US$21 million investment brings molecular diagnostic testing for COVID-19 and other infectious diseases closer to patients in low- and middle-income countries

- **FIND is investing a total of US$21 million in Biomeme, Bioneer, Qlife and SD Biosensor, following an open call for proposals to accelerate the development, manufacturing, and launch of affordable point-of-care molecular diagnostic platforms that can detect multiple pathogens that cause diseases including COVID-19, in low- and middle-income countries**
- **These investments are being funded by the German Federal Ministry of Education and Research (BMBF) through KfW and other donors, in the context of the Access to COVID-19 Tools (ACT) Accelerator diagnostics pillar, which FIND co-leads**

GENEVA, SWITZERLAND – 20 December 2021. FIND, the global alliance for diagnostics, announced today an investment of US$21 million to accelerate the development, manufacturing, and launch of affordable, multi-pathogen, molecular diagnostic platforms, specifically for use in decentralized settings in low- and middle-income countries (LMICs). Following an open call for partners and a competitive selection process, four companies with promising new platforms have been selected for investment: Biomeme, Inc (USA), Bioneer Corporation (Republic of Korea), Qlife Holding AB (Sweden) and SD Biosensor, Inc (Republic of Korea).

The request for proposals (RFP) process was launched by FIND in August 2021, in the context of the Access to COVID-19 Tools (ACT) Accelerator diagnostics pillar, which FIND co-leads. The diagnostics goals of the ACT-Accelerator Strategy and Budget, refreshed in October 2021, are to: i) advance COVID-19 testing rates to a minimum of 1 test per 1000 people per day; ii) track the evolving epidemiology of the virus, including new variants; and iii) optimize the use of tests to control the pandemic. This RFP aimed to support the ACT-Accelerator strategy by identifying platforms that will increase access to testing: the development and market entrance of accurate, affordable, multi-pathogen, point-of-care molecular tests that differentiate between COVID-19 and other respiratory pathogens.

In total, 47 companies responded to the call, and a shortlist of 13 was reviewed by a panel of external experts appointed by FIND. Criteria for the awards included the technical performance of the platform, their added value to the diagnostics market, suitability for use in decentralized settings, and affordability for LMICs.

Following a due diligence process, four companies have now been selected. Collectively, these technologies could fill critical gaps across different healthcare settings in LMICs. The aims are to diversify the platforms available in district hospitals and other Level 2 facilities, and to broaden access to testing in places that are close and convenient for patients. With COVID-19 highlighting

the chronic lack of equitable access to tests, all companies have agreed to accessible pricing terms for LMICs so that these aims might be achieved.

The investment announced today is funded by the German Federal Ministry of Education and Research (BMBF) through KfW and other donors, by way of grants to FIND. It will support the companies for a period of 12 months to develop assays for the differential diagnosis of COVID-19 and other respiratory pathogens (such as influenza) and to optimize their systems to meet the needs of LMICs, in addition to the requirements for authorization under the World Health Organization (WHO) emergency use listing (EUL) and/or prequalification process (PQ). The funds will also support the companies' manufacturing processes, to enable price reductions and increased volumes, and support regulatory submissions.

The molecular diagnostic systems being developed by SD Biosensor and Bioneer are suited for use in Level 2 settings. They are both designed for rapid and accurate diagnosis, and have high multiplexing capacity, to enable detection of multiple diseases in a single test (potential for up to 12 targets for SD Biosensor, and up to 40 for Bioneer). Both companies are planning to validate assays for tuberculosis on the same platform.

SD Biosensor has committed to public sector prices for LMICs of less than US$10 for their COVID-19 test run on the STANDARD M10 platform, which is already CE marked, and less than US$15 for a COVID-19/flu/RSV test that is in development (both prices "ex works" [EXW]). Bioneer will also develop a COVID-19/flu/RSV test for use on their IRON-qPCR platform at a target end-user purchase price (EXW plus distribution and service warranty, but exclusive of customs and import fees and taxes) of less than US$15 in LMICs.

Biomeme and Qlife are developing platforms that target primary care settings (Level 1 and Level 2). Both of these platforms include highly portable, easy-to-use instruments. While the Biomeme automated sample-to-answer platform has the potential to identify up to 27 target pathogens in a single-test, the Qlife platform promises to run other types of assays, such as immunoassays and chemistry assays, using the same instrument.

Biomeme has committed to target prices starting at under US$14 in LMICs for its COVID-19/flu test currently in development; this price could reduce to under US$11 with increased manufacturing volumes (EXW). Qlife will also develop a COVID-19/flu test for its Egoo.Health platform, which has already received CE mark for its COVID-19 assay, and intends to offer the COVID-19/flu test to LMICs at under US$15, with the goal of reducing the price to under US$10 as manufacturing capacity ramps up (both final end-user purchase prices, being EXW plus distribution and service warranty, but exclusive of customs and import fees and taxes).

All of the companies are aiming to complete product development of the multi-respiratory pathogen tests by late 2022 with a view to commercial launch of the products in 2023. All companies have committed to the submission of regulatory dossiers for evaluation by WHO EUL/PQ, as well as transparency in their cost structure.

Max Perelman, Biomeme Co-Founder, said: "Over the last decade, Biomeme has developed a vertically integrated company that includes assay design, software and hardware R&D, reagent lyophilization, consumables and equipment manufacturing, as well as distributed lab testing services. Our newest decentralized molecular testing platform is designed with the vision to deliver point-of-care diagnostic testing to anyone, anywhere. The support of FIND and the ACT-Accelerator will help us realize that vision. While our immediate goals focus on SARS-CoV-2 and other respiratory viral pathogens, Biomeme aspires to deliver a diverse array of pathogen detection tests and host immune response tests to the world that will answer pressing clinical problems focused on viral infections, tuberculosis, mosquito- and tick-borne infections, and strategies to distinguish bacterial from viral infection."

Han-Oh Park, Founder & CEO of Bioneer, said: "BIONEER is fully prepared for large scale production of the Iron-qPCR system, with the Global Center that opened up last month. We see this as a great opportunity to move forward with deals at the country level in LMICs. BIONEER will target the global molecular diagnostics market with Iron-qPCR at the forefront."

Thomas Warthoe, CEO of Qlife, said: "It is a unique opportunity for Qlife to enter into a partnership with FIND of this scale. We will be able to participate in making a difference to people and communities in these countries in the near term. We are excited to put our specialist knowledge to work in developing a two-in-one respiratory assay."

Taylor Heo, CEO of SD Biosensor, said: "We are very pleased to offer STANDARD M10 at an affordable price to many low-and middle income countries through this investment from FIND. We hope that the M10, which is an innovative point-of-care molecular diagnostic platform, will help many patients who are suffering from respiratory disease, including COVID-19."

Marta Fernández Suárez, Chief Technology Officer of FIND, said: "These investments create a major opportunity for these new market entrants to serve LMICs while kick-starting a pipeline of critical point-of-care molecular diagnostics. Given the multi-pathogen capabilities of these tools, we also expect to see increased access to other essential molecular tests, such as those used in the diagnosis and management of HIV and tuberculosis, and strengthened local disease surveillance systems. This new generation of point-of-care molecular diagnostic platforms has the potential to transform healthcare delivery in LMICs for COVID-19 and beyond."

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countries. The ACT Accelerator partnership was formed at the onset of the pandemic in response to a call from G20 leaders, and was launched by WHO, the European Commission, France, and the Bill & Melinda Gates Foundation.

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