

# OCT Clinical, contracted to run CanSinoBIO's Covid-19 vaccine study in Russia, reports on progress

ST. PETERSBURG, RUSSIA, December 29, 2020 /EINPresswire.com/ -- [OCT Clinical](#), a leading European CRO headquartered in Russia, today announced it has been appointed for a full range of [clinical trial services](#) in 8,000 healthy volunteers for the Ad5-nCoV vaccine candidate, co-developed by CanSino Biologics Inc. ("CanSinoBIO") (SHSE: 688185, HKEX:06185) and Beijing Institute of Biotechnology, Academy of Military Medical Science (BIB). In November, the Ministry of Health of Russia granted approval to Petrovax Pharm, a Russian biopharmaceutical company, to conduct a comprehensive international, multicenter, placebo-controlled phase III trial on behalf of CanSinoBIO.



OCT Clinical, a leading Eastern European CRO, contracted to run a full scope of trial services for the Ad5-nCoV vaccine candidate, co-developed by CanSinoBIO and BIB, has reported on the progress of the study and the interim results of the vaccination in Russia.

The overall enrollment target for the international study is 40,000 volunteers over 18 years old, 8,000 of which will be recruited in Russia. OCT Clinical is responsible for a full range of activities in Russia, including [regulatory and logistics support](#), project management, volunteer recruitment and monitoring.

"Despite the challenges coming from the newly imposed sanitary and epidemiological constraints at medical facilities, the study is running smoothly, and all activities are being carried out in strict accordance with the protocol. We have not seen any difficulties in recruiting volunteers either. Moreover, we observe a genuine interest expressed by the general population, many of whom approach us directly, willing to participate in the study," commented Dmitry Lioznov, M.D., the Head of the A.A. Smorodintsev Research Institute of Influenza, and a chief co-investigator of the multinational vaccine study in Russia.

More than 1,5 thousand volunteers have been already enrolled in the study so far. The first

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*Dmitry Sharov, President, OCT Clinical*

groups of subjects have already been successfully vaccinated, with the rest set to receive a single dose of the vaccine candidate within the coming months. The IM administered vaccine is being studied in research sites across several cities in Russia, including Moscow, St. Petersburg, Yaroslavl, Perm, Saratov, Omsk, Murmansk, Novosibirsk, Chita.

The vaccine is administered in a single dose. After the vaccination, the volunteers will be monitored for 12

months to detect possible adverse events. The results will be analyzed by an international team of scientists, comparing the incidence rate of Covid-19 in the Ad5-nCoV vaccine group with that of the control group. The research sites report that all volunteers tolerate the vaccine well. A small number had a single low grade fever the day after vaccination, which would normally go away on its own or be easily treated with paracetamol. No serious adverse events or other abnormalities have been detected in any of the volunteers so far.

In August of 2020, OCT Clinical and Petrovax Pharm launched the local stage of the phase III clinical study of the Ad5-nCov vaccine candidate in Russia, with 500 volunteers vaccinated as a result.

"We all have been working hard to ensure the widest possible vaccination coverage for our population," said Dmitry Sharov, President, OCT Clinical. "The phase three clinical study is a key step in a comprehensive program to assess the safety and efficacy of the vaccine candidate against Covid-19."

#### Reference:

#### About OCT Clinical

OCT Clinical is the leading CRO in Russia, with operations in Central and Eastern Europe and the CIS region. With a team of over 200 professionals, the company provides a full range of high-quality clinical research services for phase I-IV and BE studies. With strong local expertise and focus on quality, OCT ensures seamless clinical trial conduct and drug registration on time and within budget. OCT's experienced team delivers both standalone services such as medical writing, consultancy, project management/monitoring, data management/biostatistics and turnkey service for clinical development. Since 2005, OCT Clinical Trials has worked on over 300 full-service and functional service projects in more than 20 therapeutic areas. OCT Clinical, a CRO operating in 12 countries, was selected as a principal CRO, responsible for the full range of activities for the vaccine trial in Russia, including regulatory and logistic support, project management, subject enrollment, site monitoring. Learn more at [www.OCT-ClinicalTrials.com](http://www.OCT-ClinicalTrials.com)

#### About CanSino Biologics Inc.

CanSinoBIO (SHSE: 688185, HKEX: 06185), founded in 2009, is dedicated to the research,

production and commercialization of innovative vaccines for China and global public health security. The company possesses four integrated platform technologies, including adenovirus-based vectors, conjugation, protein engineering, and recombination and formulation. As of today, it has established a robust pipeline of 16 vaccines covering 13 diseases, including a globally innovative Ebola virus vaccine approved in 2017 as well as the investigational Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector).

Additional information can be found online at [www.cansinotech.com](http://www.cansinotech.com)

#### About Petrovax

Petrovax is a Russian full-cycle biopharmaceutical company with a 20-year successful experience of operating in the pharma market. It is a Top-5 immunobiological manufacturer in Russia. Petrovax's product portfolio includes its own original pharmaceutical products and vaccines produced in cooperation with leading domestic and foreign companies, as well as generic products. The company's production operates in full compliance with Russian and international GMP and ISO: 9001 standards. A modern pharmaceutical production complex located in the Moscow region is one of the most high-tech biopharmaceutical facilities in Russia. The company exports the products to 12 countries, including the countries of the EAEU, the Middle East (Iran) and the EU (Slovakia). Additional information can be found online at [www.petrovax.ru](http://www.petrovax.ru)

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