Windward Bio Doses First Patients in Phase 2 SIRIUS COPD Study of Ultra Long-Acting Anti-TSLP Antibody WIN378

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- *COPD study initiation expands WIN378 development into a second major respiratory disease*
- *WIN378 is currently being evaluated in the Phase 2/3 POLARIS asthma study, with initial Phase 2 data expected in the second half of 2026*
- *WIN378 has the potential to be the first-to-market, ultra long-acting anti-TSLP antibody for asthma and COPD, with Phase 3 initiation in asthma planned for Q4 2026*

BASEL, Switzerland, June 09, 2026 (GLOBE NEWSWIRE) -- Windward Bio, a private, clinical-stage biotechnology company committed to improving outcomes for people living with serious immunological diseases, today announced that the first patients have been dosed in the Phase 2 SIRIUS study of WIN378, the company's ultra long-acting anti-TSLP monoclonal antibody, in patients with chronic obstructive pulmonary disease (COPD).

COPD is a progressive, irreversible lung disease and the third-leading cause of death worldwide. Driven by immune-mediated airway inflammation and persistent airflow obstruction, the disease makes even routine daily activities a struggle. Its defining feature is exacerbations — sudden, severe flare-ups that lead to emergency room visits, hospitalizations, and lasting declines in lung function. Despite currently available inhaled background therapies, more than 3 million patients with moderate-to-severe COPD remain at high risk of recurrent exacerbations, underscoring an urgent need for better treatment options.

"People living with COPD face significant morbidity and mortality from exacerbations, which take a devastating toll on lung function and quality of life. Today's biologic options are limited, and all require frequent dosing," said Omar Khwaja MD, PhD, Chief Medical Officer. "We believe WIN378 has the potential to deliver longer-lasting disease control with substantially less frequent dosing, an advance that could meaningfully address the unmet needs of people living with COPD."

SIRIUS is a global, Phase 2, randomized, double-blind, placebo-controlled, dose-finding study. It is designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of WIN378 in patients with moderate-to-severe COPD.

The initiation of SIRIUS marks an important expansion of Windward Bio's respiratory development program, which also includes the ongoing Phase 2/3 POLARIS study in asthma. The Phase 2 portion of POLARIS is fully enrolled, with initial data expected in the second half of 2026. Windward Bio expects to initiate the first Phase 3 study of WIN378 by the fourth quarter of 2026.

About WIN378

WIN378 is a next-generation, fully human monoclonal antibody that potently inhibits the TSLP ligand. This clinically validated target plays a key role in the development and progression of a wide array of immunological diseases, including asthma and COPD. WIN378 has been engineered to achieve half-life extension (HLE) and silenced effector function. It has been studied in a Phase 1 trial, which confirmed an extended half-life suitable for twice-yearly dosing, demonstrated a low rate of antidrug antibodies, and was safe and well tolerated up to the highest dose tested. WIN378 is administered subcutaneously. Windward Bio licensed the global rights (excluding Greater China and several Southeast and West Asian countries) for WIN378 from Kelun-Biotech (also known as SKB378) and Harbour BioMed (also known as HBM9378). WIN378 is currently being evaluated in the POLARIS Phase 2/3 asthma study with initial readouts expected in the second half of 2026. WIN378 is also being evaluated in the SIRIUS Phase 2 COPD study. The first Phase 3 study of WIN378 in asthma is expected to begin in the fourth quarter of 2026.

About Windward Bio

Windward Bio is a clinical-stage biotechnology company with deep discovery, development, and commercialization expertise committed to transforming the treatment of people living with serious immunological conditions. Its lead program is WIN378, a potential best-in-disease, ultra long-acting anti-TSLP monoclonal antibody currently in a Phase 2/3 trial for asthma and in a Phase 2 study for COPD. The pipeline also includes WIN027, a clinical-stage, long-acting anti-TSLPxIL-13 bispecific with broad therapeutic potential across immunological diseases, which is currently in Phase 1. The company is building a discovery pipeline of long-acting bispecific antibodies, targeting validated biology in respiratory and dermatological conditions.

Contacts

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