

Sputnik V

THE FIRST REGISTERED COVID-19 VACCINE
PROVEN HUMAN ADENOVIRAL VECTOR TECHNOLOGY



Международный
Гам-КОВИД-Вак (Комплексный)
раствор для внутримышечного
введения, 1 доза - 0,5 мл
номер серии: I-001
дата выпуска: 06.04.2020
годен до: 04.04.2021
хранение при температуре
от -18 °С. Не допускается
размороженного препарата

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Sputnik V Key Facts

- **The first registered COVID-19 vaccine** in the world
- **Prime-boost vaccination achieves recognized long lasting immune response**
- **Safe and well-studied platform since 1953** and used for the vaccination of over 10 mln people
- **Safety and immunogenicity study results published** in peer-reviewed medicine journal **Lancet***
- Over **44,000 people** in Sputnik V clinical trials worldwide
- **Countries with over 50% of world population have expressed interest in Sputnik V vaccination**
- **Over 1 bn people to be vaccinated by Sputnik V in 2020-2021**

* Please follow the [link](#) to have access to Lancet article

Collaboration

The Gamaleya Center

- **National Research Center of Epidemiology and Microbiology**
n. a. **N.F. Gamaleya** is the world's **leading research institution** founded in 1891
- The Center successfully created the **world's first Ebola virus vaccine**. A **MERS vaccine** is currently in advanced stages of clinical trials. Both vaccines are based on the **human adenovirus vector platform used for Sputnik V**
- The Center runs one of the **world's only "virus collections"** and has its own vaccine production facility

Russian Direct Investment Fund (RDIF)

- **Sovereign Wealth Fund of Russia established in 2011**
- **RDIF** has played a **key role in fighting COVID-19 in Russia**. The Fund has selected and funded the most promising **testing system (COVID-19 SmartAmp)**, **drug (Avifavir)** and **vaccine (Sputnik V)** for COVID-19
- **RDIF** is **supporting the development of Russia's COVID-19 vaccine** by the Gamaleya Center
- **RDIF** has the **exclusive license** for the sale and manufacture of Sputnik V vaccine in international markets

Sputnik V

- On August 11, 2020, in partnership with the Gamaleya Center RDIF launched the **first information website** on a Russian coronavirus vaccine at www.sputnikvaccine.com
- This website has been created to provide accurate and **up-to-date information** about Sputnik V

Key Development Milestones

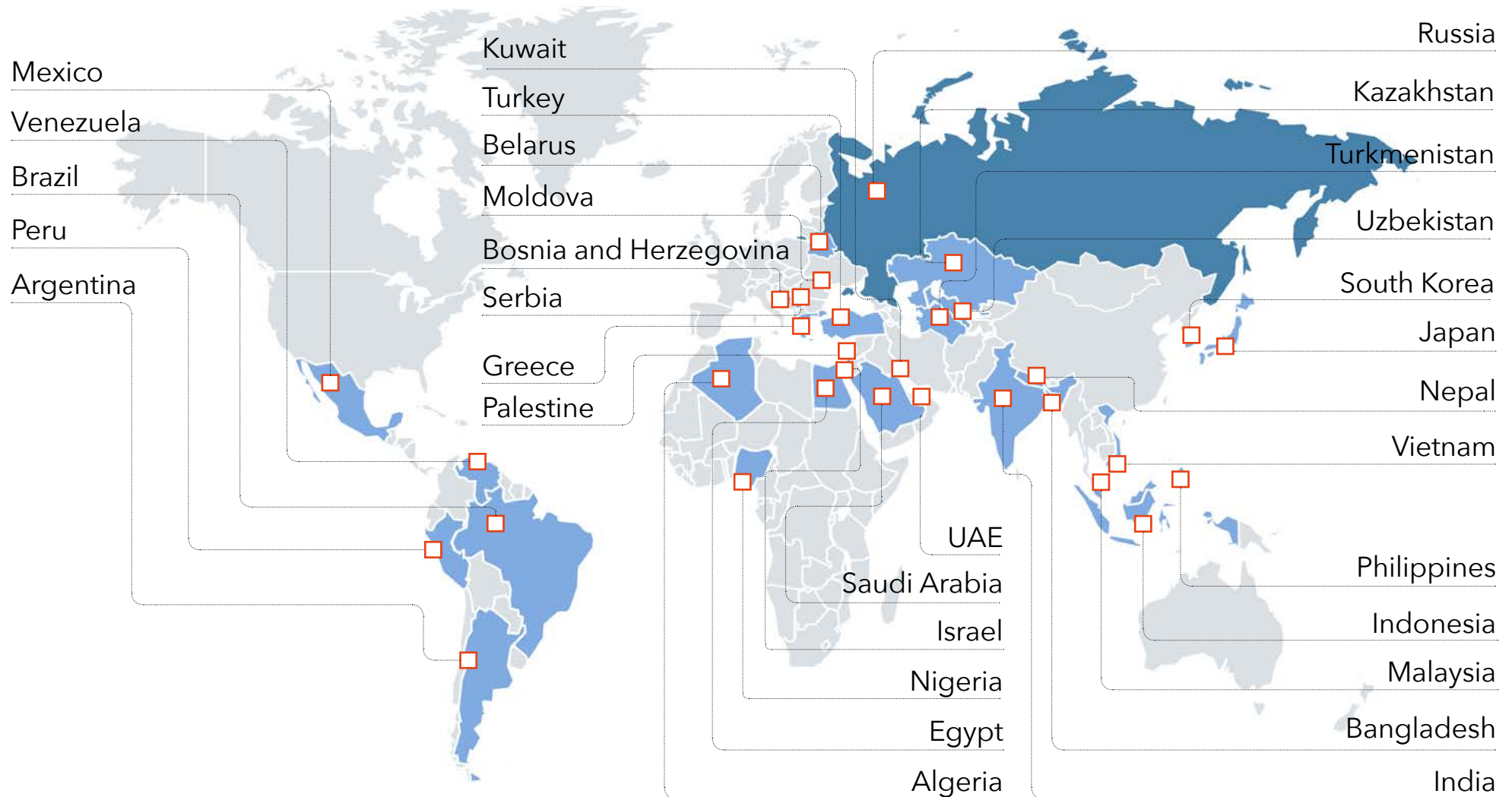
Russian Sputnik V is the world's first Human Adenovirus Vector-based COVID-19 vaccine



