide both rapid bronchodilation and anti-inflammatory effects at the point of symptom onset. This strategy is particularly relevant given evidence that even mild asthma can be associated with airway inflammation.1

Study Design and Findings

The clinical program for AIRSUPRA® (albuterol 90 mcg/budesonide 80 mcg) included two pivotal Phase 3 trials, MANDALA and DENALI, which evaluated its efficacy and safety in patients with moderate to severe asthma.3 The MANDALA trial was a randomized, double-blind, parallel-group, event-driven study that compared AIRSUPRA® to albuterol monotherapy in patients aged 12 years and older who were receiving maintenance ICS with or without a

long-acting beta-agonist (LABA).3 The primary endpoint was the time to first severe asthma exacerbation.3
The MANDALA trial enrolled 3,132 patients across 295 sites globally.3 Patients were randomized to receive either AIRSUPRA® (albuterol 90 mcg/budesonide 80 mcg) or albuterol 90 mcg as needed for asthma symptoms.3 Over a median follow-up of 51 weeks, AIRSUPRA® demonstrated a statistically significant reduction in the risk of severe asthma exacerbations.3 Specifically, AIRSUPRA® reduced the risk of a severe asthma exacerbation by 27% compared to albuterol monotherapy (Hazard Ratio (HR) 0.73, 95% Confidence Interval (CI) 0.65-0.82, P).3 This reduction was consistent across various subgroups, including those on different background maintenance therapies.3 The trial's event-driven design ensured sufficient power to detect a difference in exacerbation rates, reflecting a real-world clinical outcome of high importance. The patient population included individuals with a history of asthma exacerbations in the year prior to enrollment, indicating a cohort at higher risk for future events.
The DENALI trial, a 12-week randomized, double-blind, parallel-group study, focused on lung function and safety.4 It enrolled 1,001 patients aged 12 years and older with mild to moderate asthma.4 DENALI showed that AIRSUPRA® provided superior improvement in forced expiratory volume in 1 second (FEV1) compared to albuterol alone and budesonide alone, 15 minutes post-dose.4 The mean change from baseline in FEV1 at 15 minutes post-dose was 0.28 L for AIRSUPRA® versus 0.13 L for albuterol alone (difference 0.15 L, 95% CI 0.11-0.19 L, P).4 The safety profile of AIRSUPRA® was generally consistent with its individual components, with common adverse events including headache and nasopharyngitis.3,4 No new safety signals were identified.3,4 The inclusion of a budesonide-alone arm in DENALI helped to isolate the contribution of the ICS component to the observed lung function improvements, demonstrating the synergistic effect of the combination.
These findings suggest that the inclusion of budesonide in a rescue inhaler provides a clinically meaningful benefit in reducing severe asthma exacerbations, beyond the bronchodilatory effects of albuterol alone. The data supports the concept of anti-inflammatory reliever therapy as a strategy to improve asthma control and reduce exacerbation frequency. The trials did not report on long-term effects beyond the study durations, nor did they directly compare AIRSUPRA® to other combination maintenance and reliever therapies (SMART regimens). Future research could explore these comparative effectiveness questions and the impact on overall healthcare resource utilization. While the studies demonstrated efficacy in diverse populations, the generalizability to patients with very severe or brittle asthma, or those with specific comorbidities, requires further investigation. The mechanism of action involves albuterol's rapid bronchodilation through beta-2 adrenergic receptor agonism and budesonide's anti-inflammatory effects via corticosteroid receptor binding, reducing airway hyperresponsiveness and inflammation. The co-delivery of these agents during symptomatic periods offers a targeted approach to managing acute asthma episodes.

CLINICAL IMPLICATIONS

The introduction of AIRSUPRA® into the asthma treatment landscape represents a pragmatic step forward, particularly for patients who rely heavily on SABA monotherapy for symptom relief. For too long, the disconnect between acute symptom management and underlying inflammation has contributed to preventable exacerbations. This dual-action rescue inhaler, by integrating an ICS, directly addresses that gap. It is a logical evolution, bringing the anti-inflammatory principle into the 'as-needed' context, which could simplify adherence for some patients who struggle with daily maintenance regimens.

> Clinicians should view AIRSUPRA® not just as another inhaler, but as a tool to re-educate patients on the nature of their disease. The message that 'every puff counts' towards both symptom relief and inflammation control is powerful. This could be particularly beneficial for patients with mild to moderate asthma who may not perceive a need for daily ICS, yet are still at risk of severe exacerbations. The challenge, however, will be integrating this into existing treatment algorithms, especially given the established role of single maintenance and reliever therapy (SMART) regimens with formoterol/budesonide. The evidence base for AIRSUPRA® is robust for its specific indication, but head-to-head comparisons with SMART would provide further clarity on its optimal placement in the treatment pathway.
> From an industry perspective, AstraZeneca has positioned AIRSUPRA® to capture a segment of the market currently dominated by SABA monotherapy. This move aligns with global guideline shifts, such as those from GINA, which increasingly advocate against SABA-only treatment. The commercial success will hinge on effective communication of its distinct benefits and its differentiation from existing combination therapies. Payers will likely scrutinize its cost-effectiveness against generic SABA and ICS options, requiring clear demonstrations of reduced exacerbation-related healthcare costs. Ultimately, this product offers a tangible improvement for patients, potentially reducing hospitalizations and improving quality of life, provided it is prescribed judiciously and with a clear understanding of its role.

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