

Press Release

ReiThera, LEUKOCARE and Univercells announce pan-European consortium for the fast-track development of a single-dose adenovirus-based COVID-19 vaccine

Rome, Munich and Brussels, April 23, 2020

Italian ReiThera Srl. (Rome), German LEUKOCARE AG (Munich), and Belgian Univercells S.A. (Brussels), today announced a strategic collaboration for the development and large-scale manufacturing of a novel adenoviral vector-based vaccine against COVID-19. The vaccine candidate is expected to enter clinical trials during summer 2020 with large-scale vaccine production planned to start soon after. The partners will contribute to the program combining their individual strengths and expertise to accelerate the development of the vaccine. In support of the fight against a long-lasting pandemic outbreak, the three European biotech companies have formed a pan-European consortium to pursue this strategy and develop a single-dose vaccine.

The current coronavirus (COVID-19) pandemic, caused by the novel coronavirus SARS-CoV-2, has imposed, in just four months, a massive global burden on humanity. To protect high-risk groups, contain the spread and manifestation of the disease as well as mitigate the burden on healthcare systems, a vaccine is urgently required to address the global need to protect people, communities and economies. Besides the challenge of developing a safe and protective vaccine, it is equally important to be able to manufacture billions of affordable vaccine doses in record time.

The pan-European consortium of ReiThera, LEUKOCARE and Univercells brings together a highly efficient and ultra-fast vaccine development group to address these challenges by combining their unique expertise in vector-based vaccine development, vaccine formulation and manufacturing, respectively.

The consortium partners are jointly boosting the development of an adenoviral vector-based vaccine candidate targeting the spike protein of SARS-CoV-2. The vaccine technology is based on a novel, ReiThera-proprietary simian adenoviral vector with strong immunological potency and low pre-existing immunity in humans. Vaccines based on simian adenoviral vectors have been extensively evaluated in Phase 1 and 2 clinical trials and proved to be safe and immunogenic. ReiThera is currently preparing for a COVID-19 first-in-human trial to be started in Italy in summer 2020.

In parallel to its clinical development, the consortium will start manufacturing and stockpiling the vaccine. With these pilot scale processes, approximately 6 million doses of the vaccine are expected to be available early in 2021. Based on the Phase 1/2 clinical results and a path agreed with regulatory authorities, the intention with these doses will be to vaccinate the most exposed people such as medical and healthcare professionals and highly vulnerable individuals.

LEUKOCARE contributes to the drug product development by developing a highly stable liquid vaccine formulation based on its well-established technology platform for formulations of viruses and viral vectors.

Univercells will capitalize on the previous successes of its scale-X™ bioreactor and NevoLine™ biomanufacturing platform to adapt and scale-up the technology platform and enable the mass production of ReiThera's vaccine candidate. Univercells will provide its highly efficient bioproduction platform for ultra-fast ramping up of GMP manufacturing of the adenoviral product. This NevoLine technology significantly reduces the infrastructure required for the production of vaccines while simplifying and automating operations.

Stefano Colloca, Chief Technology Officer of ReiThera stated: "Covid-19 has transformed our society on a global scale, and has had a devastating effect, particularly in Italy. We are very eager to answer the calls from our industry and society to join the global effort against this rapidly spreading virus. Our expertise and positive preclinical and clinical data on adenovirus-based vaccines, allows us to react to this unprecedented situation in a prompt and timely framework. We look forward to working with our partners, whose complementary expertise and capabilities will help this new consortium respond as quickly as possible to this global health emergency."

"By combining the experience of the partners, the advanced stages of this vaccine development will allow for a swift response to the COVID-19 pandemic. The LEUKOCARE team is perfectly prepared to contribute to this eminently important co-development", said Michael Scholl, Chief Executive Officer of LEUKOCARE. "Facing the current challenges, our approach for the fast and low-risk development of drug products with superior stability characteristics is even more important regarding timelines and social impact."

José Castillo, Chief Technology Officer of Univercells, added: "The world is facing a crisis never seen before and we are committed to doing our part to make a COVID-19 vaccine available and affordable as quickly as possible. We will adapt our bioproduction platform to the specific needs in record time and will ramp up manufacturing capacities at Univercells and third parties to answer this urgent need."

ReiThera Srl is a biotech company dedicated to the technology development, GMP manufacturing and clinical translation of genetic vaccines and medicinal products for advanced therapies. The company's management and scientific teams have developed a highly innovative technological platform based on simian adeno-vectored vaccines against several infectious diseases, such as RSV and Ebola.

ReiThera is led by an experienced management team that has worked together for many years in previous successful enterprises, including Okairos (acquired by GSK), and has a long-standing expertise in scalable processes for viral vector manufacturing, supported by a cGMP facility inclusive of filling suite and quality control laboratories.

ReiThera has its headquarters, R&D laboratories and GMP facilities in Rome, Italy.

For further information see: www.reithera.com

LEUKOCARE AG, located in Martinsried, Germany, is a biotech company specialized in the field of formulation development. LEUKOCARE develops superior formulations based on its pioneering SPS[®] formulation technology platform. The technology platform consists of two elements: a library of up to 100 different regulatory well-established and employed excipients and, moreover, a rational development approach which employs statistical software and self-learning algorithms as well as state of the art design of experiment (DoE) matrices. By utilizing these artificial intelligence elements, LEUKOCARE is able to specifically combine excipients to generate tailored formulations that meet both the drug product requirements and needs of the relevant target product profile (TPP).

LEUKOCARE's superior and innovative drug product formulations can be applied to a broad range of applications: biologics & biosimilars, vaccines & viral vectors and biofunctionalized devices.

For further information see: www.leukocare.com

Univercells is an innovative bioprocessing provider focused on increasing the availability of affordable biologics. Capitalizing on unmatched bioprocessing and engineering expertise, the company is offering leading-edge manufacturing solutions to alleviate the industry's current shortfall in supply of cell and gene therapies, vaccines and biotherapeutics. Univercells is dedicated to deliver technologies, services and turnkey solutions to accompany industry experts unlock and expedite critically needed therapies. A global company headquartered in Gosselies, Belgium, Univercells benefits from the support regional and national players as well as from the Bill & Melinda Gates Foundation (BMGF), Global Health Investment Fund (GHIF), European Investment Bank (EIB) and other international players in the health industry.

For further information see: www.univercells.com

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