* Vector platform based on human adenoviruses

International Sales Footprint

Over 30 countries comprising over 50% of the world's population have expressed interest in using Sputnik V for vaccinations, including in Latin America, India, UAE, Saudi Arabia, Indonesia, Philippines



Recognition from the Global Scientific Community

Selected Quotes

// Polina Stepensky

Chair of the Bone Marrow Transplantation and Cancer Immunotherapy Department at Hadassah hospital, Israel

The first thing I should say to Russian scientists and Russian health professionals is 'Bravo!'. This technology and scientific approach we perfectly understand and absolutely approve. You have achieved a real breakthrough in science and in medicine. We are really grateful that you have done a wonderful job

// Zhong Nanshan

Director of the Guangzhou Institute of Respiratory Diseases, China

I am highly complimentary about the COVID-19 vaccine, developed by the Gamaleya Center. Let me congratulate your country on the completion of the state registration procedure. The Russian adenoviral vaccine is safe and should successfully complete its clinical trials

// Hildegund Ertl

Professor, Vaccine & Immunotherapy Center at the Wistar Institute in Philadelphia, USA

From what I've seen out there, they are probably the most promising platform

// Ian Jones

Virology professor at Reading University, United Kingdom

There is enough general background data on recombinant adenovirus-based vaccines to assume the vaccine itself will be safe at the usual doses

