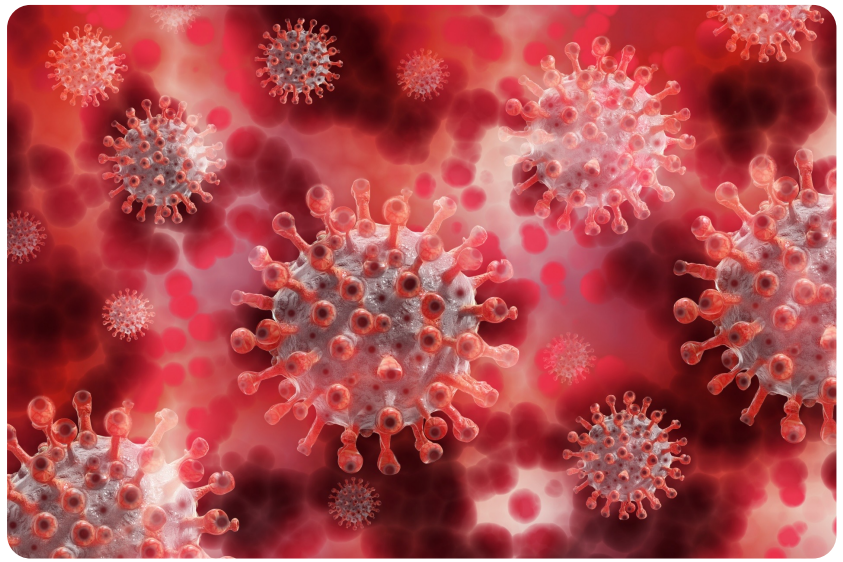
An Overview about ISR`s Vaccine Business by

