

Support package including US\$7 million investment accelerates availability of affordable COVID-19 self-tests in low- and middle-income countries

- FIND is providing ACON Biotech (Hangzhou) Co. Ltd, Osang Healthcare, Jiangsu Bioperfectus Technologies Co. Ltd, and Premier Medical Corporation with a support package that includes total funding of US\$7 million, following an open call for proposals to accelerate the availability of affordable SARS-CoV-2 self-tests in low- and middle-income countries (LMICs)
- FIND will also conduct independent clinical evaluations of the performance of these selftests
- The companies have committed to manufacturing up to 60 million COVID-19 self-tests per month and making them available to LMICs at \$1.00-\$2.00 per test
- The 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 – 24 February 2022. FIND, the global alliance for diagnostics, announced today a support package that includes a total investment of US\$7 million alongside technical assistance and clinical evaluations to accelerate the availability of affordable SARS-CoV-2 self-tests in low- and middle-income countries (LMICs). Following an open call for partners and a competitive selection process, contracts with the following companies have now been finalized: <u>ACON Biotech (Hangzhou) Co. Ltd</u> (China), <u>Osang Healthcare</u> (Republic of Korea), <u>Jiangsu BioPerfectus Technologies Co. Ltd</u> (China) and <u>Premier Medical Corporation</u> (India).

The request for proposals (RFP) process was launched by FIND in March 2021, in the context of the Access to COVID-19 Tools (ACT) Accelerator diagnostics pillar, which FIND co-leads. The diagnostics goals of the <u>ACT-Accelerator Strategy and Budget</u> include strengthening capacity for countries to expand access to COVID-19 testing, based on strategies to reach people where they live, work, and seek care, such as decentralized community-based testing and self-testing.

This RFP was launched in response to overburdened healthcare systems in LMICs, and the realization that an urgent step change in the use of diagnostics was needed to narrow the global equity gap. Reducing this gap requires strengthening existing testing models and expanding genomic sequencing efforts, while also implementing new, decentralized, community-based testing models, including in non-traditional settings, such as schools and workplaces, and at border crossings. While self-testing is now a mainstay of pandemic control in many high-income countries, only a limited number of LMICs are implementing it due to a lack of affordable, quality

assured self-tests, and clear guidance on when and how to use the tests, as well as what to do following test results.

Over 80 applicants responded to the RFP, and a shortlist of 26 companies was reviewed by a panel of external experts appointed by FIND. Criteria for the awards included the technical performance of the test, suitability for self-administration, and affordability for LMICs.

Following a due diligence process, contracts with four companies have now been finalized, all of which have COVID-19 self-tests in the final stages of commercial development. Additional partnerships are expected to be announced in the coming weeks.

The investment is funded by the German Federal Ministry of Education and Research (BMBF) through KfW and other donors, by way of grants to FIND. FIND will supplement this financial investment with technical support, and will conduct an independent evaluation of the performance and usability of the tests in the settings of intended use. All support is dependent on a series of mutually agreed project milestones being successfully met.

The World Health Organization (WHO) is currently drafting guidance on SARS-CoV-2 self-testing; data from the evaluations will be provided to WHO to support the development of global policy guidance and potential future regulatory submissions.

All four companies have either launched or are ready for commercial launch of their self-tests, and have committed to the submission of regulatory dossiers for evaluation by WHO if/when possible, as well as transparency in their cost structure.

ACON Biotech has committed to a price of US\$1.00 "ex-works" (EXW) for their Flowflex™ SARS-CoV-2 Antigen Rapid Test, with a minimum volume commitment of 30 million tests per month to be made available in LMICs.

Osang Healthcare has committed to a price of US\$1.25 EXW for their GeneFinder[™] COVID-19 Ag Self Test, with a minimum volume commitment of 10 million tests per month to be made available in LMICs.

Jiangsu Bioperfectus Technologies Co. Ltd has committed to a price of US\$1.25 EXW for their bioPerfectus COVID-19 Ag Self-test Kit, with a minimum volume commitment of 10 million tests per month to be made available in LMICs.

Premier Medical Corporation has committed to a price of less than US\$2.00 EXW including distribution margin for their SureStatus[®] COVID-19 Home Test, with a minimum volume commitment of 10 million tests per month to be made available in LMICs.

Winston Chen, General Manager of ACON Biotech, said: "It is a great honor to work with FIND for the ACT-Accelerator diagnostics pillar, and we believe ACON could help people in LMICs to access high quality COVID-19 self-tests at an affordable price through this partnership. With their reliable performance, our Flowflex SARS-CoV-2 Antigen Rapid Tests have contributed a lot in the

fight against the pandemic in the past 2 years. ACON is committed to developing and providing high-quality tests continuously to the world, especially to developing countries."

Seung-Euk Hong, CEO of Osang Healthcare, said: "We are privileged to be a part of this FIND project. Our commitment at Osang Healthcare is to contribute to LMICs by supplying quality assured and affordable self-testing. We hope that all our efforts and dedication will help overcome the COVID-19 pandemic and eventually narrow the equity gap in the world in partnership with FIND."

Jin Wei, General Manager, R&D Center of Jiangsu Bioperfectus Technologies Co. Ltd, said: "We are very honoured to cooperate with FIND to bridge the gap between the LMICs and HICs (highincome countries) in COVID-19 self-testing. With more than ten years of experience in the global in-vitro diagnostic market for infectious diseases, Bioperfectus is pleased to participate in the ACT-Accelerator campaign and provide easy-to-use, accurate, and affordable self-testing kits for COVID-19. The cooperation means a lot to us and bolsters efforts in future R&D, manufacturing, quality control, sales & marketing of the COVID-19 self-testing kits."

Nilesh Mehta, CEO of Premier Medical Corporation, said: "As a global leader in rapid diagnostics for 25 years, we at Premier Medical Corporation understand the enormous positive consequences that high-quality and affordable diagnostics can provide to LMICs. We have always been committed to breaking the healthcare barriers in LMICs, and are proud to partner with FIND in helping us achieve that goal. Self-testing is an extremely important tool in long-term healthcare for all individuals, from all backgrounds, and we are extremely happy to help in bringing that vision to life."

Marta Fernández Suárez, Chief Technology Officer of FIND, said: "Self-testing can uniquely empower people to take control of their health, and has proved an important tool in the pandemic response in the Global North – but multiple barriers to access in LMICs means the Global South is being left behind yet again. The packages that these four companies are committing to are a major step towards making self-testing more accessible in LMICs, with volume commitments totalling at least 60 million tests per month and EXW pricing that is half that of current HIV self-tests."

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About FIND

FIND, the global alliance for diagnostics, seeks to ensure equitable access to reliable diagnosis around the world. We connect countries and communities, funders, decision-makers, healthcare providers and developers to spur diagnostic innovation and make testing an integral part of sustainable, resilient health systems. We are working to save 1 million lives through accessible, quality diagnosis, and save US\$1 billion in healthcare costs to patients and health systems. We are co-convener of the Access to COVID-19 Tools (ACT) Accelerator diagnostics pillar, and a WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation. For more information, please visit www.finddx.org

About the ACT-Accelerator

The <u>Access to COVID-19 Tools (ACT) Accelerator</u> is a global coalition of organizations developing and deploying the new diagnostics, treatments and vaccines needed to end the acute phase of the pandemic. Pooling the expertise of its many partners, the ACT-Accelerator has quickly ushered in rapid, affordable tests and effective medicines for low and middle-income countries and established the COVAX facility for the equitable procurement and distribution of vaccines in low- and lower-middle-income 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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