Recognition from the Global Scientific Community

Selected Quotes

// **Muhammad Munir**

*Molecular Virologist at Lancaster University, **United Kingdom***

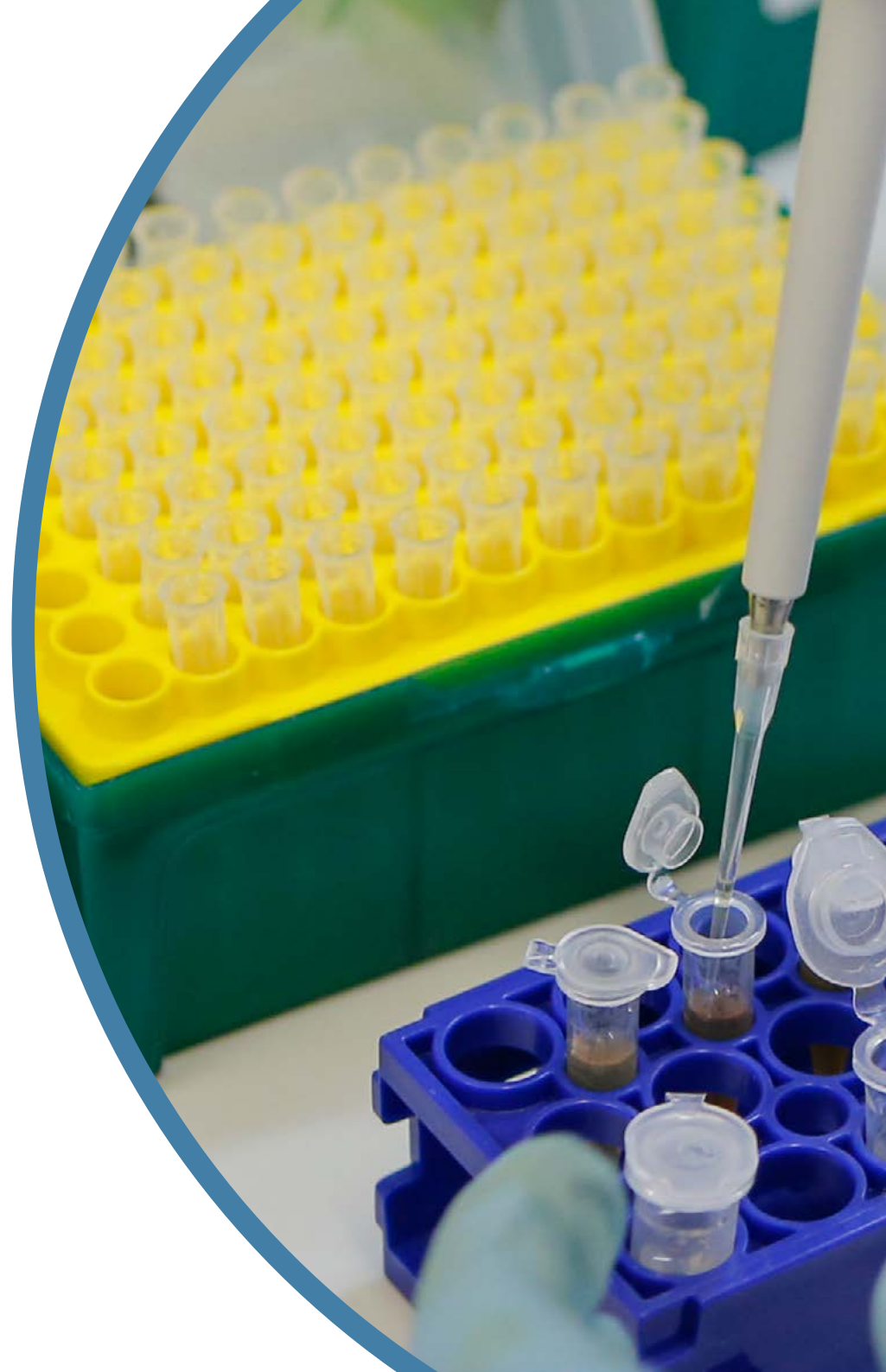
Russian scientists have an advantage as they used the same technology to develop an Ebola vaccine. Having registered the vaccine, Russia is ahead of others. This is an important step given this unprecedented situation, this is good news. Based on the data published in Lancet, the Sputnik V showed an acceptable safety and profound immunogenicity. There are features that make Sputnik V a promising candidate. The idea of using two different adenoviruses as vector is superior over many vaccines in the frontline

// **Stephane Gayet**

*Professor at Strasbourg University, doctor at Strasbourg University Hospital, **France***

This is a valuable and effective vaccine that I personally look forward to. I am very interested in the work that Russian researchers have done. I realized that one of the most advanced methods was being used - the adenoviral vector method

