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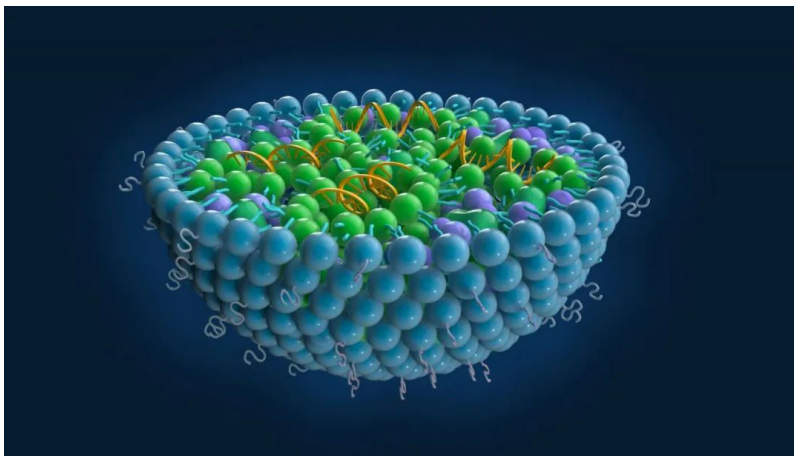
JOINN Helped Haichang Biotech's HC016 Lipoplex Injection to Pass FDA IND

On January 18, 2025, HC016 Lipoplex Injection, independently developed by Zhejiang Haichang Biotech Co., Ltd. (hereafter, "Haichang Biotech"), was approved by the US FDA for new drug registration and clinical trial application (IND). This drug is the first toll-like receptor 9 (TLR9) small nucleic acid immune agonist delivered by lipid nanoparticles (LNP), adopting QTsome™ core technology. Haichang Biotech's independently developed lipid nanoparticle (LNP) delivery system is used in treating various solid tumors such as melanoma, head and neck cancer, and osteosarcoma. The approval of HC016 demonstrates China's strengths and potential in core drug development and innovation.

About TLR9 Agonists

The human TLR family consists of 10 members (TLR1-10). Among them, TLR9 is located in intracellular vesicles and is involved in recognizing the nucleic acid components of microorganisms. It can recognize the specific nucleotide motif-CpG ODN in bacterial and viral DNA and induce the body's inflammatory response and Th1 immune response. Currently, three types of CpG ODNs, A, B, and C, have been verified. Type A mainly induces type I interferon IFNα/β; type B can activate B cells to produce antibodies; type C has the characteristics of type A and type B, that is, it can activate B cells, stimulate pDC to produce IFNα, and promote the activation and maturation of APC and NK cells.



Source: Haichang Biotech

HC016's innovative TLR9 agonist has a better activation effect on T cells, macrophages, NK cells, etc., which are the core of anti-tumor immunity. Circulating memory immune cells can effectively monitor and kill distant metastases and circulating tumor cells.

JOINN Helps Clients Apply for FDA IND

JOINN participated in the innovative research and development process of HC016 small nucleic acid and undertook the preclinical pharmacokinetics and safety evaluation of the drug. Preclinical data showed that the QTsome™ delivery system can effectively accumulate the drug at the tumor site, with almost no significant upregulation of cytokines in the blood, solving the safety problem that is difficult to overcome with traditional TLR9 agonists, while greatly reducing the onset dose and mitigating the patient's medication burden later, decreasing the risk of adverse reactions.

JOINN has significant advantages in applying for FDA IND. The company has comprehensive international qualifications, including FDA, NMPA, OECD and other GLP certifications, and its completeness of qualifications leads the industry. It has advanced facilities and equipment, as well as experimental facilities in various locations, and can conduct a large number of experiments at the same time. With its rich industry experience and professional capabilities, JOINN has extensive experience in the evaluation of innovative biotechnology applications and provides customers with high-quality preclinical research and strong support for FDA IND applications.

About Haichang Biotech

Headquartered in Hangzhou Biopharma Town, Zhejiang Haichang BiotechCo. Ltd. (Haichang Biotech) is a global trailblazer committed to pushing the boundaries of biomedical technologies, integrating pharmaceutical research, production and sales. Our mission is to improve global health and well-being. Uniting research and development, manufacturing, marketing, and services, we strive towards a healthier, brighter future for all. Our expertise lies in nucleic acid technologies. We actively contribute to the evolution of mRNA vaccine, small nucleic acid drugs, and complex injections. At present, paclitaxel for injection (albumin-bound) has been approved in nearly 40 countries including China, the UK, and the EU, and is in the process of registration application in countries along the Belt and Road. HC0301, a new class 1 small nucleic acid drug, has been dually approved by the FDA and NMPA for clinical trials, and is in phase II clinical trials globally. The mRNA COVID vaccine booster shot has been approved for clinical use by the FDA, making it the first Chinese mRNA vaccine product to obtain clinical approval in the US. Our broad product pipelines span various fields, encompassing infectious disease prevention, tumor immunotherapy, antitumor therapy, analgesia and more.

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