Prof. Ola Winquist

Chief Executive Officer

Immune System Regulation Holding AB

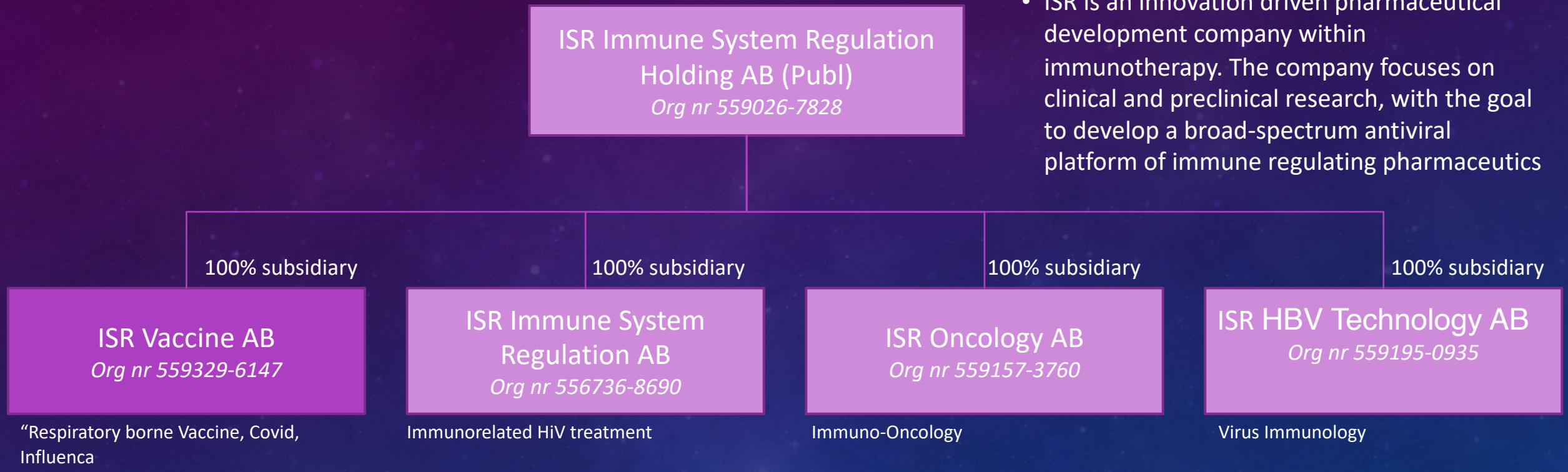
1st Edition – 2022



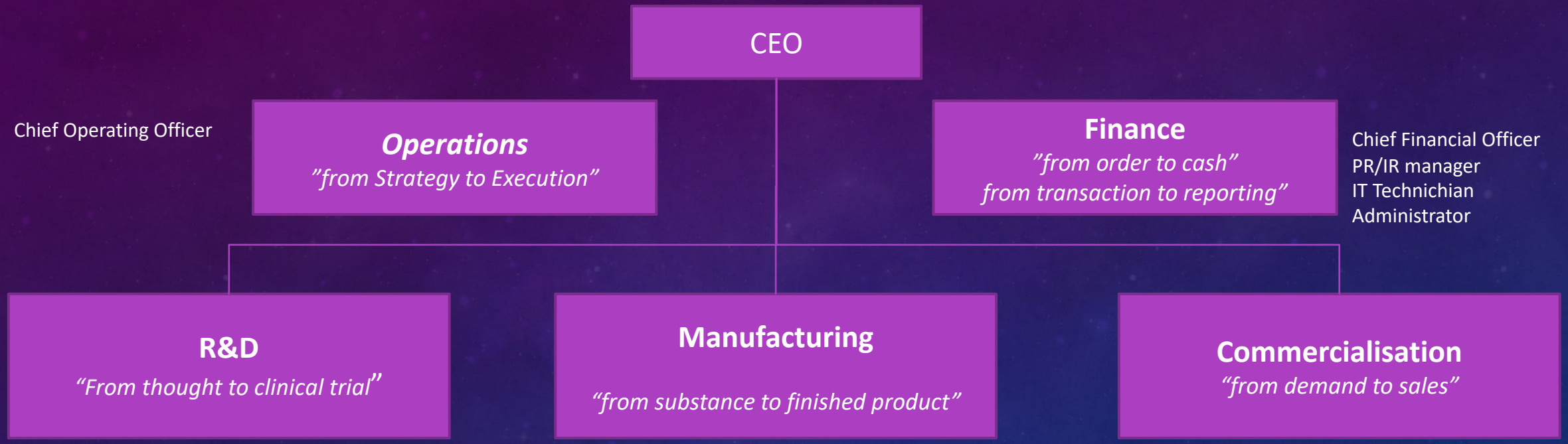
ISR

IMMUNE SYSTEM REGULATION HOLDING AB: STRUCTURE

- Listed on Nasdaq First North
- ISR is an innovation driven pharmaceutical development company within immunotherapy. The company focuses on clinical and preclinical research, with the goal to develop a broad-spectrum antiviral platform of immune regulating pharmaceutics