Vaccine Overview



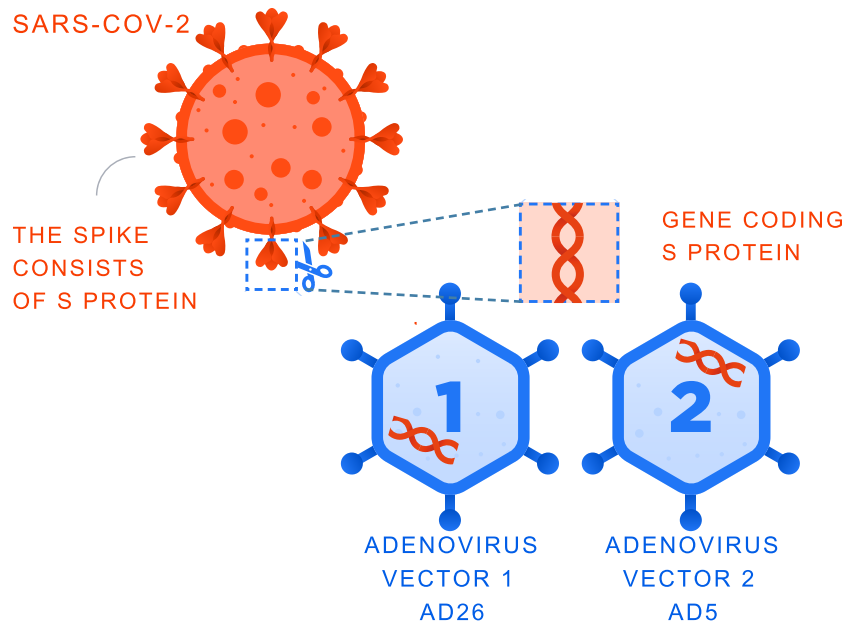
Human Adenovirus Vector (Ad 5) and Vector (Ad 26) Platform

- Vaccine does not contain live human adenoviruses, but contains human adenovirus vectors that cannot multiply in the body and are completely safe
- The approach of the Gamaleya Center with the vaccine using the most prudent prime-boost (two doses) vaccination regimen with two vector serotypes: number 5 (Ad5) and number 26 (Ad26) has a clear advantage over the one-vector approach used by other pharmaceutical companies
- The vaccine induces strong response forming antigen-specific cells of both populations of T-lymphocytes: T-helper (CD4+) and T-killer (CD8+)
- It has elicited IgG response in 100% immunized participants in mean titers significantly higher than titers of COVID-19 convalescents

Two-Boost Vaccination with Different Vectors

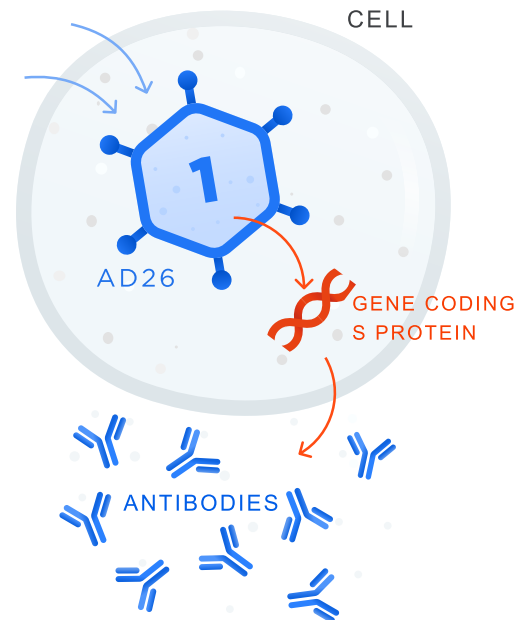
Vector creation

- A **vector** is a virus that lacks a gene responsible for reproduction and is used to transport genetic material from another virus that is being vaccinated against into cell
- A gene coding **S-protein** of SARS-COV-2 spikes is inserted into each vector



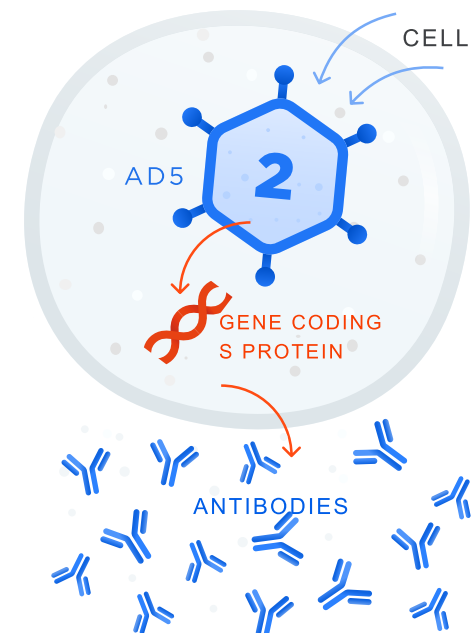
First vaccination

- **Vector (Ad 26)** with a gene coding **S-protein** of coronavirus gets into cell
- As cell synthesizes **S-protein**, the development of **immunity** begins



