A vaccine for all mankind: Sputnik V's efficacy in fighting COVID-19 is validated by internationally peer reviewed data published in The Lancet

- In an interim analysis of a Phase III clinical trial, Sputnik V showed strong efficacy, immunogenicity and safety results.
- Efficacy of Sputnik V against COVID-19 was reported at 91.6%.
- Sputnik V provides full protection against severe cases of COVID-19.
- Among the cases analyzed, over 98% of volunteers developed humoral immune response and 100% – cellular immune response.

The level of virus neutralizing antibodies of volunteers vaccinated with Sputnik V is 1.3-1.5 times higher than the level of antibodies of patients who recovered from COVID-19.

- **Excellent safety profile. Most adverse events (94%) were mild and included flu-like syndromes, injection site reactions, headache and asthenia.**

- **Sputnik V is one of the three vaccines in the world with efficacy of over 90%. Furthermore, Sputnik V stands out among these vaccines thanks to a number of key advantages:**

- **Sputnik V is already registered in 16 countries: Russia, Belarus, Serbia, Argentina, Bolivia, Algeria, Palestine, Venezuela, Paraguay, Turkmenistan, Hungary, UAE, Iran, Republic of Guinea, Tunisia and Armenia.**

- **In the first week of February, vaccination with Sputnik V will start in the following 12 countries: Bolivia, Kazakhstan, Turkmenistan, Palestine, UAE, Paraguay, Hungary, Armenia, Algeria, Bosnian Serb Republic, Venezuela and Iran.**

Moscow, February 2, 2021 – The Gamaleya National Research

Center of Epidemiology and Microbiology of the Ministry of Health of the Russian Federation and the Russian Direct Investment Fund (RDIF, Russia's sovereign wealth fund) announce that the Lancet, one of the world's oldest and most respected medical journals, has published interim results of a Phase III clinical trial of Sputnik V, confirming the vaccine's high efficacy and safety. Sputnik V, which is based on a well-studied human adenoviral vectors platform, is the world's first registered vaccine against coronavirus.

In the interim efficacy analysis of the randomized, double-blind, placebo-controlled clinical trial, where data on 19,866 volunteers were included in the efficacy analysis (14,964 of whom received the vaccine and 4,902 the placebo), the two-dose treatment of Sputnik V administered 21 days apart demonstrated efficacy of 91.6% against COVID-19. The calculation is based on the analysis of 78 confirmed cases of COVID-19 identified in the placebo group (62 cases) and in the vaccine group (16 cases). Sputnik V generated a robust humoral and cell mediated immune response.

Alexander Gintsburg, Director of the Gamaleya Research Institute of Epidemiology and Microbiology, said:

"The publication of internationally peer reviewed data on Sputnik V's clinical trial results is a great success in the global battle against the COVID-19 pandemic. The Russian vaccine's safety and high efficacy are shown by the hard scientific data presented and I congratulate the entire team of Gamaleya National Research Center for this monumental achievement. Several vaccines have already been created based on human adenoviruses and this tool is one of the most promising for development of new vaccines in the future."

Kirill Dmitriev, CEO of the Russian Direct Investment Fund, commented:

“This is a great day in the fight against the COVID-19 pandemic. The data published by The Lancet proves that not only Sputnik V is the world’s first registered vaccine, but also one of the best. It fully protects against severe COVID-19 according to data which has been independently compiled and reviewed by peers and then published in The Lancet. Sputnik V is one of only three vaccines in the world with efficacy of over 90% but outperforms them in terms of safety, ease of transportation due to storage requirements of +2 to +8 degrees and a more affordable price. Sputnik V is a vaccine for all mankind.”

Hildegund C.J. Ertl, M.D., Professor, Vaccine & Immunotherapy Center, The Wistar Institute, USA, said:

“The vaccine is 100% effective in preventing serious disease or death, which in the end is the most crucial parameter; we can all deal with the sniffles as long as we stay out of the hospital or the graveyard. Even after a single dose of this prime-boost regimen protection against disease was at 87.6%. Sputnik V is thus more effective than the AstraZeneca or Johnson&Johnson. Sputnik V, which, unlike the equally efficacious RNA vaccines of Pfizer and Moderna, can be stored in the fridge, will be of tremendous value to combat the global COVID-19 pandemic.”

Cecil Czerkinsky, PhD, M.D., Research Director, National Institute of Health and Medical research (Inserm), France, said:

“The interim results of the phase 3 clinical trial of Sputnik V COVID adenovirus vector vaccine are fairly impressive. This vaccine appears to be highly efficacious and immunogenic across age groups. This is clearly good news as this dual formulation vaccine is comparatively easy to manufacture and to deploy amid the anticipated global shortage of vaccines and logistical problems in vaccination roll-out of temperature-sensitive vaccines recently authorized for emergency use.”

Omar Sued, President of the Society of infectologists, Argentina, said:

“The paper, published in The Lancet, confirms successful results and provides additional information about the efficacy and the safety of this vaccine in different subgroups. From the public health´s point of view, the efficacy of the vaccine was very high. The safety profile was very good. The dissemination of this information is vital for informing the scaling up and rollout of this vaccine worldwide.”

David Livermore, Professor of Medical Microbiology at the University of East Anglia, UK, said:

“Presently the world needs all the good vaccines that it can get against COVID-19. And these are impressive results: Sputnik V is the first adenovirus vector vaccine to achieve the 90% efficacy seen with the two mRNA vaccines.”

According to the peer-reviewed study results, the vaccine provides full protection against severe cases of the novel coronavirus infection. Among the confirmed severe cases of COVID-19, 20 were recorded in the placebo group, while none were recorded in the vaccine group. Due to the time needed for the immune response to develop, in the first week after vaccination there was no significant difference in protection

against severe cases of COVID-19 between the vaccine and placebo groups, while in the period from 7 to 14 days the vaccine's efficacy rose to 50%, in the period from 14 to 21 days to 74.1%, and to 100% from the 21st day, giving full protection against severe cases of the coronavirus.

Importantly, the study included 2,144 volunteers over 60 years old with the maximum ages of 87 years (vaccine group) and 84 years (placebo group), showing great safety results for the elder age strata. The vaccine's efficacy for the elderly was shown at 91.8% and did not differ statistically from the group of 18-60 years old, also demonstrating great safety and immunogenicity results.

Sputnik V has demonstrated an excellent safety profile: 70 episodes of serious adverse events (SAE) not related to COVID-19 were recorded in 68 study participants: in 45 volunteers from the vaccine group and 23 volunteers from the placebo group. None of these events were associated with the vaccination as confirmed by Independent Data Monitoring Committee. Most adverse events (94%) were mild and were limited to flu-like syndromes, injection site reactions, headache and asthenia.

Sputnik V is one of only three vaccines in the world to have demonstrated efficacy of over 90%. Sputnik V stands out among these vaccines thanks to a number of key advantages, namely: a well-studied and highly efficient human adenoviral vector mechanism proven safe over decades; the vaccine's low cost in comparison to other approaches; and fewer logistics requirements with a storage temperature of between two to eight degrees Celsius allowing for easier distribution worldwide.

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 to generate a stable immune response.

In addition, Sputnik V uses two different vectors – based on human adenovirus serotypes Ad5 and Ad26 – in two separate shots, allowing for a more effective defense against the coronavirus than vaccines using the same vector for both shots. By deploying two different vectors, Sputnik V avoids a possible neutralizing effect and generates a durable and longer-lasting immune response.

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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 www.gamaleya.org

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 RUB2 tn 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 www.rdif.ru