PRESS RELEASE: Visit of His Majesty the King of the Belgians Philippe and Her Majesty the Queen of the Belgians Mathilde to Afrigen Biologics

Under embargo till March 25, 2 pm (CET)

Belgian Royal delegation visits the Afrigen facilities where Univercells and Etherna will be supporting the development of the first African-owned mRNA COVID-19 vaccine.

CAPE TOWN (SOUTH AFRICA) & BRUSSELS (BELGIUM), MARCH 25, 2023 – HM King Philippe and HM Queen Mathilde, currently on a state visit to South Africa until March 27, visited the Afrigen Biologics facility in Cape Town to learn more about how two Belgian companies, Univercells and Etherna, are supporting the development of the first African-developed mRNA COVID-19 vaccine. The King and The Queen are accompanied by five ministers of federal and regional governments, as well as a business delegation including several Belgian companies. The intention is to further discuss cooperation and partnership between the two countries and focus, among other things, on business and development.

Given the strong commitment from Belgium and the European Union towards supporting regional production autonomy in the region, and the fact that the mRNA Technology Transfer Programme co-led by the World Health Organization (WHO) and Medicines Patent Pool (MPP), is at the epicenter of this global effort, the Royal delegation made it a point to include a visit to Afrigen as part of their stay.

This royal visit takes place just one year after a visit from former Belgian Minister for Development Cooperation Meryame Kitir, who visited the premises with Dr. Tedros Adhanom Ghebreyesus, Director-General of WHO and virologist Marc Van Ranst, when looking for a key partner to develop a patent-free affordable vaccine against COVID-19. Belgium invested € 4 million in the mRNA Technology Transfer Programme in December 2021 an agreement was signed between Afrigen, Univercells Group and Etherna for the development of a novel mRNA vaccine in June 2022.

Quantoom Biosciences, a Univercells’ company, is leading the development of the mRNA production technology that encompasses all the steps of RNA production, from sequence construct to large scale production, allowing for rapid growth and scale-up. Dramatically more efficient than existing methods, it was built with distributed and de-centralized manufacturing in mind – ensuring that processes can be easily transferred across low- and middle-income countries (LMICs). Today, the project has delivered exceptional results based on the analytical characterization proven to be compliant to Critical Quality Attributes (CQA) specifications, allowing the company to transfer its process to Afrigen.

Afrigen and Univercells are supported in the collaboration by mRNA expert development partner Etherna. The company has enabled the development of the RNA production equipment and developed a thermostable COVID-19 vaccine and platform which enables distribution across the continent to even the remotest rural communities, an essential part of the collaboration, and is sharing the way this LNP formulation needs to be produced.
It is in this context that the King and the Queen decided to visit Afrigen and meet both Belgian companies and South African partners who are working together for the development of this milestone vaccine.

The Afrigen guided tour started in the production area, followed by the R&D department and laboratories. As part of the tour, each partner provided the delegation with an update on their involvement and the status of work.

As they were passing by the R&D facilities, Bernard Sagaert, interim Chief Executive Officer of Etherna, explained how the project is benefiting from Etherna’s technologies, at multiple levels and stages: “We are delighted to partner with Univercells and Afrigen Biologics on this important project by providing expert support and knowhow in all the key areas of mRNA vaccine development. The resulting vaccines validates our integrated approach using our unique skillset - from optimizing RNA payload, through formulation of the lipid nanoparticle delivery system to enhancing thermostability for mass manufacturing. This will allow for storage in normal fridges which are more accessible than -20 or -80°C freezers, especially in LMICs and significantly improve the prospects of making vaccines more accessible globally.”

José Castillo, co-founder of Univercells Group and CEO of Quantoom Biosciences continued: “Almost one year after signing the agreement we are thrilled to be back at Afrigen and meet all partners to discuss the progress and project deliverables. Over the last months, three batched of RNA were produced and Quantoom’s Ntensify™ midi system will be delivered at Afrigen within the next weeks.”

Petro Terblanche, Afrigen Chief Executive Officer, declared: “The COVID-19 pandemic has shown that there is a pressing need to build sustainable capabilities in vaccine development and manufacturing in African and other LMICs. I am thrilled to see how the project is moving forward bringing cutting edge technology to Afrigen to integrate into the technology and manufacturing platforms we are building and transferring to partners in Africa and other LMICs. This is driven by our quest for enabling access to life-saving vaccines and medicines for the people living in the global South.”

