Press release

**The first gene therapy trial in Slovenia was approved to treat cancer patients to the Institute of Oncology Ljubljana. Entire development and production of the therapeutic is result of domestic collaboration between research institutions and the industry.**

***Domestic industry and academic science put Slovenia on the gene therapy world map with the successfully completed SmartGene.si project***

**Ljubljana, 25 October 2021** - The Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) has approved a clinical trial to the SmartGene.si consortium for the head-and-neck cancer treatment with gene therapy. This makes the Institute of Oncology Ljubljana the first holder of a license to conduct a clinical trial with a novel genetic drug. The therapeutic, preparation and the entire production platform are result of Slovenian knowledge and experience of the project consortium. The SmartGene.si project lasted for more than three years and ended in September this year. In addition to the Institute of Oncology Ljubljana, which is the project applicant, the consortium included COBIK, Iskra PIO, JAFRAL and the Faculty of Electrical Engineering of the University of Ljubljana. The Faculty of Veterinary Medicine University of Ljubljana and the Department of Otorhinolaryngology and Cervicofacial Surgery of the University Medical Center Ljubljana (ORL clinic) also helped with the project realization.

The project was partially funded by the Republic of Slovenia and the European Regional Development Fund. **Dr. Matjaž Peterka, CEO of COBIK**: “We estimate that this is probably the most successful publicly co-funded project in the field of medicine and biotechnology in Slovenia. For the first time, we actually brought innovative therapies to people by developing technologies and an environment that enables the production of such advanced drugs and therapeutic approaches.”

**Prof. Dr. Gregor Serša, head of the Department of Experimental Oncology at the Institute of Oncology Ljubljana,** said,“A platform for the preparation of gene therapies has been established and a phase I clinical trial is starting, in which we will enroll the first patient. Patients will be treated with gene therapy by first injecting them with an interleukin-12 gene transcript, which will be delivered to the tumor cells by electrotransfer. The cells themselves will produce interleukin-12, which has the ability to stimulate the immune system and thus also has an anti-tumor effect.”

The SmartGene.si project is based on the long experience of all partners, improving the safety, efficiency and accessibility of gene therapy. This collaboration also increases the innovative capacity of domestic biotechnology environment.

The gene drug includes an interleukin-12 (IL-12) gene, which is incorporated into circular DNA backbone, called a plasmid. The novel manufacturing and purification processes of the therapeutic plasmid DNA were developed at the Centre of Excellence for Biosensors, Instrumentation and Process Control (COBIK). The established biotechnological processes enabled reliable production of highly pure therapeutic product. The developed procedures were transferred to consortium partners for final production at clinical grade and larger scale. COBIK is harnessing the developed plasmid DNA production platform to fulfill the increasing needs in biotechnology and the pharmaceutic industry.

“We have fully achieved the goal of the project, including the last piece of the puzzle, i.e., the receipt of JAZMP approval to conduct a clinical trial. The start of clinical trials is the first step towards the deployment of the therapy, and the project partners are already in the phase of raising funds for further clinical trials.” explain the project partners. The established production platform for the advanced gene drug opens new avenues for DNA- or RNA-based gene therapies and vaccines. This allows process development, production, preclinical and clinical testing for the domestic and global markets.

A genetic drug for the treatment of cancer, which is developed and produced exclusively on the basis of domestic knowledge, represents a major achievement in both biotechnology and science. Therefore, a symposium on the development and challenges of gene therapy in Slovenia will be jointly organized by the Slovenian Academy of Sciences and Arts (SAZU) and the SmartGene.si consortium at the end of November 2021.

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