



News

Jul 10, 2025

Hongene Supports Clinical Advancement of siRNA DNV001 Using Proprietary Chemoenzymatic Ligation Platform

Press Release



Hongene Biotech Corporation, a contract development and manufacturing organization (CDMO) specializing in nucleic acid therapeutics, today announced its critical role in advancing DNV001, a novel GalNAc-conjugated siRNA targeting dyslipidemia. The therapy, developed by Hangzhou Dingle Xinwei Biotechnology, recently received investigational new drug (IND) clearance from China's Center for Drug Evaluation (acceptance number: CXHL2500095).

Hongene provided comprehensive CDMO support, including raw material supply, chemoenzymatic synthesis process development, drug substance (DS) and drug product (DP) manufacturing, and regulatory documentation to help bring DNV001 from preclinical to clinical phase of development.



“What differentiates Hongene is our vertically integrated platform, strategic investments in advanced technologies such as chemoenzymatic ligation, and our scalable manufacturing infrastructure – all of which enable the accelerated, high-purity, and cost-efficient production of RNA-based therapeutics,” said Dr. David Butler, Chief Technology Officer at Hongene.

DNV001 is designed to reduce low-density lipoprotein cholesterol (LDL-C) by silencing the expression of PCSK9 in liver cells. Leveraging Hongene’s proprietary chemoenzymatic synthesis platform, the project achieved high-purity clinical-grade batches with enhanced scalability and reduced downstream complexity.

Hongene’s vertically integrated CDMO services cover a range of oligonucleotide formats, including siRNAs, sgRNAs, antisense oligonucleotides (ASOs), aptamers, phosphorodiamidate morpholino oligomers (PMOs), and conjugates, supporting programs from early research through to commercial launch. With scalable end-to-end global manufacturing capabilities and comprehensive in-house analytics, the company is positioned to accelerate nucleic acid therapy development globally.

“The scalability and efficiency of our chemoenzymatic technology translates directly into lower production costs and simplified development,” said Dr. Butler. “This is critical for delivering large volumes of next-generation RNA therapeutics that meet global access and pricing expectations.”

Preclinical studies indicate that DNV001 offers durable lipid-lowering efficacy with just two injections per year. The candidate demonstrated pharmacological activity comparable to a competitor’s in vitro and in vivo, including dose-dependent reductions in PCSK9 and LDL-C in animal models.



“Our work on DNV001 exemplifies Hongene’s commitment to scientific rigor and manufacturing innovation,” said Dr. Butler. “We look forward to collaborating with other partners to bring their transformative medicines to market.” To learn more about Hongene’s oligo CDMO services or discuss partnership opportunities, contact info@hongene.com.

About Hongene

Hongene is a leading CDMO serving the global nucleic acid therapeutics industry. The company offers end-to-end support across oligonucleotide design, synthesis, analytics and scale-up, enabling clients to progress rapidly from discovery through commercialization.