

The first interim data analysis of the Sputnik V vaccine against COVID-19 phase III clinical trials in the Russian Federation demonstrated 92% efficacy

- *The Sputnik V vaccine efficacy amounted to 92% (calculation based on the 20 confirmed COVID-19 cases split between vaccinated individuals and those who received the placebo). Currently 40,000 volunteers are taking part in double-blind, randomized, placebo-controlled Phase III of Sputnik V clinical trials, out of which over 20,000 have been vaccinated with the first dose of the vaccine and more than 16,000 with both the first and second doses of the vaccine.*
- *Efficacy was demonstrated on the basis of a first interim analysis obtained 21 days after the first injection.*
- *There were no unexpected adverse events during the trials. Monitoring of the participants is ongoing.*
- *The world's first registration of COVID-19 vaccine, done in Russia on the 11th of August under the emergency use authorization mechanism, enables the Russian Federation to administer the vaccine outside of the clinical trials to volunteers such as medics and other high-risk groups. Trials conducted under the civil use of the vaccine in Russia (not being a part of clinical trials) based on the monitoring of additional 10,000 vaccinated confirmed vaccine efficacy at a rate of over 90%.*
- *The interim research data will be published by the Gamaleya Center team in one of the leading international peer-reviewed medical journals. Following the completion of Phase III clinical trials of the Sputnik V vaccine, Gamaleya Center will provide access to the full clinical trial report.*
- *Currently Sputnik V Phase III clinical trials are approved and are undergoing in Belarus, UAE, Venezuela and other countries, as well as Phase II-III – in India.*
- *The Sputnik V vaccine is based on a well-studied human adenoviral vector platform that had proven safe and effective with no long-term side effects in more than 250 clinical trials globally conducted during the past two decades (while the history of use of human adenoviruses in vaccine development started in 1953). More than 100,000 people have received approved and registered drugs based on the human adenoviral vectors.*
- *The uniqueness of the Russian vaccine is in using two different human adenoviral vectors that enable to provide strong and long-term immune response after the second injection.*

Moscow, 11.11.2020 – The National Research Center for Epidemiology and Microbiology named after N.F. Gamaleya of the Ministry of Health of the Russian Federation (Gamaleya Center) and the Russian Direct Investment Fund (RDIF, Russia’s sovereign wealth fund), announce that the Sputnik V vaccine, the world's first registered vaccine against coronavirus (registered on the 11th of August under the emergency use authorization mechanism) created on the well-studied platform of human adenoviral vectors, demonstrated high efficacy. The confirmation is based on the first interim data from the largest double-blind, randomized, placebo-controlled Phase III clinical trials in Russia involving 40,000 volunteers.

The trials evaluated efficacy among over 16,000 volunteers who received the vaccine or placebo 21 days after the first injection. As a result of a statistical analysis of 20 confirmed cases of coronavirus, the case split between vaccinated individuals and those who received the placebo indicates that the Sputnik V vaccine had an efficacy rate of 92% after the second dose.

Separately, in September the vaccine was first administered to a group of volunteers from the “red zones” of Russian hospitals. The observation of additional 10,000 vaccinated volunteers representing medics and other high-risk groups under the civil use of the vaccine out of clinical trials also confirmed the vaccine’s efficacy rate of over 90 percent.

The data received will be published by Gamaleya Center researchers in one of the world’s leading peer-reviewed medical academic journals following an independent valuation of the data by leading epidemiology experts. Following the completion of Phase III clinical trials of the Sputnik V vaccine, Gamaleya Center will provide access to the full clinical trial report.

As of November 11, as part of the clinical trials in Russia’s 29 medical centers, more than 20,000 volunteers were vaccinated with first dose and over 16,000 volunteers with the first and the second dose of the vaccine.

In addition, as of November 11, no unexpected adverse events were identified as part of the research. Some of those vaccinated had short-term minor adverse events such as pain at the injection site, flu-like syndrome including fever, weakness, fatigue, and headache.

During the clinical trials, the safety of the vaccine is constantly being monitored; information is analysed by the Independent Monitoring Committee comprising of leading Russian scientists. Collection, quality control and data processing is

conducted in line with ICH GCP standards and involving active participation of Moscow's Health Department and Crocus Medical, the contract research organization (CRO).

Observation of study participants will continue for six months after which the final report will be presented. Currently Sputnik V Phase III clinical trials are approved and are undergoing in Belarus, the UAE, Venezuela and other countries, as well as Phase II-III in India. A separate detailed study of the vaccine's safety and immunogenicity for elderly people is being conducted.

