

ISR's application submitted to Bangladesh Medical Research Council (BMRC) to lead the approval process to conduct a Phase I/II study with ISR52 nasal powder vaccine against SARS CoV-2

"The team from Sweden and Bangladesh has done a fantastic and record-breaking job in compiling documentation for the application in Bangladesh. We now look forward to jointly implementing the clinical trial program to produce robust safety and efficacy data for our nasal dry powder vaccine in humans" Ola Winqvist, CEO of ISR, comments.

- ISR's vaccine-candidate is based on full-length extracellular spike protein from SARS-CoV-2, in combination an immunostimulatory adjuvant, as a dry-powder formulation. The vaccine is self-administered as a nasal inhalation, to initially stimulate the immune system in the nasal mucosa as a common point of entry for the virus.
- After receiving all approvals, the clinical trial can proceed in 90 healthy volunteers, as a double-blinded, randomized, placebo-controlled, dose- finding study of intranasal ISR52 vaccine against SARS-CoV-2 infections, to assess safety, tolerability, and immunogenicity in healthy subjects aged 18 to 59 years. Safety is assessed after the first dose of ISR52 vaccine administration (Day 1 to Day 27,) and after the second dose of the ISR52 vaccine administration (Day 28 to Day 56). Efficacy is assessed via the induction of SARS-CoV-2 spike protein-binding antibodies and SARS-CoV-2 spike protein-specific T-cell mediated immune responses, after each vaccine administration
- This Phase I/II study will be followed by the implementation of a placebo-controlled, randomized phase III, multicenter study, to obtain the pivotal data for a future regulatory application for ISR52 as a primary vaccination.

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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 chronic infections such as HIV, HBV and cancer by developing the company's pipeline of immunostimulatory immunolides and immunohelins 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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