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HUYABIO reports Phase 3 success for HBI-8000 in advanced melanoma

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The global study showed improved progression-free survival for HBI-8000 plus nivolumab compared with nivolumab plus placebo.

HUYABIO International has reported statistically significant and clinically meaningful topline Phase 3 results for HBI-8000 in combination with nivolumab in advanced melanoma.

The global Phase 3 study enrolled 404 patients across 15 countries. It met its primary endpoint, with patients receiving HBI-8000 plus nivolumab achieving median progression-free survival of 11.7 months, compared with 7.4 months for patients receiving nivolumab plus placebo.

This is relevant because advanced melanoma treatment has improved with immunotherapy, but many patients still do not achieve durable benefit. Combination strategies remain important as companies look to improve response depth, delay progression and expand treatment benefit across patient groups.

HBI-8000 is an oral drug already approved for lymphoma in China and Japan. According to HUYABIO, it has been prescribed to more than 90,000 patients, giving it an established clinical exposure base in those markets.

The Phase 3 result positions HBI-8000 as a potential new frontline treatment component for advanced melanoma, where nivolumab-based therapy is already part of established immunotherapy practice.

The development also reflects HUYABIO’s model of accelerating global development of biopharmaceutical assets originating in China. The company has operations in the United States, Japan and China, and focuses on advancing China-sourced compounds into international markets.

Adoption will depend on full data presentation, safety profile, regulatory strategy, overall survival trends and how the regimen compares with existing immunotherapy combinations. Advanced melanoma is a competitive space, so differentiation will require clear evidence of benefit and manageable toxicity.