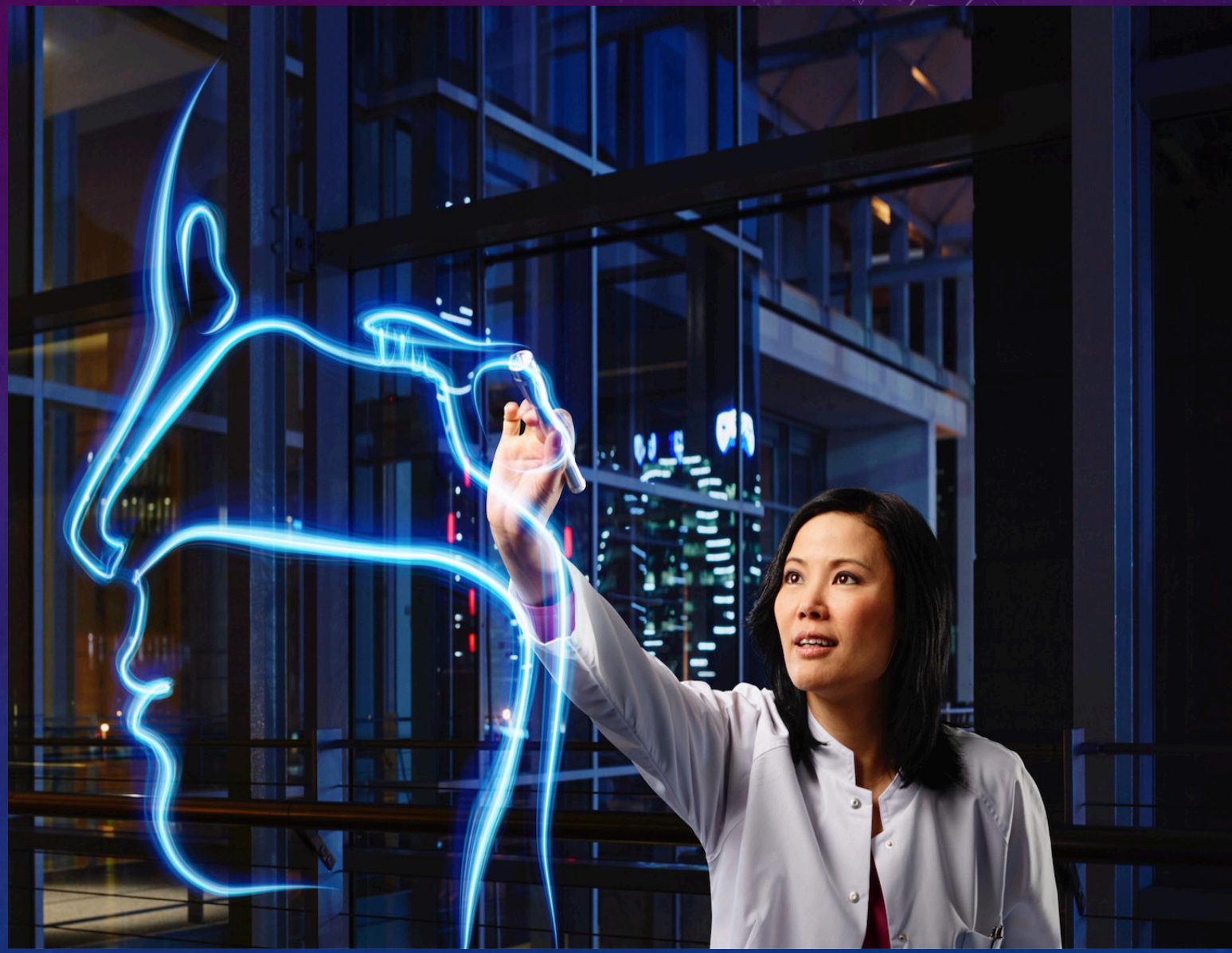
IMMUNE SYSTEM REGULATION HOLDING AB: ORGANISATION



2022-01-20

IMAGINE A FUTURE WHERE VACCINES ARE:

MAXIMALLY EFFECTIVE
OPTIMALLY SAFE
AND
EASILY ADMINISTERED



ISR VACCINE AB: PORTFOLIO

- COVID-19 Primary Vaccine (RoW)
- COVID-19 Booster (WW)
- COVID-19 Children (USA + Europe)
- Influenza – (WW)

RoW = Rest of the World
WW = World Wide

ISR`S NASAL COVID-19 VACCINE

USES A 1,273 AMINO ACID **FULL SPIKE PROTEIN** COMBINED WITH A PROVEN ADJUVANT AND IS FORMULATED INTO A DRY POWDER. FILLED AND SEALED IN OUR OWN DESIGNED DISPOSABLE DEVICE

