Innorna receives IND clearance for its first-in-class bivalent RSV mRNA vaccine in China

IN006, a bivalent RSV vaccine developed by Innorna's proprietary mRNA-LNP technology, has broad-spectrum potency against both the A and B subgroups of RSV.

UNITED STATES, June 14, 2024 /EINPresswire.com/ -- Innorna, a clinical-stage biotech company pioneering its proprietary lipid nanoparticle (LNP) technology to develop novel mRNA vaccines and therapeutics, is delighted to announce a significant regulatory milestone. Its first-in-class bivalent Respiratory Syncytial Virus (RSV) mRNA vaccine, IN006, has received Investigational New Drug (IND) clearance from the National Medical Products Administration (NMPA) in China (https://www.cde.org.cn/main/xxgk/listpage/9f9c74c73e0f8f56a8bfbc646055026d, reference number CXSL2400187). This is a crucial step for Innorna in bringing this innovative vaccine to the Chinese market and making a global impact on the prevention and control of RSV-related diseases.

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> *Linxian Li, Ph.D., CEO and Founder of Innorna*

IN006, a bivalent RSV prophylactic vaccine product developed by Innorna based on its proprietary mRNA-LNP technology platform, was designed to code stable prefusion F proteins and has broad-spectrum potency against both A and B subgroups of RSV (two mRNAs' encapsulated in one LNP) compared to the marketed monovalent vaccines. IN006 received IND clearance from the U.S. FDA in January 2024. The IND clearance from China's NMPA marks another important milestone for IN006. It is the first non-COVID-19 mRNA prophylactic vaccine approved for clinical trials in China.

"We are delighted to receive IND approval for IN006 from the NMPA. We will accelerate its clinical development to provide more effective measures to prevent and control RSV-related diseases worldwide," affirmed Linxian Li, Ph.D., CEO and Founder of Innorna.

About RSV and IN006

Respiratory syncytial virus (RSV) is a common respiratory virus with two major subtypes, A and B. RSV is highly contagious and can lead to outbreaks in communities and hospitals. There are still possibilities of re-infection with RSV in people who have been infected. Children under the age of five, adults over 65 years of age, or the immunocompromised population are at high risk of severe manifestation and exacerbation of chronic diseases. Currently, only supportive care and symptomatic treatment are available in clinical settings, and there is still a lack of specific anti-RSV therapy. Therefore, active immunization via vaccination is crucial to avoid severe manifestations of RSV infection and reduce case fatality.

After decades of research and development, only two recombinant protein vaccines against RSV were approved in the market by 2023, including AREXVY® (monovalent) from GlaxoSmithKline and ABRYSVO® (bivalent) from Pfizer. Moderna's RSV mRNA vaccine, mRESVIA® (monovalent), was approved in the United States in May 2024. There is no RSV vaccine currently approved in China.

IN006 uses Innorna's proprietary prefusion F protein design and LNP delivery system. This bivalent mRNA vaccine targets RSV subgroups A and B, which usually alternate or circulate simultaneously during the individual season. In preclinical studies, IN006 has demonstrated a well-tolerated safety profile and a high potency to induce immune response and protect animals from viral infection, offering a promising solution to the global health challenge of RSV.

About Innorna

Founded in 2019, Innorna focuses on developing best-in-class LNP delivery technology and advancing innovative RNA therapies to address unmet medical needs globally. Innorna has built a diversity-oriented lipid library (DOLL) of over 5,000 ionizable lipids, which can be applied in various modalities or scenarios, including mRNA vaccines and therapeutics, cell therapies (CAR-T, CAR-NK, etc.), and genome editing therapies. Innorna’s comprehensive R&D capability fully supports the end-to-end process of innovative therapies for internal development and external collaboration partners, from discovery to clinical development. Innorna has developed an extensive global patent portfolio and filed over 40 patent applications regarding the innovation of LNP and mRNA technology.

Innorna has built extensive internal R&D pipelines for infectious and rare diseases based on its proprietary technology platform. In addition, the company has established partnerships with pharma and biotech companies to explore the technology's potential in broader therapeutic areas. Since its establishment five years ago, Innorna has been widely recognized by the investment community and industry. It has won many awards, including MIT Technology Review's Global 50 Smartest Companies (2020 and 2022) and Fortune China's Most Socially Influential Startups.

At Innorna, we value INNOVATION, INTEGRITY, EFFICIENCY, and OPENNESS. Innorna is committed to exploring the frontier of mRNA application based on platform technologies and

leading the revolutionary step toward expanding the clinical application of mRNA in various therapeutic approaches to fulfill the unmet medical needs of patients worldwide!

Please visit the Innorna website at www.innorna.com for more information.

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