

MaxiVAX and Minaris Regenerative Medicine Enter into a Manufacturing Partnership for MVX-ONCO-2 Cancer Immunotherapy

GENEVA, Switzerland and MUNICH, Germany – Feb 22, 2021 — MaxiVAX SA, a private Swiss clinical-stage biotech company developing novel anti-cancer vaccines, and Minaris Regenerative Medicine GmbH (“Minaris”), a leading contract development and manufacturing service provider for the cell and gene therapy industry, have entered into a manufacturing agreement for MVX-ONCO-2, a cell-based immunotherapy for the treatment of cancers such as chordoma, head and neck, and other solid tumors.

The MVX-ONCO-2 consists of two components: 1) biocompatible capsules, loaded with a genetically modified cell-line that secretes a strong immune-booster GM-CSF (granulocyte-macrophage stimulating factor) and 2) irradiated autologous patients’ tumor cells, isolated from patients which serve as tumor antigens. To induce an efficient anti-tumor response against the patients’ own tumor cells, the encapsulated GM-CSF secreting cells are implanted subcutaneously at the site of tumor-cell vaccination.

Minaris will be responsible for the GMP manufacturing, freezing and shipping of the MVX-ONCO-2 capsules, which will be delivered to clinical sites. The autologous patients’ tumor cells will be processed at the clinical sites.

The scope of the manufacturing agreement includes process development for scale-up and technology transfer with the goal of supplying Phase 2 and 3 clinical studies initially in the EU and eventually in the United States. Services will be performed at Minaris’ European site in Ottobrunn near Munich, Germany.

“We are excited to support MaxiVAX with their innovative product,” said Dusan Kosijer, CEO of the European operations of Minaris. “Their unique approach on cancer immunotherapies addresses a significant unmet medical need for patients with difficult-to-treat tumors.”

“We are confident that our partnership with Minaris will accelerate MaxiVAX’s breakthrough cancer immunotherapy development from clinical trial to market success,” said Ksenija Pavletic, an executive board member of MaxiVAX. “Minaris has the expertise and industry experience to enable the delivery of MaxiVAX’s innovative lead product MVX-ONCO-2 to the patients stringently and reliably.”

“Our mission is to develop life changing therapies. It can only be achieved if we manage to effectively deliver such therapies to our patients. In Minaris, we have found a partner that will not only help us in this aspect, but also in developing integrated manufacturing solutions and provide the appropriate infrastructure to support our future commercial production both in the US and in Europe,” added Julien Grogg, VP Technology of MaxiVAX.

The transfer of manufacturing process to an experienced CMO to generate commercial grade MVX-ONCO-2, also fulfills the first milestone obligation of MaxiVAX's European Commission H2020 funded project – "MaxONCO". In January 2020, MaxiVAX initiated a two- and half-year project under the SME Instrument Phase 2 H2020 Programme, for which MaxiVAX was awarded € 2,785,300. The SME Instrument supports high-potential small and medium-sized enterprises to help them develop and bring onto the market new innovative products, services and business models that could drive economic growth.

About Minaris Regenerative Medicine

Minaris Regenerative Medicine is a global contract development and manufacturing organization (CDMO) for cell and gene therapies. We offer our clients high value clinical and commercial manufacturing services, development solutions, and technologies. We are pioneers in the field with more than 20 years' experience providing outstanding quality and reliability. Our facilities in the US, Europe, and Asia allow us to supply patients worldwide with life-changing therapies. Minaris Regenerative Medicine is wholly owned by Showa Denko Materials Co., Ltd. For more information, please visit www.rm.minaris.com.

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About MaxiVAX

MaxiVAX is a Phase II clinical-stage biotechnology company advancing patient-specific immunomodulatory strategies for the treatment of cancers. The company has safely treated over 30 patients in Phase I clinical trial and initiated a 40-patient Phase II clinical trial in head and neck cancers in several clinical sites in Switzerland. The company successfully filed an IND with the US FDA in 2018 for chordoma Phase II trials in the US and EU. For more information, please visit <https://www.maxivax.ch/>.

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