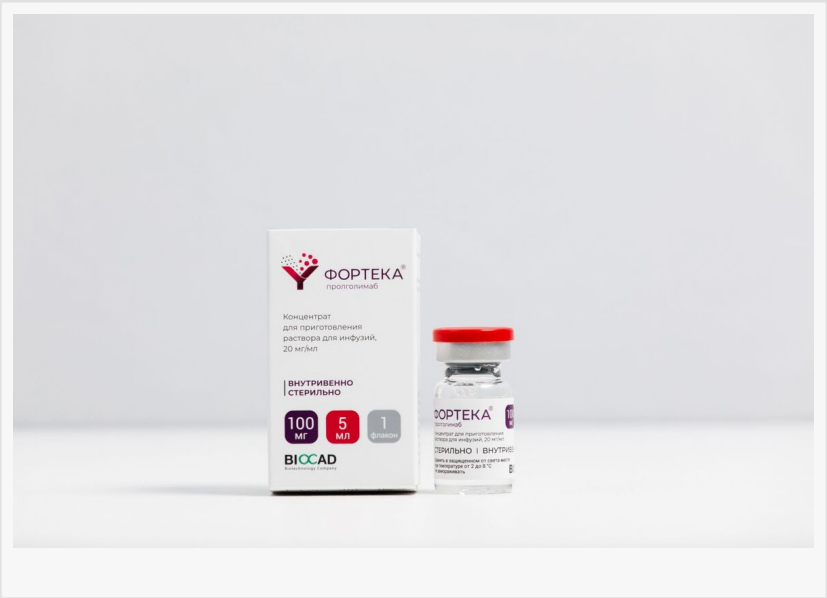
Clinical trial of an original Russian drug for the treatment of lung cancer starts in China



SAINT PETERBURG, RUSSIA, November 2, 2021 /EINPresswire.com/ -- A Joint Venture Company of BIOCAD and Shanghai Pharmaceuticals Holding announced the enrollment of the first Chinese patient in Phase III international multicenter clinical trial of prolgolimab. BCD-100-3/DOMAJOR is an international clinical trial of an original anti-PD1 check point inhibitor in patients with non-small cell lung cancer (NSCLC) by BIOCAD. The clinical trial in China is conducted by SPH-Biocad (HK) Ltd., the co-sponsor of the international clinical research program of prolgolimab. The drug is expected to be available to Chinese patients as early as in 2026.

The clinical trial in China was approved by the CDE of NMPA this February, and the final permission of HGRAC – Human Genetic Resource Administration of China - was obtained in July. The completion of the clinical trial is planned for the second half of 2025, which will allow the drug to be launched on the Chinese market in 2026.

"The Chinese market is very important for us for many reasons, primarily because of the efforts of the Chinese authorities to update and modernize the healthcare system," said Dmitry Morozov, CEO of BIOCAD biotech company. Assistance programs offered to citizens of the country for the treatment of cancer open up broad prospects for knowledge-intensive businesses around the world. It is also a matter of principle for us that this is our first experience of integrating the company's products in China, and we are grateful to Shanghai Pharmaceuticals Holding, our Chinese partner, for their well-coordinated efforts and sincere interest in cooperation. I hope that this partnership will expand over time, not limited only to the sales of drugs."

The BCD-100-3/DOMAJOR clinical trial is also simultaneously taking place in the European Union and in Russia and is an international multicenter, randomized, double-blind, placebo-controlled

clinical trial to evaluate the efficacy and safety of BCD-100 in combination with pemetrexed + cisplatin/carboplatin versus placebo in combination with pemetrexed + cisplatin/carboplatin as the first-line therapy for patients with non-small cell lung cancer. It is planned that the study will involve 88 patients from China diagnosed with lung cancer (NSCLC). At the end of the study, a dossier will be submitted for obtaining a registration certificate of the drug prolgolimab in the territory of the People's Republic of China.

In China, to be conducted another clinical trial of prolgolimab in patients with cervical cancer – BCD-100-5 / FERMATA. At least $20 million will be invested in both research in China. Total investment (including partners investments) in international multicenter clinical trials (MMCI) of prolgolimab will be more than $35 million.

Prolgolimab is a monoclonal antibody that binds the PD-1 programmed cell death receptor and blocks its interaction with PD-L1 and PD-L2 ligands. Prolgolimab is an immunoglobulin. The Fc fragment of prolgolimab was modified to prevent cytotoxic effects on target cells expressing PD-1. In Russia, prolgolimab is included in the list of vital and essential medicines (VED).

An increase in the number of studies of PD1/PDL1 inhibitors and their various combinations has been recorded in China, and the market itself demonstrates a significant demand for such inhibitors. Chinese experts estimate the market of PD1/PDL1 inhibitors in the five-year perspective to be more than 30 billion yuan annually ($4.7 billion). Thanks to the assistance programs in the country, Chinese patients pay a small part of the cost of drugs for cancer therapy, a large share of the costs is covered by the national health insurance fund of China that holds more than 2.44 trillion yuan ($373 billion) and so covers 95% of the country's residents.

About BIOCAD

BIOCAD is one of the largest innovative biotech companies in Russia. It brought together world-class R&D centers, modern pharmaceutical and biotechnological production, and preclinical and clinical trials, compliant with international standards.
BIOCAD is a full-cycle drug development company, from molecule search to mass production and marketing support. The drugs are intended for the treatment of oncological and autoimmune diseases. Present product portfolio includes 61 medical products, 22 of them are biological. Over 40 products are now in different development stages. Development of drugs for cancer therapy is one of the priorities of the company.
There are 2600 people working in BIOCAD, 1/3 of them are researchers and scientists.

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