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Second interim data analysis of Sputnik V vaccine indicates 95% efficacy rate

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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



Gamaleya Center and the Russian Direct Investment Fund (RDIF) have announced positive results obtained during the second interim data analysis of the largest double-blind, randomised, 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 (seven 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 per cent efficacy rate for the Sputnik V vaccine.

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.

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 per cent.

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.

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 centres 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.