Windward Bio

Windward Bio announces positive Phase 2 results of WIN378 in asthma demonstrating significant improvements in lung function and airway inflammation with twice-yearly dosing, and initiates Phase 3

- *The POLARIS-1 study enrolled 147 patients with uncontrolled, moderate-to-severe asthma, and the interim analysis was conducted on the first 98 patients. The analysis demonstrated a half-life of up to 75 days, with clinical effects consistent with twice-yearly dosing.*
- *WIN378 produced significant and sustained effects on FEV_1 (placebo adjusted mean increase up to 256 mL, p=0.033), FeNO and blood eosinophils, key biomarkers that correlate with asthma exacerbations. These effects were rapid and sustained through Week 24 after a single dose of WIN378.*
- *WIN378 was well tolerated with favorable safety results — there were no treatment-related serious adverse events, withdrawals or discontinuations; adverse events were balanced between active arms and placebo, with low rates of injection site reactions and antidrug antibodies.*
- *The first Phase 3 study of WIN378 has been initiated evaluating two, twice-yearly doses. A second Phase 3 trial is planned to begin in the first half of 2027.*

BASEL, Switzerland, September 8, 2026 (GLOBE NEWSWIRE) — Windward Bio, a clinical-stage biotechnology company developing ultra-long-acting antibodies for patients with serious respiratory and dermatologic diseases, today announced positive interim results from the Phase 2 portion of the POLARIS-1 clinical trial evaluating twice-yearly dosing of WIN378 in asthma.

WIN378 is a novel fully human, ultra-long-acting monoclonal antibody with a unique binding mode to inhibit thymic stromal lymphopoietin (TSLP). It was engineered for improved potency, extended half-life and silenced effector function. It is the only known investigational drug that blocks TSLP signaling by binding to two different sites on TSLP, interfering with binding of TSLP to both of its co-receptors on the cell surface of epithelial cells.

POLARIS-1 is an operationally seamless, global Phase 2/3 study. The Phase 2 portion of the study is a 48-week, randomized, double-blind study evaluating three dose levels of WIN378 against placebo. It is designed to evaluate the pharmacokinetics, safety, immunogenicity and pharmacodynamic activity of WIN378 in patients with uncontrolled, moderate-to-severe asthma. The study also evaluates the effects of WIN378 on lung function and biomarkers of airway inflammation and informed dose selection for Phase 3 development. The Phase 2 portion of the study enrolled a total of 147 patients, exceeding the initial enrollment target of 120 patients, with the interim analysis conducted on the first 98 patients.

The interim analysis demonstrated the following at Week 24 after a single dose of WIN378:

- Dose-dependent, placebo-adjusted mean increases in FEV_1 of up to 256 mL (p=0.033).
- Dose-dependent reductions in FeNO of up to 24 ppb (or -43% change, p=0.006).
- Reductions in blood eosinophil count (EOS) of up to 200 cells/μL (or -51% change, p<0.0001).

- Near maximal effects seen as early as Week 2 and sustained through Week 24.

FEV_1 (forced expiratory volume in one second) is a key measure of lung function. FeNO (fractional exhaled nitric oxide) and EOS are key markers of inflammation that correlate with exacerbations.

WIN378 was well tolerated with favorable safety results, and there were no treatment-related serious adverse events, withdrawals or discontinuations observed as of the cut-off date. Adverse events were balanced between active arms and placebo. Less than 1% of participants experienced injection site reactions and 2% developed antidrug antibodies (ADAs), a measure of immunogenicity. ADAs had no impact on the pharmacology of WIN378.

The results of the interim analysis and population pharmacokinetic modeling support the potential of twice-yearly dosing of WIN378.

“These data reinforce our confidence in WIN378 and its potential to offer a meaningful new treatment option for people living with severe asthma,” said Luca Santarelli, MD, Founder, Chief Executive Officer, and Board Chair of Windward Bio. “We are excited by these results demonstrating favorable safety and clinically meaningful effects across key measures of lung function and inflammation in asthma with twice-yearly dosing of WIN378.”

Two twice-yearly doses have been selected for the Phase 3 portion of POLARIS-1 which is designed to evaluate the effect of WIN378 on annualized asthma exacerbation rate and other key efficacy measures in patients with severe asthma. The Phase 3 portion of the study has been initiated, and a second Phase 3 study, POLARIS-2, is planned to begin in the first half of 2027. Data from the Phase 2 portion of POLARIS-1 will be presented at an upcoming medical congress.

About POLARIS-1 Study

POLARIS-1 (NCT07120503) is an operationally seamless, global Phase 2/3 study of WIN378 in adults with uncontrolled asthma. The Phase 2 portion is a randomized, double-blind, study evaluating three dose levels of WIN378 administered subcutaneously against placebo, with primary objectives of characterizing pharmacokinetics, safety, immunogenicity and pharmacodynamic activity, as well as informing dose selection for Phase 3. The Phase 3 portion is evaluating two, twice-yearly doses of WIN378 against placebo, with a primary endpoint of annualized asthma exacerbation rate in patients with severe asthma.

About WIN378

WIN378 is a novel fully human, ultra-long-acting monoclonal antibody with a unique binding mode to inhibit thymic stromal lymphopoietin (TSLP). This clinically validated target plays a key role in the development and progression of a wide array of immunological diseases, including asthma, chronic obstructive pulmonary disease (COPD), chronic rhinosinusitis with nasal polyps, and eosinophilic esophagitis. WIN378 was engineered for improved potency, extended half-life and silenced effector function. It is the only known investigational drug that blocks TSLP signaling by binding to two different sites on TSLP, interfering with binding of TSLP to both of its co-receptors on the cell surface of epithelial cells. Phase 2 interim results support the potential of twice-yearly dosing. WIN378 produced significant, sustained and dose-dependent increases in FEV_1, a measure of lung function, together with significant and sustained reductions in FeNO and blood eosinophils — key markers that correlate with asthma exacerbations. WIN378 is being evaluated in the global Phase 2/3 POLARIS-1 study in asthma and the Phase 2 SIRIUS study in COPD, with a second pivotal Phase 3 asthma trial, POLARIS-2, planned to begin in the first half of 2027. 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).

About Windward Bio

Windward Bio is a clinical-stage biotechnology company with deep discovery, development, and commercial expertise, developing ultra-long-acting antibodies for patients with serious respiratory and dermatologic diseases, including asthma, COPD, and atopic dermatitis. The Company is advancing a pipeline of potentially differentiated biologics targeting clinically validated molecular pathways, with the goal of improving clinical outcomes while reducing treatment burden through less frequent dosing. Windward Bio's lead program is WIN378, a novel, fully human monoclonal antibody engineered for improved potency, extended half-life and silenced effector function, targeting TSLP. WIN378 is in clinical development for asthma and COPD. The Company's second program is WIN027, an ultra-long-acting, humanized bispecific antibody targeting TSLP and IL-13 in development for respiratory and dermatologic diseases. Windward Bio was founded in 2024 and is headquartered in Basel, Switzerland, with operations in the United States. For more information, visit www.windwardbio.com.

Contacts

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