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Preclinical study shows that ISR-052 provides long-term protection against SARS-CoV-2

ISR has conducted an animal study showing that immunological memory remains 6 months after two doses of the company's nasal vaccine candidate, ISR-52, were given against SARS-CoV-2

"The study shows that vaccination with application in the upper respiratory tract gives immunological long-term memory, which in turn indicates long-term protection against SARS-CoV-2. Six months after the second dose of ISR-052 given as an intranasal dry powder preparation, it now demonstrates a specific immunoglobulin response to the virus's spike protein in the blood. In addition, we see a robust T cell response. These results provide strong support for the further development of our SARS-CoV-2 specific vaccine and for the company's nasal dry powder technology to develop other types of vaccines against respiratory pathogens", comments Ola Winqvist, CEO of ISR.

The company is now in dialogue with the Medical Products Agency of Bangladesh BMRC and the ethics committee to obtain approval for the start of the clinical phase I/II study.

The study will include 120 healthy volunteers to compare different vaccine doses. Two doses of vaccine will be administered nasally at 4-week intervals. In the first instance, the safety and tolerability of the vaccine is evaluated, regarding side effects, - in addition, the immunological response is evaluated with the analysis of specific and neutralizing spike antibodies, as well as the specific T cell response. ISR has conducted audits at the clinical trial center, the clinical laboratory and our CRO, which will be responsible for the operational operation and conduct of the clinical study. Audit, is done in order to ensure compliance with regulatory requirements and requirements according to GCP. Important and decisive final steps, for us to shortly receive a decision by the authorities on the start of the clinical phase I/II study.

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About ISR Immune System Regulation Holding AB (publ)

ISR is an innovation-driven drug development company in the field of immunotherapy. The company's business



concept is to convert preclinical immunological research into clinical trials in order to, with the assistance of a stimulated immune system, fight chronical infections such as HIV, HBV and cancer by developing the company's pipeline of immunostimulatory immunolides and immunohelines and take advantage of the immune system by developing specifically designed vaccines. The company has its headquarters in Stockholm. Mangold Fondkommission AB is the company's Certified Adviser and can be reached at +46 8 503 01 550

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