The research data will be provided by RDIF to the national regulators of countries interested in purchasing the Russian vaccine in order to streamline the registration process.

Mikhail Murashko, Minister of Health of the Russian Federation:

“The use of the vaccine and the results of clinical trials demonstrate that it is an efficient solution to stop the spread of coronavirus infection, a preventive healthcare tool, and this is the most successful path to defeat the pandemic.”

Alexander Gintsburg, Gamaleya Center Director:

“The publication of the interim results of the post-registration clinical trials that convincingly demonstrate Sputnik V vaccine's efficacy gives way to mass vaccination in Russia against COVID-19 in the coming weeks. Thanks to the production scale up at new manufacturing sites, Sputnik V vaccine will soon be available for a wider population. This will break the current trend and lead to an eventual decrease in COVID-19 infection rates, first in Russia, then globally.”

Denis Logunov, Gamaleya Center Deputy Director:

“Positive interim results of Phase III give reasons to expect a successful outcome of Sputnik V clinical trials. We will continue to process and analyse all the data and look to the future with optimism, expecting that results of our work will help end the pandemic sooner.”

Kirill Dmitriev, CEO, Russian Direct Investment Fund:

“Sputnik V is the first registered vaccine against COVID-19 in the world, the vaccine is based on safe and effective platform of human adenoviral vectors. More and more countries are recognizing the human adenoviral vector platform and plan to include these vaccines, as the most studied and known, in their respective national vaccine

portfolio. I would also like to stress the importance of international cooperation and close partnership among vaccine-developing states. Vaccines should be above politics. The world needs a diversified portfolio of high-quality vaccines with Sputnik V, based on the well-tested human adenoviral vector platform, being an important element of it.”

The safety of vaccines based on human adenoviruses was confirmed in more than 75 international publications and more than 250 clinical trials conducted during the past two decades (while the history of use of human adenoviruses in vaccine development started in 1953). Adenovirus vectors are genetically modified viruses of the regular flu that cannot reproduce in a human body. When Sputnik V vaccine is used, the coronavirus itself does not enter the body as the vaccine only contains genetic information about part of its outer protein coat, the so called "spikes" forming its crown. This completely eliminates the possibility of getting infected as a result of vaccination while also causing the body's stable immune response.

On September 4, The Lancet, one of world's leading medical journals, published a research paper on the results of Phase I and Phase II clinical trials of the vaccine that showed no serious adverse events and an effective immune response of those vaccinated.

Requests for more than 1.2 billion doses of Sputnik V vaccine came from over 50 countries. The vaccine supplies for the global market will be produced by RDIF's international partners in India, Brazil, China, South Korea and other countries. The existing RDIF contracts with international partners enable the production of 500 million doses of the Sputnik V vaccine outside Russia annually. RDIF is now considering additional requests from a number of countries and companies to further increase its foreign production capacities.

On August 11, the Sputnik V vaccine developed by the Gamaleya Center was registered by Russia's Health Ministry and became the world's first registered vaccine against COVID-19. Detailed information on the Sputnik V vaccine, its human adenoviral vectors technological platform, and other details are available at sputnikvaccine.com

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Russian Direct Investment Fund (RDIF) is Russia's sovereign wealth fund established in 2011 to make equity co-investments, primarily in Russia, alongside reputable international financial and strategic investors. RDIF acts as a catalyst for direct investment in the Russian economy. RDIF's management company is based in Moscow. Currently, RDIF has experience of the successful joint implementation of more than 80 projects with foreign partners totaling more than RUB1.9 trillion and covering 95% of the regions of the Russian Federation. RDIF portfolio companies employ more than 800,000 people and generate revenues which equate to more than 6% of Russia's GDP. RDIF has established joint strategic partnerships with leading international co-investors from more than 18 countries that total more than \$40 bn. Further information can be found at rdif.ru

The Gamaleya National Research Center for Epidemiology and Microbiology of the Ministry of Health of the Russian Federation is one of the oldest research centers in Russia, which celebrated its 100th anniversary in 1991. The main focus of the center's research are the fundamental problems in epidemiology, medical and molecular microbiology, and infectious immunology. More information can be found at gamaleya.org

For additional information contact:

Arseniy Palagin

Russian Direct Investment Fund

Press Secretary

Tel: +7 495 644 34 14, ext. 2395

Mobile: +7 916 110 31 41

E-mail: arseniy.palagin@rdif.ru

Powerscourt

rdif@powerscourt-group.com

Tel: +44 (0)20 7250 1446