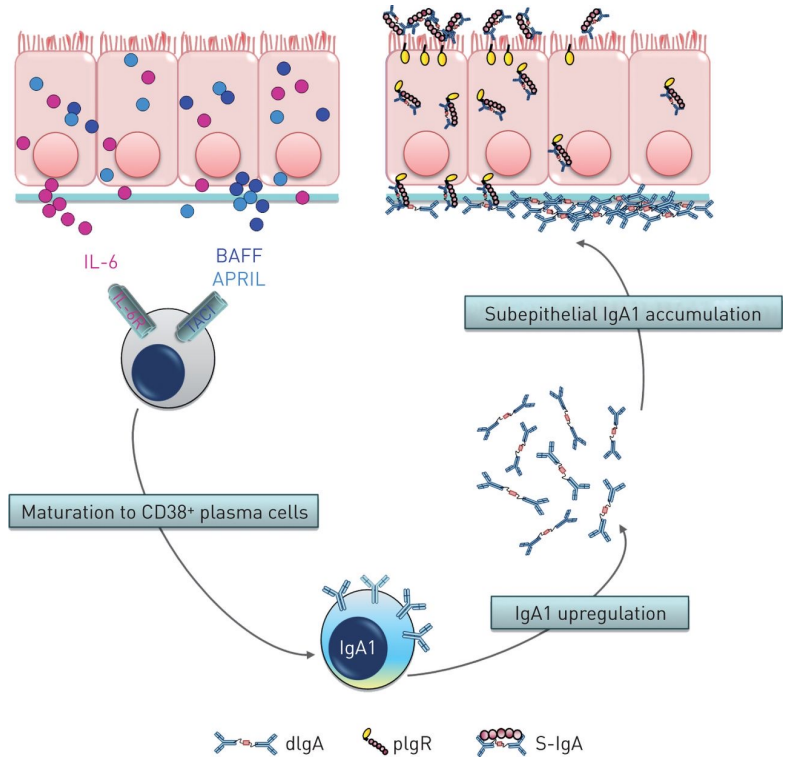
Spike Protein

+

Adjuvant

=

Dry Powder for Nasal Inhalation



ISR'S INHALANT DEVICE

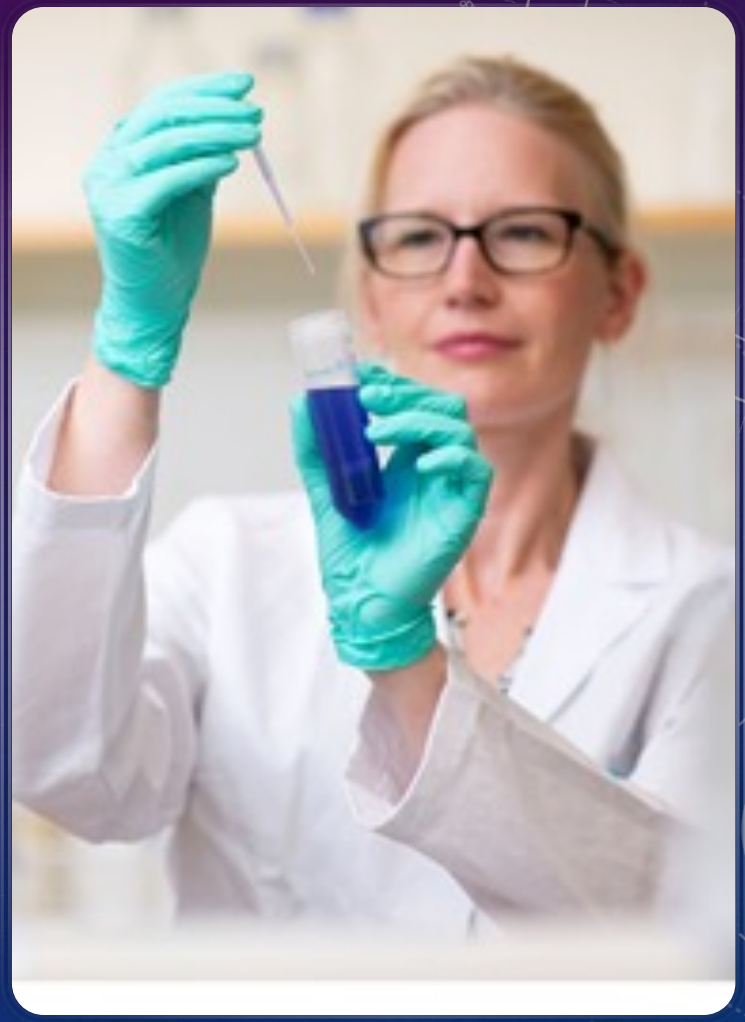
UNIQUE USER-FRIENDLY DESIGNED, PROPRIETARY DEVICE

VACCINE FOR COVID-19: 2021 ACHIEVEMENTS

- Spike protein produced
- Pre –Clinical Study conducted
- Speed toxicology testing
  Nasal/Inhalation formulation done
- Scientific advice requested from EMA

