Website address:
https://www.gesundheitsindustrie-bw.de/en/article/press-release/celonic-and-curevac-announce-agreement-manufacture-over-100-million-doses-curevacs-covid-19-vaccine-candidate-cvncov

Celonic and Curevac announce agreement to manufacture over 100 Million doses of Curevac's Covid-19 vaccine candidate, CVnCoV

CureVac N.V. (Nasdaq: CVAC), a biopharmaceutical company developing a new class of transformative medicines based on messenger ribonucleic acid (mRNA) and Celonic Group, a premium biopharmaceutical Contract Development and Manufacturing Organization (CDMO) specializing in the development and production of Advanced Therapy Medicinal Products (ATMPs) and mammalian cell line-expressed bio-therapeutics, today announced their partnership for the production of CureVac's mRNA-based COVID-19 vaccine candidate, CVnCoV.

The parties entered into a commercial supply agreement to produce CureVac's coronavirus vaccine candidate at Celonic's state-of-the-art commercial manufacturing facility for biologics and ATMPs, in Heidelberg, Germany. In total Celonic will be prepared to manufacture more than 100 million doses of CVnCoV. More than 50 million doses are expected to be produced before the end of 2021. Under the terms of the initial agreement, technology and knowledge transfer is already underway. The commercial supply agreement includes manufacturing of the mRNA drug substance as well as LNP formulation of the bulk drug product.

CureVac reaffirms an expected output capacity of its broad European manufacturing network of up to 300 million doses in 2021.

"Manufacturing of sufficient quantities of vaccine is critical to combating the COVID-19 pandemic," said Dr. Florian von der Mülbe, Chief Production Officer of CureVac. "With this partnership, we are further extending our integrated European manufacturing network, reinforcing the overall production capacity for our COVID-19 vaccine candidate, CVnCoV."

"Since the onset of the pandemic, Celonic has committed extensive breadth of complex bio-solutions development expertise and manufacturing resources to this global challenge," added Dr. Konstantin Matentzoglu, Chief Executive Officer of Celonic. "We have invested heavily to support our partners in bringing novel COVID-19 therapeutics and vaccines to patients, at an accelerated pace. Celonic is proud to collaborate with CureVac as part of an expansive manufacturing network in this global fight against COVID-19 by contributing to the production of its mRNA-based COVID-19 vaccine candidate, CVnCoV. With a dedicated and highly motivated team in place, Celonic is well positioned to have produced the first 50 million doses before end of 2021."

About CVnCoV

CureVac began development of mRNA-based COVID-19 vaccine candidates in January 2020. The vaccine candidate chosen for first clinical development, CVnCoV, is an optimized, non-chemically modified mRNA, encoding the prefusion stabilized full-length spike protein of the SARS-CoV-2 virus, and formulated within Lipid Nanoparticles (LNPs). Phase 1 and 2a clinical trials of CVnCoV began in June and September 2020, respectively. Phase 1 interim data reported in November 2020 showed that CVnCoV was generally well tolerated across all tested doses and induced strong antibody responses in addition to first indication of T cell activation. The quality of the immune response was comparable to recovered COVID-19 patients, closely mimicking the immune response after natural COVID-19 infection. In December 2020, CureVac initiated a pivotal Phase 2b/3, the HERALD study, with a 12µg dose of CVnCoV. In February 2021, CureVac initiated a rolling submission with the European Medicines Agency (EMA) for CVnCoV.

CureVac has entered into several strategic partnerships for the further development, production and commercialization of CVnCoV. The company signed a collaboration agreement with Bayer in January 2021 with regards to CureVac´s current CVnCoV currently in clinical Phase 2b/3. In February 2021, CureVac and the British pharmaceutical company GlaxoSmithKline (GSK) agreed to jointly develop next-generation mRNA vaccines against COVID-19. The development of new vaccine candidates is strengthened by a partnership with the UK Government and its Vaccines Taskforce, which CureVac also entered in February 2021.

About CureVac

CureVac is a global biopharmaceutical company in the field of messenger RNA (mRNA) technology, with more than 20 years of expertise in developing and optimizing the versatile biological molecule for medical purposes. The principle of CureVac's proprietary technology is the use of non-chemically modified mRNA as a data carrier to instruct the human body to produce its own proteins capable of fighting a broad range of diseases. Based on its proprietary technology, the Company has built a deep clinical pipeline across the areas of prophylactic vaccines, cancer therapies, antibody therapies, and the treatment of rare diseases. CureVac had its initial public offering on the New York Nasdaq in August 2020. It is headquartered in Tübingen, Germany, and employs more than 600 people at its sites in Tübingen, Frankfurt, and Boston, USA.

About Celonic

Celonic, a global contract development & manufacturing organization (CDMO) for innovative biopharmaceuticals, including cell and gene therapy products, is part of the private and independent family-owned company J.RETTENMAIER & Söhne (JRS-Group), with currently two production sites – in Basel, Switzerland (headquarters) and Heidelberg, Germany. Celonic provides comprehensive development and manufacturing services for biotherapeutics including cell line development, USP and DSP development, GMP and non-GMP manufacturing of biopharmaceutical drug substances and drug products, along with cell expression platforms and diagnostics. With a new state-of-the-art GMP manufacturing facility for gene vectors and cell therapy, Celonic is expanding its existing ATMP development and GMP manufacturing capacity in the upcoming Life Science Park Rheintal in Stein, Switzerland.

Press release

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Further information

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