

RDIF and Hetero agree to produce over 100 million doses of the Sputnik V vaccine in India

Moscow, Russia/Hyderabad, India, November 27, 2020 – The Russian Direct Investment Fund (RDIF, Russia’s sovereign wealth fund), and Hetero, one of India’s leading generic pharmaceutical companies (through its biologics arm “Hetero Biopharma”) have agreed to produce in India over 100 million doses per year of the world’s first registered vaccine against the novel coronavirus infection – Sputnik V.

The parties intend to start the production of Sputnik V in the beginning of 2021.

The Gamaleya Center and RDIF announced on November 24 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.

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%.

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. 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.

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.

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

“We are delighted to announce the agreement between RDIF and Hetero that will pave the way to production of the safe and highly effective Sputnik V vaccine on Indian soil. The vaccine’s interim clinical trial results show 95% efficacy on the 42nd day after the first dose. I am confident that Sputnik V should become an integral part of the national vaccine portfolio of every country willing to protect its population from the coronavirus. Thanks to our cooperation with Hetero, we will be able to significantly increase production capacity and provide people of India with an efficient solution in this challenging period of the pandemic”.

B. Murali Krishna Reddy, Director – International Marketing, Hetero Labs Limited commented:

“We are pleased to collaborate with RDIF as a manufacturing partner for the most anticipated Sputnik V vaccine for the treatment of Covid-19. While we look forward to the clinical trial results in India, we believe that manufacturing the product locally is crucial to enable swift access to patients. This collaboration is another step towards our commitment in the battle against Covid-19 and realizing the objective of ‘Make-in-India’ campaign as envisioned by our Hon’ble Prime Minister of India.”

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 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 rdif.ru

Hetero is one of India's leading generic pharmaceutical companies and the world's largest producer of anti-retroviral drugs. Backed by 25 years of expertise in the pharmaceutical industry, Hetero's strategic business areas spread across APIs, Global Generics, Biosimilars, Custom pharmaceutical services. The company is globally recognized for its strengths in Research and Development, manufacturing and commercialization of a wide range of products. Hetero has 36 state-of-the-art manufacturing facilities strategically located worldwide, approved by stringent global regulatory authorities. Our portfolio includes 300 plus products encompassing major therapeutic categories such as HIV/AIDS, Oncology, Cardiovascular, Neurology, Hepatitis, Nephrology, Urology, Diabetes, Ophthalmology, Hepatology and Immunology etc. Hetero has a strong global presence in over 126 countries and focusses on making affordable medicines accessible to patients worldwide. Further information can be found at www.heteroworld.com

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