ISR`S VACCINE VALUE PREPOSITIONS:

1. **Dry powder inhalation vaccine that does not require cold distribution or storage**
2. **Unique Patient Friendly designed device**
2. **Less need for skilled medical personnel**
3. **No fear of needle injection**
4. **No risk of transmission of blood-borne viruses (for staff)**
5. **Intranasal administration - immune response begins in the nasal mucosa**
   - ISR vaccine induces antibodies and T-cell activity that recognize and block the virus already when it enters the lung
6. **Protective in lethal challenge study.**



VACCINE FOR COVID-19: 2022 TARGETS

- API and Inhaler for Clinical Studies produced
- Phase I/II Trial(s) Initiation (FPI)
- Phase III Trials(s) Initiation (FPI)
- API and Inhaler for Market Entry produced

PRIMARY VACCINATION: CLINICAL PHASE 1 DESIGN

Phase I, Randomized controlled dose finding study with 90 (nasal inhalation) healthy adults This study will test the safety and protective immunological responses to two doses of the SARS-CoV-2 inhalation vaccine, administered with 4 weeks apart.

Inclusion criteria:

- Healthy volunteers
- Age 18-55
- Negative SARS-CoV-2 serologi
- Negative history of SARS-CoV-2 infection
- Negative SARS-CoV-2 PCR at inclusion

Exclusion criteria:

- Lung disease
- Uncontrolled hypertension
- Immunodeficiency
- Autoimmune disease
- Coagulation disturbances
- Immunosuppressive medication

PRIMARY VACCINATION
ISR 006 PHASE III EFFICACY TRIAL

Phase III placebo controlled randomized double-blind study including 100 000 individuals, size depending on the transmission rate of Covid 19 in the region enrolling participants, where participants will receive 2 doses of the inhalation vaccine or 2 doses of placebo, with 4 weeks apart.

Inclusion criteria:

Healthy volunteers

Age 18-55

Negative SARS-CoV-2 serology

Negative history of SARS-CoV-2 infection

Negative SARS-CoV-2 PCR at inclusion

SECURING PHASE III TO MARKET PRODUCTION BY PARTNERING

Northway Tech transfer-initiated phase III, market production spike

Oncovir (Dalton) adjuvant production tech transfer to be initiated

Device production large scale under negotiation

Formulation large scale under negotiation

RoW - MoU for Bangladesh

RoW - MoU for Malaysia

RoW = Rest of the World

LET`S BUILD THIS FUTURE WHERE OUR VACCINES ARE:

NASAL INHALED, PROTECTIVE, AND SAFE

Prof. Ola Winqvist, CEO
E-post: ola.winqvist@israb.se
Phone: +46 (0)70 5427939

https://israb.se

IMPORTANT NOTICE AND DISCLAIMER

This presentation contains certain forward-looking statements based on uncertainty, since they relate to events and depend on circumstances that will occur in future and which, by their nature, will have an impact on the results of operations and the financial condition of Immune System Regulation AB (ISR). Such forward-looking statements reflect the current views of ISR and are based on the information currently available to the company. ISR cannot give any assurance as to the correctness of such statements. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied in these forward-looking statements. These factors include, among other things, risks or uncertainties associated with the success of future clinical trials; risks relating to personal injury or death in connection with clinical trials or following commercialization of the company's products, and liability in connection therewith; risks relating to the company's freedom to operate (competitors' patents) in respect of the products it develops; risks of non-approval of patents not yet granted and the company's ability to adequately protect its intellectual property and knowhow; risks relating to obtaining regulatory approval and other regulatory risks relating to the development and future commercialization of the company's products; risks that research and development will not yield new products that achieve commercial success; risks relating to the company's ability to successfully commercialize and gain market acceptance for IRS's products; risks relating to the future development of the pricing environment and/or regulations for pharmaceutical products; risks relating to the company's ability to secure additional financing in the future, which may not be available on favourable terms or at all; risks relating to currency fluctuations; risks associated with technological development, growth management, general economic and business conditions; risks relating to the company's ability to retain key personnel; and risks relating to the impact of competition.