

Iconovo signs agreement with ISR for the development of inhaled covid-19 vaccine

Iconovo AB (publ), a company developing complete inhalation products for a global market, today announced that it has signed an agreement with the immunotherapy company Immune System Regulation AB (ISR), an affiliate to ISR Immune System Regulation Holding AB (publ), for the development of an inhaled covid-19 vaccine in Iconovo's inhaler ICOone®. The agreement is Iconovo's second agreement within its newest strategic area innovative inhalation projects and confirms the suitability of ICOone to be used also for vaccines.

The agreement gives ISR exclusive rights to use ICOone for the treatment of covid-19 and its variants with a technology based on so-called spike proteins with an adjuvant. Iconovo will contractually develop an inhalation product with the aim to test the product in a human clinical trial targeted to start during the second half of 2021. In the agreement ISR receives an option to also use its vaccination technology in ICOone for influenza, RS-virus, and new strands of covid-virus vaccines based on the same technology.

The agreement includes stepwise payments of a 9 MSEK technology access fee, set up as five increasing milestone payments over the development to market authorization. The first milestone of 0.2 MSEK was paid at the agreement signature. ISR will also pay Iconovo for the contract development of the inhalation product which in a first binding feasibility trial amounts to 3.6 MSEK, followed by the production of clinical trial material at a preliminary value of 5.5 MSEK. Additionally, the agreement will give Iconovo low single-digit percentage royalties over a period of 14 years from market launch.

Today there are 3.9 billion people in lower-middle-income and low-income countries who will have a late access to covid-19 vaccines, according to the World Bank. With a price corresponding to the vaccines from AstraZeneca or J&J (8 – 10 USD per vaccination) this represents a full market potential of totally 31 – 39 billion USD. The size of the sales potential for an inhaled covid vaccine will depend on the rate of vaccination in these countries. There is also a scenario where the virus will mutate and, in the future, create the need for annual vaccinations similar to how influenza is managed today. As a comparison, the market for annual influenza vaccinations amount to at least 5.5 billion USD per year.

"With this project Iconovo widens its experience within the new strategic area *innovative inhalation projects*, and we look forward to more similar projects where we can contribute with our inhalation experience. It sends a strong signal to the market that more companies see ICOone as a suitable inhaler for innovative applications," says Johan Wäborg, CEO of Iconovo.

ISR has previously shown in animal models that its vaccine gives good protection against covid and this is the next step in the development of a spray-dried inhaled vaccine formulation for use in Iconovo's single-use inhaler ICOone. An inhaled formulation gives important benefits such as ease of use, cheaper transportation, storage without the need for

refrigeration and no handling of needles and syringes. To remove the need for refrigeration and the handling of contagious material represent a large savings potential and can potentially eliminate the risk of spreading disease through infected needles. Another important benefit is that the vaccine directly reaches the affected area in the pulmonary tissue that will give the needed type of immune response for protection.

“This is a very important step towards taking our inhaled covid-19 vaccine to the market quickly with a suitable single-use inhaler. We believe that the product will be of greatest use in developing countries with restricted access to refrigeration and where the vaccination programs have not advanced yet. We also hope that an inhaled vaccine will give a more adequate immune reaction in the lung which is patrolled by another type of anti-body,” said Ola Winqvist, CEO of ISR

“The potential for an innovation like this will be huge if it reaches the market. We believe that ICOone has the potential to replace injections of vaccines and other important molecules, thereby offering a smarter way to administer these pharmaceuticals. Iconovo is a global leader and wants to act as a driving force in this development,” said Johan Wäborg.

Contact

Johan Wäborg, VD

+46 707 78 51 71

joan.waborg@iconovo.se

About Iconovo

Iconovo was founded in 2013 by people with long experience in inhalation development. The company develops inhalers and associated drug preparations that are used to treat asthma and COPD. However, Iconovo also has the competence to develop products for new types of inhaled drugs such as vaccines.

By working with Iconovo, pharmaceutical companies and generic companies can access a complete pharmaceutical product, thereby eliminating the complex and costly early stages of the development phase. Iconovo licenses its patented products to customers and offers a faster way to the inhalation market with lower risk and at a lower cost.

More information about the company can be found at www.iconovo.se.

About ISR

ISR is an innovation-driven development company of pharmaceuticals within immunotherapy. The business idea is to convert preclinical immunological research to clinical development stimulating the immune system to fight chronic infections like HIV, HBV and cancer by developing the company's pipeline of immunostimulants Immunolider and Immunorheliner and utilize the immune system to develop designer vaccines. The company has its headquarter in Stockholm. Mangold Fondkommision AB is the certified advisor and can be reached at telephone +46 8 503 01 550.

About ICOone®

ICOone is a unique, patented dry powder inhaler for single use. The smart design generates an ultra-low manufacturing cost combined with simple and discreet use. It is particularly suitable for short-term treatment and as-needed use as it provides an unsurpassed low treatment cost and price point

for treatments with a low number of doses. The simple design also enables patients and caregivers to learn how to handle the inhalers with minimal training. ICOone can deliver large inhalation doses that are well protected against moisture, an important factor for many biomolecules.