Innorna's broad-spectrum SARS-CoV-2 mRNA vaccine receives Phase II clinical trial approval from the FDA

FDA has approved Phase II trial for IN002.5.1 SARS-CoV-2 mRNA vaccine. This approval paves the way for the development of combined respiratory virus vaccines.

MILLINGTON, NEW JERSEY, UNITED STATES, April 26, 2024 /EINPresswire.com/ -- Innorna, a clinical-stage biotech company at the forefront of developing novel mRNA vaccines and therapeutics with its proprietary lipid nanoparticle (LNP) technology, has achieved a significant milestone. Innorna's broad-spectrum IN002.5.1 SARS-CoV-2 mRNA vaccine has received Phase II clinical trial approval from the FDA.

> We are thrilled with the FDA's approval to start SARS-CoV-2 mRNA vaccine phase II clinical trials. This paves the way for the development of combined respiratory virus vaccines on Innorna's roadmap.""
>
> *Linxian Li, Ph.D., CEO and Founder of Innorna*

Central to Innorna's innovative and unique approach is its proprietary mRNA-LNP technology platform, a key driver in the development of IN002.5.1. This vaccine, which received an IND (Investigational New Drug) approval from the U.S. FDA in February 2023, has successfully completed the Phase I clinical trial, underscoring the effectiveness and safety of Innorna's innovative technology.

The Phase I clinical trial utilized Moderna's commercialized SARS-CoV-2 mRNA vaccine Spikevax (mRNA-1273 and mRNA-1273.222) as the control to assess the safety, reactogenicity, and immunogenicity of different dosage levels (30 micrograms and 60 micrograms) of IN002.5.1. The safety and immunogenicity results at 28 days post-administration demonstrated that the vaccine has an excellent safety and tolerance profile with a strong neutralizing antibody titer and favorable Th-1-dominant T cell activation. There were no reports of Grade 3 or higher adverse reactions or serious adverse events.

The positive results from the Phase I clinical trial of IN002.5.1 strongly validate Innorna's pioneering mRNA-LNP technology platform. This platform has also paved the way for Innorna to

receive FDA IND clearances on two other promising mRNA vaccine candidates, the herpes zoster (HZ) vaccine, IN001, and the respiratory syncytial virus (RSV) vaccine, IN006, in September 2023 and January 2024, respectively. Both products are now poised to enter Phase I clinical studies, further demonstrating the robustness of Innorna's technology.

"We are thrilled with the positive outcomes from IN002.5.1's Phase I clinical trial and the FDA's approval to start Phase II clinical trials," said Dr. Linxian Li, the founder and CEO of Innorna. “This fortifies our confidence in the subsequent clinical development of Herpes Zoster (HZ) and respiratory syncytial virus (RSV) vaccines employing the same technology platform. Additionally, the promising clinical progress of IN002.5.1 paves the way for the development of other combined respiratory virus vaccines on Innorna’s roadmap."

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, rare diseases, in vivo cell therapies, and other modalities for patients with incurable illnesses. Innorna has a robust and diverse pipeline, and its comprehensive R&D capability fully supports the end-to-end development of innovative treatments for internal development and external collaboration partners, from discovery to clinical development.

We are one of the few companies worldwide that have mastered the underlying technology of mRNA delivery and proprietary LNP and mRNA technologies, with more than 40 invention patents filed globally in LNP and mRNA innovative technology platforms. Innorna has developed a proprietary, diversity-oriented LNP platform to safely and effectively deliver the mRNA into the correct cells and commercialize this innovative technology. This enables us to use a wide range of potential prophylactic and therapeutic strategies to advance a diversified portfolio of mRNA medicine pipelines.

In addition, Innorna has established partnerships with pharma and biotech companies, such as BeiGene, to jointly explore the potential of the mRNA/LNP technology 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 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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