Second vaccination

- Another vaccination with **Vector (Ad 5)** takes place in 21 days
- The vaccine based on another adenovirus vector unknown to the body boosts the immune response and provides long-lasting **immunity**



Unique Combination of Different Vector Types to Form Long Lasting Immunity

University of Oxford/ AstraZeneca

Change from single-shot to double-shot regimen with **ChAdOx1** for both prime and boost immunization

Loss of boost immunization efficacy due to anti-vector response

Johnson & Johnson

Ad26 for both prime and boost immunization

Sputnik V

A **breakthrough** idea of using **two different types** of adenovirus vectors

The Gamaleya Center

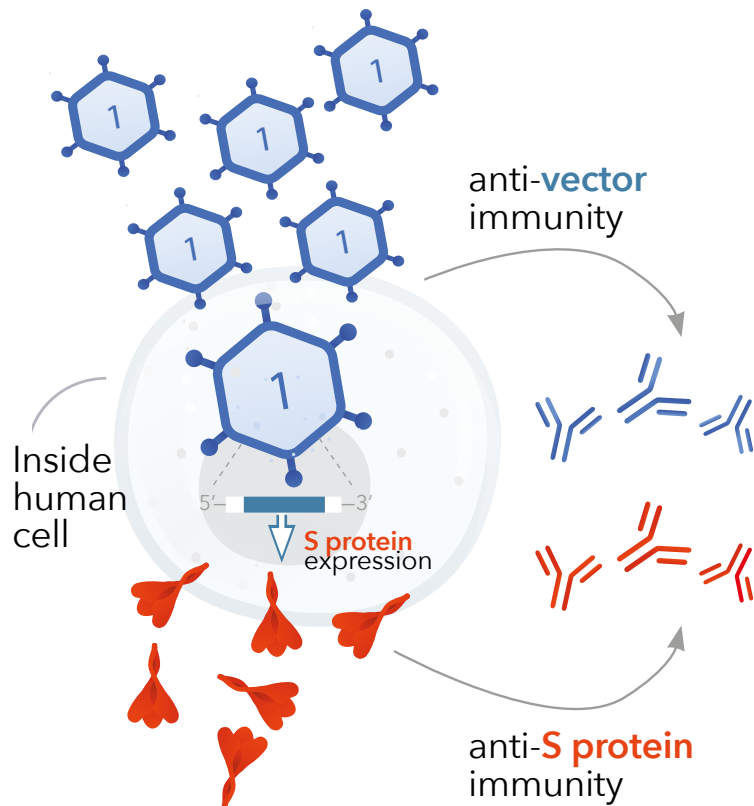
Ad26 for prime immunization

Ad5 for boost immunization

High efficacy of both prime and boost immunization

Advantages of Two Different Vectors During Immunization

First immunization



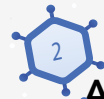
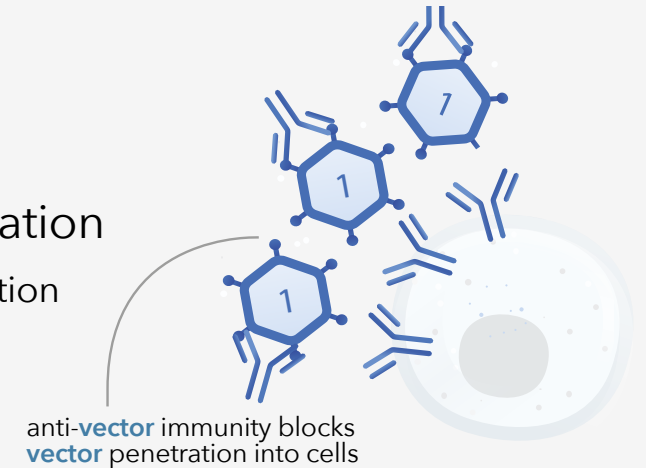
Second immunization - boost



