

HELIXNANO'S SUBSIDIARY, HELIXNANO AUSTRALIA, RECEIVES HREC APPROVAL TO INITIATE A PHASE 1 CLINICAL TRIAL

First participants anticipated to be dosed with HN-0001, a next-generation COVID19 mRNA vaccine candidate, in April 2024

BOSTON, MA, UNITED STATES, March 20, 2024 /EINPresswire.com/ -- HelixNano, a leading biotechnology startup developing next-generation mRNA technologies, today announced that its subsidiary HelixNano Australia has received Human Research Ethics Committee (HREC) approval in Australia for its Phase 1 clinical trial of HN-0001, a second-generation COVID-19 mRNA vaccine candidate specifically designed to prevent COVID-19 in immunosuppressed and immunocompromised populations. The first Phase 1 clinical trial participants are anticipated to be dosed in April 2024.

The HREC approval allows HelixNano Australia to obtain confirmation from the Australian Therapeutics Goods Administration (TGA) to activate the clinical trial site and begin recruitment. The CPHN-01 study will be conducted in healthy volunteers, and will include an approved vaccine comparator arm.

"The COVID-19 pandemic is not over, especially for the millions of immunosuppressed patients worldwide," said Hannu Rajaniemi, PhD., co-founder and CEO of HelixNano. "This milestone brings us one step closer to providing them with a much-needed preventative option. It is a testament to the outstanding work by our team and all our manufacturing and regulatory partners".

HN-0001 incorporates two HelixNano-patented technologies to improve vaccine efficacy: a next generation mRNA chemistry to improve tolerability, and a novel vaccine design element which increases the magnitude of the immune response against COVID-19. HelixNano's preclinical studies demonstrated a potent immune response against SARS-CoV-2 in both healthy and immunosuppressed animals.

George Church, Professor of Genetics at Harvard Medical School and the chair of HelixNano's scientific advisory board, commented: "HelixNano has built a deep stack of mRNA technologies to interface with immune cells with unprecedented precision. HREC approval to begin a Phase 1 trial marks the point where they can start bringing the benefits of this exciting work from the lab to patients. The immune system is our most powerful weapon against nearly all disease,

including cancer and aging, and we can now augment it when it struggles.”

About HelixNano Australia Pty Ltd

HelixNano Australia Pty Ltd is a fully-owned subsidiary of Helix Nanotechnologies Inc, headquartered in Melbourne, Victoria. HelixNano Australia focuses on clinical research and bringing products to market in Australia.

About Helix Nanotechnologies Inc

Helix Nanotechnologies Inc is a biotechnology company headquartered in Boston, MA. HelixNano is focused on building a universal interface to the immune system to tap into the innate power of the human body to fight disease. HelixNano is currently developing mRNA-based therapeutics in infectious disease, oncology, and other indications.

Helix Nanotechnologies Inc and HelixNano Australia Pty Ltd make no medical, treatment, or health benefit claims about HN-0001. The US Food and Drug Administration, Australian Therapeutics Goods Administration, and other similar regulatory authorities have not evaluated claims regarding HN-0001. The efficacy and safety of HN-0001 has not been confirmed by approved research. Any references to the safety, efficacy, quality, and consistency of HN-0001 or other potential products do not imply that Helix Nanotechnologies Inc or HelixNano Australia Pty Ltd verified such in trials or will complete such trials.

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