**Sputnik V**

The First Registered COVID-19 Vaccine

Proven Human Adenoviral Vector Technology
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**
- **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**
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 coronavirus 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

- **EARLY 2014:** Ebola* vaccine developed by the Gamaleya Center
- **EARLY 2018:** MERS (Middle East Respiratory Syndrome)* candidate vaccine developed by the Gamaleya Center
- **FEBRUARY 2020:** Start of work on Sputnik V* vaccine developed by the Gamaleya Center
- **AUGUST 3rd 2020:** Completion of phase I-II of clinical trials
- **AUGUST 11th 2020:** Vaccine registration in Russia
- **SEPTEMBER 2020:** Start of mass vaccine production in Russia
- **NOVEMBER 2020:** Start of global vaccine supplies
- **BY YEAR END 2021:** Global supply of vaccine over 1 bn doses
- **END OF AUGUST 2020:** Launch of unprecedented post-registration multinational Phase III clinical trials on over 44,000 volunteers

* Vector platform based on human adenoviruses
Over 25 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.
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

**Johnson & Johnson**
Ad26 for both prime and boost immunization

Loss of boost immunization efficacy due to anti-vector response

**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**

- **Inside human cell**
- **anti-vector immunity**
- **anti-S protein immunity**

**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

**S protein expression**

**anti-vector immunity blocks vector penetration into cells**
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
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 17\(^{th}\) 2020
  - Completion of the 28\(^{th}\) day of observation: July 20\(^{th}\) 2020
  - Completion of the 42\(^{th}\) day of observation: August 3\(^{rd}\) 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
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PROVEN HUMAN ADENOVIRAL VECTOR TECHNOLOGY