PRESS RELEASE

ProBioGen and DIOSynVax Partner to Manufacture Groundbreaking Multivalent Vaccine for Hemorrhagic Fever

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ProBioGen, a globally recognized and experienced Contract Development & Manufacturing Organization (CDMO), proudly announces a partnership with DIOSynVax Ltd to manufacture DIOS-HFVac3, a trivalent hemorrhagic fever (HF) vaccine that was developed in collaboration with Prof. Wagners team (Molecular Virology, Institute of Medical Microbiology and Hygiene, University of Regensburg). The novel vaccine targets HF diseases caused by Ebola, Marburg, and Lassa viruses. Epidemics of viral hemorrhagic fevers are a major public health concern and a major economic burden. Especially the increase of simultaneous epidemics in low and middle-income African regions stresses the urgency of a multivalent vaccine produced on a production platform resilient against supply limitations. The pre-clinical efficacy of the novel trivalent vaccine has been demonstrated in challenge studies in animal models. ProBioGen's MVA CR19 vector will be used to deliver the three HF vaccine antigens.

DIOS-HFVac3 will be manufactured on ProBioGen's cutting-edge industrial platform, which was developed for the production of a broad range of viral vaccines. The platform consists of the company's proprietary AGE1.CR.pIX suspension cell line, proprietary chemically defined media and advanced scalable production and purification process. Under the terms of the agreement, ProBioGen will conduct process and analytical development followed by manufacturing of DIOS-HFVac3 for clinical trials and subsequent regulatory approval.

"Our collaboration with DIOSynVax represents a significant milestone in ProBioGen's journey," said Dr. Volker Sandig, Chief Scientific Officer at ProBioGen. "Our innovative platform for the manufacturing of DIOS-HFVac3 underscores our commitment to advancing robust and resilient biopharmaceutical solutions for global health challenges, independent of the geographic region where these challenges may occur."

This project marks the company's dedication to pioneering technologies and expanding its service value chain. "We are thrilled to embark on this transformative journey with DIOSynVax," stated Dr. Lutz Hilbrich, CEO of ProBioGen. "This partnership exemplifies our unwavering commitment to driving advancements in biopharmaceutical manufacturing and delivering life-saving therapies to those in need."

DIOSynVax's CEO Prof. Jonathan Heeney expressed confidence in the collaboration, emphasizing ProBioGen's role as a trusted partner. "We are delighted to continue our fruitful partnership with ProBioGen," stated DIOSynVax's CEO. "Their expertise, dedication, and collaborative spirit have been instrumental in our joint efforts. Together, we are poised to make a significant impact by bringing this vital vaccine to developing countries, mainly in Africa."

This research is funded by the Department of Health and Social Care as part of the UK Vaccine Network (UKVN), a UK Aid program to develop vaccines for diseases with epidemic potential in low and middle-income countries (LMICs).

About AGE1.CR.pIX®: Avian Cell Line Platform for Industrial Viral Vaccine Manufacturing

The AGE1.CR.pIX cell line is derived from primary cells of a duck embryo and is designed to comply with health authority guidelines. It was developed as an alternative to the use of chicken eggs for large-scale vaccine production. The AGE1.CR.pIX cell line grows in true suspension and has been optimized for viral vaccine production and stability. It grows in a commercially available, chemically defined medium without animal components and is an excellent host

for a variety of different virus strains, including different strains of attenuated poxviruses such as fowlpox virus, MVA and MVA CR19.

About MVA-CR19

MVA is a proven and save vector and the production of MVA in AGE1.CR.pIX® cell lines has significant advantages compared to the CEF platform. For example, the total yield of infectious units and the concentrations achieved where higher in preparations obtained with AGE1.CR.pIX® and cost of goods were lower.