The same Ad vector

Homologous immunization

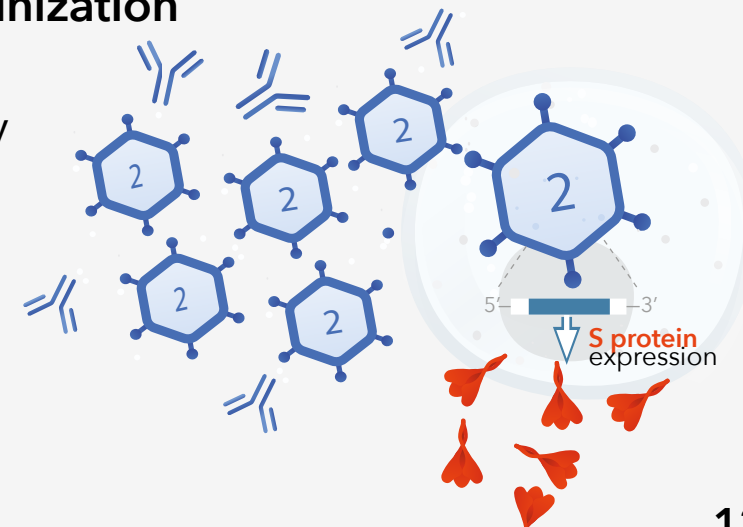
Inefficacy of boost immunization due to anti-vector immunity



Another Ad vector

Heterologous immunization

Efficient boosting of anti-S protein immunity



Clinical Trials



Pre-Clinical Study

Study:

- Immunogenicity:
 - mice *Mus musculus*, Balb/C
 - hamsters (*Mesocricetus auratus*)
 - Marmosets (*Callithrix jacchus*)
 - Rhesus macaque (*Macaca mulatta*)

Results:

- Vaccine **protects 100%** immunosuppressed hamsters (*Mesocricetus auratus*) from lethal infection with SARS-CoV-2
- Vaccine elicited **robust humoral and cellular immune** response in non-human primates and allowed to protect them from SARS-CoV-2 infection
- **No adverse drug event** was observed in vaccinated and SARS-CoV-2 challenged animals

**Protects 100%
of animals**

**Immediate
availability of
antibodies**

Phase I/II Study

- **Design:** Non-Randomised, Open Label, two-stage study in Parallel Assignment
- **Number of subjects:** 76 healthy volunteers of both sexes
- **Age group:** 18 to 60 inclusively
- **Study duration:**
 - First participant screening: June 17th 2020
 - Completion of the 28th day of observation: July 20th 2020
 - Completion of the 42th day of observation: August 3rd 2020

Results:

- The heterologous rAd26- and rAd5-vectored COVID-19 vaccine has a good safety profile, does not cause serious adverse events and induces strong humoral and cellular immune response in 100 % of participants
- There is no scientific or clinical evidence of any side effects associated with the vaccine

**No unforeseen
or unwanted side
effects...**

**...additionally
supported by track
record of past
clinical studies**

Phase III Study

Multicenter clinical trials

- **Design:** Randomized, double-blind, placebo controlled, multi-centre clinical trial in parallel assignment of the efficacy, immunogenicity and safety
- **Number of subjects:** 44,000 participants, 3:1 vaccine to placebo
- **Age group:** 18 to 60+
- **Current status:** ongoing
- **Countries:**
 - Russia
 - Saudi Arabia
 - Egypt
 - India
 - UAE
 - Philippines
 - Brazil
 - Others

**Studies on over
44,000 people
worldwide under
international
standards and
supervision**

Sputnik V - Recap



The Human Adenovirus Vaccine is a Safe and Well-Studied Platform

- Sputnik V is **the first registered COVID-19 vaccine**
- Sputnik V is based on a **breakthrough idea of the unique combination of two vector types (Ad5 and Ad26)** that allow to form **long lasting immunity**. This approach therefore has a **clear advantage over the one-vector technology** used by other pharmaceutical companies
- Human adenovirus vector was **tested on tens of thousands of people worldwide**
- It has a **long history of approved and registered vaccines and drugs**, including cancer therapy drugs
- Human adenovirus vaccines are **proven to have no long-term health risks**, including **no risk of carcinogenicity and no risk of affecting fertility**
- Sputnik V vaccine **does not contain live human adenoviruses**, but contains human adenovirus vectors that **cannot multiply in the body and are completely safe**
- Human adenoviral vectors are **used in the development of vaccines against coronavirus by the world's leading pharmaceutical companies**. At the same time, their vaccines are **single-vector**: CanSino (China) uses the Ad5 vector, Johnson & Johnson (USA) uses the Ad26 vector
- Over **44,000 people in Sputnik V clinical trials expected worldwide**
- Countries with **over 50% of world population have expressed interest in Sputnik V vaccination**
- Over **1 bn people to be vaccinated by Sputnik V in 2020-2021**

The Russian Direct Investment Fund (RDIF)

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