



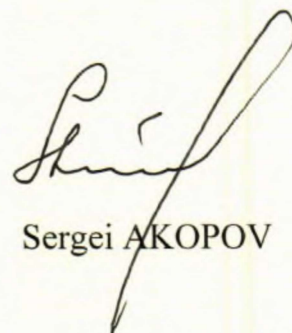
O Embaixador da Rússia

Brasília, em “10” de dezembro de 2020

Excelentíssimo Senhor Ministro,

Apresentando os meus melhores cumprimentos, venho por este meio encaminhar a carta do Exmo. Sr. Kirill Dmitriev, Diretor-Executivo do Fundo de Investimentos Diretos da Rússia, endereçada a Vossa Excelência.

Aproveito a oportunidade para renovar a Vossa Excelência os protestos da minha mais alta consideração.



Sergei AKOPOV

A SUA EXCELÊNCIA
O SENHOR EDUARDO PAZUELLO,
MINISTRO DA SAÚDE
DA REPÚBLICA FEDERATIVA DO BRASIL
BRASÍLIA – DF



RUSSIAN DIRECT
INVESTMENT FUND
Joint Stock Company
«Management Company of Russian Direct Investment
Fund»

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His Excellency
Eduardo Pazuello

Minister of Health,
Federative Republic of Brazil

07.12.2020 № 939/12-20

Your Excellency,

We are pleased to inform you that the National Research Center for Epidemiology and Microbiology named after N.F. Gamaleya of the Ministry of Health of the Russian Federation and the Russian Direct Investment Fund ("RDIF") announced that the Sputnik V vaccine ("Vaccine"), the world's first registered vaccine against COVID-19 (registered in Russia on August 11, 2020, under the emergency use authorization mechanism) created on the platform of human adenoviral vectors, demonstrated efficacy rate of 91.4% based on the interim data analysis from the large scale clinical trials in Russia. The safety of the Vaccine is not only proven by the ongoing clinical trials, but more importantly by decades of research of human adenoviruses compared to unverified previously unused mRNA and chimpanzee adenovirus technologies.

The first batch of mass supplies of the Vaccine by RDIF to select markets is expected to be launched in February 2021 subject to regulatory approvals currently arranged by RDIF. The price of the Vaccine for the international markets will be less than 10 USD per injection (one dose comprising of two injections), therefore, Sputnik V vaccine will be two or more times less expensive than mRNA vaccines with similar efficacy levels. In addition, RDIF together with partners has launched production of the lyophilized (dry) form of the Vaccine, which is stored at a temperature of +2 to +8 °C comparing with similar vaccines of other producers, which require a temperature from -70 to -20 °C. Such a temperature regime enables the distribution of the Vaccine in international markets and allows for dramatic reduction of the logistics costs.

In this regard and as part of ongoing cooperation on procurement of the Vaccine for the needs of Brazil, we kindly ask you to provide the contact details of the authorized Government official/officials, responsible for approving supply terms and demand for the first batch of the Vaccine.

We are looking forward to working closely with Brazil in this battle against the spread of the COVID-19. Enclosed please find the most recent press-release on the second interim analysis of Sputnik V clinical trial data.

Sincerely,

Kirill Dmitriev
CEO



Second interim analysis of clinical trial data showed a 91.4% efficacy for the Sputnik V vaccine on day 28 after the first dose; vaccine efficacy is over 95% 42 days after the first dose

- *The efficacy of the Sputnik V vaccine is 91.4%, based on the second interim analysis of data obtained 28 days after administering the first dose (7 days after the second dose).*
 - *Calculation was based on the analysis of data on volunteers (n = 18,794) who received both the first and second doses of the Sputnik V vaccine or placebo at the second control point (39 confirmed cases as of November 23, 2020) in accordance with the clinical trial protocol.*
- *Preliminary data from volunteers obtained 42 days after the first dose (corresponds with 21 days after the second dose) indicates an efficacy of the vaccine above 95%.*
- *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, 40,000 volunteers are taking part in the Phase III double-blind, randomized, placebo-controlled clinical post-registration study of the Sputnik V vaccine in Russia, of whom more than 22,000 volunteers were vaccinated with the first dose and more than 19,000 volunteers with the first and second doses.*
- *There were no unexpected adverse events during the trials. Monitoring of the participants is ongoing.*
- *The Sputnik V vaccine is based on a well-studied human adenoviral vector platform that has 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 the use of human adenoviruses in vaccine development began in 1953. More than 100,000 people have received approved and registered drugs based on human adenoviral vectors.*
- *The uniqueness of the Russian vaccine lies in the use of two different human adenoviral vectors which allows for a stronger and longer-term immune response as compared to the vaccines using one and the same vector for two doses.*

Moscow, November 24, 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 positive results obtained during the second interim data analysis of the largest double-blind, randomized, placebo-controlled Phase III clinical trials in Russia's history involving 40,000 volunteers. Interim trial results have once again confirmed the high efficacy of the Sputnik V vaccine, the world's first registered vaccine against coronavirus based on a well-studied platform of human adenoviral vectors. **Evaluation of efficacy was carried out among volunteers (n = 18,794) 28 days after receiving the first dose (7 days after the second dose) of the vaccine or placebo upon**

reaching the second control point of the trial in compliance with the clinical trial protocol. The analysis demonstrated a 91.4% efficacy rate for the Sputnik V vaccine.