Yet improved yields for reliable supply and reduced costs can be achieved with advanced MVAs adapted to modern production processes. One such vector is a novel strain of MVA that has been derived and fully sequenced by ProBioGen. ProBioGen and others could show that the MVA strain CR19 consistently replicate to very high titers (in the range of 10^9 IU/mL or above) in conventional stirred tank bioreactor processes, with or without intensivation by (for example) ATF. The CR19 strain is the well-known attenuated MVA that does not contain any ectopic or novel genes and does not replicate in human cells. Compared to conventional/ wild-type MVA, changes in MVA-CR19 can be summarized as loss of non-structural genes, increased gene doses for selected supportive genes, and longer inverted terminal repeats which may improve the function of the viral telomers.

Genomic stability of parental and recombinant MVA-CR19, parental wildtype and recombinant wildtype MVA, and novel vaccinia constructs have been demonstrated by serial passaging of multiple vector constructs in the AGE1.CR.pIX® production system. Stability of the karyotype and genetic markers of the AGE1.CR.pIX® cell line have also been demonstrated.

About DIOS-HFVac3

The DIOS-HFVac3 candidate vaccine delivers RNA- and codon optimized sequences encoding engineered antigens for increased breadth of protection derived from 3 different viruses - Ebola- and Marburg, and Lassa Fever viruses - via a poxviral vector, shown to protect from mpox infection and/or disease.

This vaccine candidate has shown impressive results in preclinical trials, demonstrating a robust immune response protecting relevant animal models from challenge with Ebola-Sudan, Marburg, or Lassa virus induced disease, making it a promising candidate in the fight against these important epidemic disease threats.

About the UK Vaccine Network:

The Department for Health and Social Care (DHSC) is the UK Government department which is responsible for helping people to live more independent, healthier lives for longer. This investment is part of the UK Vaccine Network (UKVN). UKVN was established to provide funding to support the development of promising vaccines and vaccine technologies that will help combat infectious diseases that have epidemic potential in low and middle-income countries (LMICs). UKVN is an UK Aid investment, which means all projects funded must support research primarily and directly for the benefit of people in low- and middle-income countries (LMICs).

About DIOSynVax

DIOSynVax is a clinical-stage biotech company specialising in the digital (computational) design and development of innovative vaccine antigens for expanded breadth of protection from variable viruses. Founded in 2017 as a spin-out from the University of Cambridge, DIOSynVax employs a multi-disciplinary team of experts in fields such as computational and structural biology, vaccinology, virology, immunology with clinical trial and regulatory expertise. This multidisciplinary approach allows DIOSynVax to address unmet needs and gaps in human vaccines, enhancing efficacy and broadening the scope of human health afforded by improved vaccines.

DIOSynVax's vaccine candidates are meticulously digitally engineered and designed antigens combined as vaccine antigen payloads, with safety and efficacy being paramount considerations in pre-clinical testing. Advanced machine learning (AI) strategies further enhance the company's capabilities, aiding in viral sequence analysis and vaccine candidate generation.

DIOSynVax operates from its base at the University of Cambridge's innovation-focused West Cambridge site, providing the company with access to top-tier talent and state-of-the-art facilities. For processes beyond its in-house capabilities, the company confidently engages with trusted CROs, ensuring timely and cost-effective delivery of its innovative solutions.

About ProBioGen (Business / Corporate)

ProBioGen is a premiere, Berlin-based specialist for developing and manufacturing biopharmaceutical active ingredients, viral vectors and vaccines with applying proprietary technologies to improve product quality and features. Combining both state-of-the-art development services, together with intelligent product-specific technologies yields biologics with optimized properties. Rapid and integrated cell line and process development, comprehensive analytical development and GMP-compliant manufacturing is performed by a highly skilled and experienced team. All services and technologies are embedded in a total quality management system to assure compliance with international ISO and GMP standards (EMA/FDA).

ProBioGen has been operational for almost 30 years. At four locations in Berlin, 300 employees contribute to the creation of new therapies in medicine and groundbreaking innovations worldwide through their creative and meticulous work. ProBioGen's growth strategy is driven by the expansion of the service value chain through organic growth and potential acquisition. Diversification is a complement driver, while the focus is strict on enabling the development of biopharmaceuticals for tomorrow.

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