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PHARMA TECH OUTLOOK







ST Pharm Streamlining mRNA Drug Development in Pharma Sector

ue to recent advancements in cellular delivery of RNA, the effectiveness of RNA-based therapeutics across various use cases, ranging from cancer to influenza, has been brought to the limelight by leading CROs/CDMOs worldwide. Organizations such as ST Pharm Co. Ltd.—an Active Pharmaceutical Ingredient (API) contract development and manufacturing organization (CDMO) in the Republic of Korea—are spearheading the development of mRNA-based drug manufacturing, which contributes to the future medical development. ST Pharm provides technology-driven gene therapy in developing small

molecule drugs, synthesis of therapeutic oligonucleotides, and formulating xRNA drugs. Since its inception as a CMO in 1983, ST Pharm has pioneered the manufacturing of oligonucleotide and nucleotide-monomers in the global market. Renowned as Asia-Pacific's Top Oligonucleotide API Manufacturer, ST Pharm also possesses integrated in-house oligonucleotides production capability with biotransformation technology. As a global API CDMO company, ST Pharm caters to the needs of the clients in drug R&D, authorization, manufacturing, and non-clinical CRO services.

"As an experienced CDMO, we are capable of handling both mRNA production and LNP (Lipid Nano Particle) formulation together," says James, Joo-sung, Yang, Vice President (Head of mRNA Business Development Div.).

ST Pharm upholds the idea that the development of mRNA-based drugs can overcome the shortcomings of existing recombinant protein-based drugs. mRNA therapeutics can target previously undruggable pathways and have fewer adverse effects due to natural

protein engineering inside the body. Driven by the scope to improve clinical outcomes through mRNA drugs, ST Pharm connects all aspects of mRNA drug development to clinical and commercialized production. ST Pharm has also pioneered the development of two essential mRNA Platforms – patented 5' capping known as SmartCap[®] and Lipid-Nanoparticle (LNP) platform called SmartLNP[®]. ST Pharm's SmartCap[®] is a costeffective in-house cap analog, which consists of different ribose and base combinations. Providing over 30 diverse cap analogs, ST Pharm's CAP Library Screening System fulfills the client's need for customized cap analogs with the highest efficiency.

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Regarding LNP technology, ST Pharm has three different LNP platform strategies named 'In-licensed LNP, STLNP[®], and SmartLNP[®]. In-licensed LNP has been globally recognized as one among the best of its kind, having been applied to COVID-19 mRNA vaccine development. Likewise, STLNP[®] is the first-generation LNP developed for use in the mRNA CDMO business; it can be applied to cancer and autoimmune diseases. ST Pharm's SmartLNP[®] (second-generation LNP), developed in collaborations with Ewha Women's University in KOREA, is focused on increasing stability and

improving immune response.

We provide constant assistance to clients in the new drug development process via regular discussions and helping the project to proceed faster

Beginning its journey as a supplier of raw materials for drug development, ST Pharm has established an oligo

GMP manufacturing facility to produce and supply oligonucleotides to companies. The company has also been engaged in mRNA R&D and is capable of producing a variety of xRNAs such as Conventional mRNA, circRNA, and Self Amplifying mRNA with polynucleotides. However, post-COVID-19, ST Pharm led the development of its own domestic vaccine for COVID-19. As per the request of the Korean Government, ST Pharm developed the nation's first LNP-based COVID-19 mRNA vaccine that can respond to variant strains of COVID-19.

The company's CDMO business is characterized by its flexibility and the ability to offer customized services in accordance with the needs of clients. For instance, ST Pharm can help clients right from the designing stage of development all the way through to enhancing the genetic sequence of the targeted protein, thereby producing plasma and mRNA LNP. With the investment and support from big global companies and government bodies, ST Pharm aims to expand its mRNA and GMP facility, in turn, contributing to the healthcare sector worldwide, especially in low-income countries.

Seok-woo Kris Choi, Sr. Vice President