HY3003, Co-developed by iCarbonX Pharmaceutical, Cleared for U.S. Clinical Trial

HY3003 injection, an investigational drug co-developed by iCarbonX Pharmaceutical and Hybio Pharmaceutical, has received clearance from the U.S. Food and Drug Administration (FDA) to proceed with a clinical trial. HY3003 is a GLP-1R/GIPR/GCGR triple receptor agonist. The investigational new drug (IND) application is numbered 184763. Following completion of its safety review, the FDA has allowed the first-in-human study to proceed under the submitted protocol.

From IND Acceptance to Clinical Trial Clearance

Hybio Pharmaceutical previously disclosed that the FDA accepted the HY3003 IND on October 5, 2026. The application was cleared within the 30-day review period without an information request (IR).

HY3003-001 is planned as a single-center, randomized, double-blind, placebo-controlled, single ascending dose study in healthy adults. It will evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, and immunogenicity. HY3003 is formulated for once-weekly subcutaneous injection. Its proposed indications include weight management, type 2 diabetes, and metabolic dysfunction-associated steatohepatitis (MASH).



Joint Development and Technology Platform

iCarbonX Pharmaceutical applies its silicon-based peptide chip and AI-driven drug discovery (AIDD) platform to early discovery and screening. Hybio Pharmaceutical leads preclinical studies, IND filing, and clinical development. The two companies formed a strategic partnership in October 2024 and signed a joint development agreement for the triple agonist peptide candidate in May 2025.

U.S. clinical trial clearance is a milestone in HY3003's development. The study will proceed under the cleared protocol to generate human safety and pharmacology data. iCarbonX Pharmaceutical will continue to advance collaborations in innovative peptide drug discovery.

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碳云智药合作创新药 HY3003 获美国 FDA 临床试验许可

近日，碳云智药与翰宇药业合作开发的创新药 HY3003 注射液获得美国食品药品监督管理局（FDA）临床试验许可。HY3003 是一款 GLP-1R/GIPR/GCGR 三重受体激动剂，研究性新药申请（IND）编号为 184763。FDA 已完成安全性审查，允许按照研究方案开展首次人体临床试验。

从受理到获准开展临床试验

翰宇药业此前披露，FDA 于 2026 年 10 月 5 日受理 HY3003 的 IND 申请。该申请在 30 天审查期内获准推进，期间未收到信息补充请求（Information Request，IR）。

拟开展的 HY3003-001 研究为一项单中心、随机、双盲、安慰剂对照、单次剂量递增的健康成人临床试验，旨在评估 HY3003 的安全性、耐受性、药代动力学、药效学及免疫原性。HY3003 采用每周一次皮下注射给药的制剂形式，拟探索的适应症包括体重管理、2 型糖尿病及代谢功能障碍相关脂肪性肝炎（MASH）。



合作研发与技术平台

在合作分工中，碳云智药运用“硅基多肽芯片×人工智能辅助药物设计（AIDD）”平台开展前端发现与筛选；翰宇药业负责临床前研究、IND 申报及临床开发。双方于 2024 年 10 月建立战略合作，并于 2025 年 5 月就三靶点激动剂多肽药物签署联合开发协议。

此次美国临床试验许可是 HY3003 研发进程中的一个阶段性节点。后续研究将按获准方案开展，以获取人体安全性及药理学数据。碳云智药将继续围绕多肽创新药研发推进合作。

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