Charles Gore, Medicines Patent Pool, added: “Since the start of the mRNA Technology Transfer Programme in June 2021, it is impressive to see the amazing developments here at Afrigen and all that has been achieved in mRNA vaccine development. None of it would have been possible without the Programme funders, and I particularly want to thank the Kingdom of Belgium for their support from the outset of the project. ”

Dr Owen Kaluwa, World Health Organization, concluded: “ The mRNA Technology Transfer Programme is built on partnerships and working closely will leading technologies and experts is essential. Through this cutting-edge technology that has been developed with LMICs in mind, and that provides an inclusive solution, Afrigen with the support of Quantoom and eTheRNA can ow move rapidly to the next phase of mRNA vaccine development. It is still WHO firm belief that a more widely distributed access to technologies and vaccine manufacturing capacity will reduce the gap in making vaccines available promptly for
everyone, everywhere and accelerates the impact of the necessary collective effort to control outbreaks.”

CONCLUSION

Next steps include receiving the Quantoom’s Ntensify™ midi system in Afrigen, and eTheRNA’s proprietary lipid to enable Afrigen to replicate the production of mRNA drug substance and drug product according to Quantoom and eTheRNA’s processes, respectively.

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Contacts

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*** About Afrigen ***

Afrigen Biologics and Vaccines is a Cape Town based biotechnology company strategically directed, supported, and capitalized by Avacare Healthcare Group and the Industrial Development Corporation (IDC) of South Africa. It was founded in 2014 by Steven G. Reed (PhD) and Erik Iverson (JD, LLM), both of the Infectious Diseases Research Institute (IDRI) in Seattle. Afrigen drives a business strategy focussing on product development, bulk adjuvant manufacturing, and supply and distribution of key biologicals to address unmet healthcare needs. Through international partnerships and local capacity building, Afrigen has established the first ever adjuvant production and formulation technology centre on the African continent. In June 2021 Afrigen was designated by the WHO to host the global mRNA vaccine technology transfer Hub. The Hub at Afrigen is developing end-to-end mRNA vaccine research, development, manufacturing and delivering capacity and capabilities for transfer to LMICs. The WHO programme is working with global health partners to create a sustainable model for vaccine production and pandemic preparedness particularly in regions of the world that is vulnerable. Afrigen Biologics’s first mRNA vaccine (Covid 19 vaccine candidate) is currently in pre-clinical development and is preparing for its GMP certification for end to end vaccine production.

www.afrigen.co.za

*** About Univercells ***

Univercells is a global life sciences company with the mission of making biologics accessible to all. Using our combined expertise in scaling, production, and bioprocessing, Univercells finds new and sustainable ways to widen access to life-changing drugs. Our affiliate companies deploy innovations in infrastructure, drug substance manufacturing, equipment manufacturing, equipment design, training, and on-the-ground health services to drive down costs, shrink manufacturing footprints and meet the needs of the entire health value chain. Headquartered in Jumet (Belgium), Univercells is supported by regional and national investors, as well as international investors active in vaccines and healthcare, such as the European Investment Bank and Global Health Investment Fund, among others. Quantoom Biosciences, a Univercells company, is focused on mRNA.

www.univercells.com

*** About Etherna ***

Etherna is an mRNA technology discovery and development company with a full platform of integrated capabilities including: mRNA construct design and optimization; proprietary lipid nanoparticle (LNP) formulations which have demonstrated organ-specific distribution preclinically; process development and manufacturing capabilities for mRNA drug substance
(gram GMP scale); and proprietary LNP / final product formulation technologies, including a lyophilized thermostable formulation in advanced development. With a focus on immune modulation and T Cell stimulation, Etherna is pursuing internal development programs to validate its core technologies and enable strategic partnerships in a range of geographic markets and therapeutic areas. Etherna is backed by a global syndicate of leading investors and is headquartered in Belgium with offices in New York and Hong Kong.

*** Disclosure Statement ***

The contents of this announcement include statements that are, or may be deemed to be, “forward-looking statements”. These forward-looking statements can be identified using forward-looking terminology, including the words “believes”, “estimates,” “anticipates”, “expects”, “intends”, “may”, “will”, “plans”, “continue”, “ongoing”, “potential”, “predict”, “project”, “target”, “seek” or “should”, and include statements the Company makes concerning the intended results of its strategy. By their nature, forward-looking statements involve risks and uncertainties, and readers are cautioned that any such forward-looking statements are not guarantees of future performance. The Company’s actual results may differ materially from those predicted by the forward-looking statements. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.