

Insulin sudelidec becomes the first home-grown long-acting insulin for T2D in China

Market Event Summary

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The approval of insulin sudelidec (INS068) is a significant milestone for domestic innovation

Background

- China has approximately 150 million adults with type 2 diabetes, making it one of the largest and fastest-growing diabetes markets. This scale presents a significant public health burden for healthcare authorities.
- Basal insulin or long-acting insulin is the foundational therapy for many patients (especially patients who present with a very high HbA1c). The market is dominated by international analogs, including insulin glargine and insulin degludec, along with biosimilars of these agents.

Event

- The NMPA approved insulin sudelidec (Jiangsu Hengrui) as a once-daily SC injection for the treatment of adults with T2D on July 29, 2026. The approval was granted based on the outcome of two Phase 3 trials—INS068-301 and INS068-302.
- In the INS068-301 study of patients previously treated with basal insulin, insulin sudelidec met the primary endpoint at week 26, demonstrating noninferior HbA1c reduction and greater FPG reduction versus insulin glargine.
- In the INS068-302 study of patients on oral antidiabetic drugs with uncontrolled HbA1c, insulin sudelidec met the primary endpoint, demonstrating comparable HbA1c and FPG reductions to insulin glargine at week 26, with sustained efficacy through week 52.

Clarivate's takeaways



Domestic innovation milestone

The approval of insulin sudelidec as mainland China's first independently developed long-acting insulin analog marks a significant milestone in domestic diabetes innovation and strengthens the country's long-term efforts to reduce reliance on multinational insulin manufacturers. Clinical studies demonstrated glycemic control comparable to insulin glargine, with favorable hypoglycemia outcomes, supporting its potential as a competitive basal insulin option.



Competitive positioning and commercial outlook

Insulin sudelidec will compete directly with established daily basal insulin analogs, including insulin glargine and insulin degludec. While differentiation on efficacy may be limited, as a domestically developed product, insulin sudelidec will be competitively priced, providing a potential advantage in market adoption. Uptake will depend on hospital access, physician confidence, and NRDL inclusion.



Growth constraints

Despite the strategic significance of the approval, the basal insulin market in China remains highly mature and competitive. Established physician familiarity with existing long-acting insulins, the widespread availability of insulin biosimilars—many of which are included in the national VBP—and the growing uptake of weekly-dosed next-gen insulins may limit the drug's near-term market penetration.

About the author



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Mr. Verma is involved in primary and secondary market research to create syndicated landscape and forecast content and provide market insights in various therapy areas in China such as obesity / overweight, chronic kidney disease, multiple myeloma, breast cancer, non-Hodgkin's lymphoma, migraine, type 2 diabetes, and multiple sclerosis. He has expertise in market forecasting, competitive intelligence, benchmarking, and brand performance analytics. He earned his M.Sc. in biomedical engineering from the University of Warwick.

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