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# Kelun-Biotech partner advances ultra-long-acting asthma antibody into Phase III

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**Interim Phase II data for SKB378/WIN378 showed sustained lung-function and biomarker improvements through 24 weeks after a single dose, supporting twice-yearly dosing.**

Kelun-Biotech has reported positive interim Phase II results for SKB378/WIN378, an investigational ultra-long-acting monoclonal antibody targeting thymic stromal lymphopoietin, as partner Windward Bio advances the programme into Phase III development.

The Phase II portion of the global POLARIS-1 study enrolled 147 patients with uncontrolled moderate-to-severe asthma.

An interim analysis of the first 98 patients showed sustained effects on lung function and inflammatory biomarkers through week 24 following a single dose.

SKB378/WIN378 is a fully human monoclonal antibody engineered for improved potency, extended half-life and silenced effector function.

The candidate uses a differentiated binding mechanism targeting two sites on TSLP, interfering with its interaction with both co-receptors on epithelial cells.

The interim analysis showed dose-dependent increases in forced expiratory volume in one second of up to 174 mL, with placebo-adjusted mean increases reaching 256 mL.

Dose-dependent reductions in fractional exhaled nitric oxide reached up to 24 parts per billion, while mean blood eosinophil counts declined by as much as 200 cells per microlitre.

Near-maximal effects were observed as early as week two and were sustained through week 24.

The therapy demonstrated a half-life of up to 75 days, supporting the potential for twice-yearly administration.

Kelun-Biotech and Windward Bio said the candidate was generally well tolerated, with no treatment-related serious adverse events, withdrawals or discontinuations reported at the interim cut-off.

Adverse events were balanced between treatment and placebo groups, while injection-site reactions occurred in fewer than 1% of participants.

The first Phase III study has now begun evaluating two twice-yearly doses of SKB378/WIN378.

A second Phase III study is planned for the first half of 2027.

“As a differentiated, ultra-long-acting anti-TSLP antibody, SKB378/WIN378 balances efficacy, safety, and patient compliance, and holds the potential to address the unmet clinical needs in moderate-to-severe asthma,” said Dr Michael Ge, Chief Executive Officer of Kelun-Biotech.

The programme reflects continued interest in extending dosing intervals for biologic therapies used in chronic inflammatory disease, potentially reducing treatment burden while maintaining disease control.