Efficacy calculation based on the number of cases				
	3:1	Number of cases	Rate	Efficacy
Vaccine	14 095	8	0,06%	91,4%
Placebo	4 699	31	0,66%	

According to the protocol of Phase III clinical trials of the Sputnik V vaccine, its interim efficacy is calculated at three statistically significant representative control points - upon reaching 20, 39 and 78 cases of novel coronavirus infection among volunteers both in the placebo group and in the group that received the vaccine. The second interim analysis of the Sputnik V vaccine efficacy was carried out on the basis of 39 confirmed cases identified in the placebo group (31 cases) and in the vaccine group (8 cases). The ratio of the placebo group to the vaccinated group is 1 to 3.

The uniqueness of the Russian vaccine lies in the use of two different vectors based on the human adenovirus, which allows for a stronger and longer-term immune response as compared to vaccines using one and the same vector for two doses. **So, preliminary data on volunteers on the 42nd day after the first dose (equivalent to 21 days after the second dose), when they have already formed a stable immune response, indicates the efficacy rate of the vaccine is above 95%.**

The next interim data analysis will be conducted upon reaching the third control point of 78 confirmed coronavirus cases among the study participants. Final data analysis will be available by the end of Phase III clinical trials.

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, the Gamaleya Center will provide access to the full clinical trial report.

As of November 24 more than 22,000 volunteers were vaccinated with the first dose and more than 19,000 volunteers with the first and the second dose of the vaccine at 29 medical centers in Russia as part of the ongoing clinical trials. Currently Phase III clinical trials are approved and are ongoing in Belarus, the UAE, Venezuela and other countries, as well as Phase II-III in India.

As of November 24, 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 point and flu-like symptoms including fever, weakness, fatigue, and headache.

During the clinical trials, the safety of the vaccine is constantly being monitored; information is analyzed by the Independent Monitoring Committee comprising leading Russian scientists. Collection, quality control and data processing is conducted in line with ICH GCP standards and involves the active participation of Moscow's Health Department and Crocus Medical, the contract research organization (CRO).

Mikhail Murashko, Minister of Health of the Russian Federation, said:

“The data demonstrating high efficacy of the Sputnik V vaccine gives us hope that we will soon obtain the most important tool in the fight against the pandemic of the novel coronavirus infection.”

Alexander Gintsburg, Gamaleya Center Director, said:

“It is very important that the second interim efficacy analysis of Sputnik V has confirmed our findings from the first stage and shown its efficacy at 91-92%. Let me stress that the second analysis was conducted a week after volunteers got the second dose, meaning that their bodies have partially reacted to both doses. We expect the efficacy rate to be even higher based on the data three weeks after the second immunization when the body's strongest and most stable response is achieved. We plan to conduct the third interim data analysis after 78 confirmed coronavirus cases among volunteers and we have every reason to believe that the results will exceed our initial expectations. The drug's final efficacy assessment will be made available after Phase III clinical trials are concluded.”

Denis Logunov, Gamaleya Center Deputy Director, commented:

“Results from the second interim analysis of the Sputnik V vaccine are in line with our expectations and predictions. The vaccine's high efficacy rate is an important indication that a stable immune response to the coronavirus infection is formed among the study's participants. We expect that the next interim results will demonstrate Sputnik V's positive traits, moving us closer to the study's completion and the beginning of a mass vaccination of our fellow citizens.”

Kirill Dmitriev, CEO, Russian Direct Investment Fund, said:

“The Gamaleya Center has developed one of the most efficient vaccines against coronavirus in the world with an efficacy rate of more than 90%. The uniqueness of the Russian vaccine lies in the use of two different human adenoviral vectors which allows for a stronger and longer-term immune response as compared to the vaccines using one and the same vector for two doses.”

The safety of vaccines based on human adenoviruses has been 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 the 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 more than 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.

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

Be the first to learn about Sputnik V on social networks:

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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 is the fundamental problems in epidemiology, medical and molecular microbiology, and infectious immunology. More information can be found at gamaleya.org

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