FOLLOWING CE MARKING, STUDIES NOW UNDERWAY TO SUPPORT LOCAL REGISTRATION OF FIRST COMBINATION TEST TO IDENTIFY MALARIA AS WELL AS POSSIBLE BACTERIAL INFECTION

- **STANDARD™ Q Malaria/CRP Duo Test can simultaneously detect malaria infection and elevated levels of C-reactive protein (CRP) from a fingerprick blood sample**
- **This rapid diagnostic test has the potential to guide appropriate prescription of anti-malarial drugs and antibiotics, transforming care of patients presenting with fever in resource-poor settings and contributing to the fight against antimicrobial resistance**
- **Following the CE marking, test performance in settings of intended use is now being assessed to support local regulatory submissions**

Suwon-si, Republic of Korea & Geneva, Switzerland – 24 April 2019 – SD Biosensor Inc. and the Foundation for Innovative New Diagnostics (FIND) announced today, ahead of World Malaria Day 2019, that following the CE marking of the STANDARD™ Q Malaria/CRP Duo Test, the test is now being evaluated in settings of intended use to support local regulatory submissions. The STANDARD™ Q Malaria/CRP Duo Test is a rapid diagnostic test (RDT) that can simultaneously detect malaria infection and C-reactive protein (CRP) from a fingerprick blood sample. Such an RDT would facilitate better management of fever in malaria elimination settings by offering healthcare workers a single, low-cost test that can determine whether a fever is due to malaria, or potentially due to a bacterial infection, to support clinician decision-making for prescribing and referral.

Malaria is an urgent public health threat high on the global health agenda, with nearly half of the world's population at risk for the disease.[1] Diagnostics are crucial to global elimination efforts, for surveillance, case detection and to ensure that patients benefit from the appropriate treatment so they can be cured and the chain of transmission can be broken. However, in the case of a malaria-negative test result, there is currently no integrated test that could also differentiate bacterial from non-bacterial infections and guide treatment decisions – especially in support of rational antibiotic prescription.[2] As global malaria elimination efforts gain ground and the number of negative malaria tests increases, information on the cause of fever in malaria-free patients will become even more important for clinicians.

CRP is a biomarker routinely used for triage in high-income countries, to effectively identify bacterial versus non-bacterial infections. Recent studies from Thailand, Myanmar and Vietnam have shown that CRP is a suitable marker to guide antibiotic prescribing (at a cutoff of 20–40 mg/L).[3,4] Hence, a combination malaria-CRP test would be a useful alternative to a malaria-only test in the low-malaria transmission setting of South East Asia, where the people presenting with fever but who are actually malaria-negative outnumber those who are malaria-positive. An RDT that combines both malaria and CRP testing can be used at the point-of-care to allow clinicians to identify malaria while simultaneously indicating whether or not an antibiotic may be needed to treat a bacterial infection.

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[1] World Health Organization. 10 facts on malaria, 2016. https://www.who.int/features/factfiles/malaria/en/ (accessed 10 April 2019)
[2] Johannson *et al*. *Mal J* 2016;15:396
[3] Lubell *et al*. *BMC Inf Dis* 2015;15:511
[4] Althaus *et al*. *Lancet Glob Health* 2019;7: e119–31

SD Biosensor and FIND partnered to develop the STANDARD™ Q Malaria/CRP Duo Test for the simultaneous diagnosis of malaria and detection of CRP at a cutoff of 20 mg/L, specifically designed for low malaria-transmission settings in Asia. The CE marking is an important step in making the test available, and FIND is now evaluating the technical performance of the test in a prospective clinical trial being conducted in India (North-East, South and Central).

“We are glad to cooperate with FIND. We believe the STANDARD™ Q Malaria/CRP Duo Test can be effectively used to fight against both malaria and antibiotic resistance,” said Taylor Hor, Vice President of SD Biosensor.

“Patients present at health facilities because they have fever, whether or not the cause is malaria,” said Catharina Boehme, CEO of FIND. “Identifying the cause of that fever is critical, to ensure that every patient receives the most appropriate care and that unnecessary, ineffective prescription of antibiotics is avoided. As global malaria elimination efforts gain ground, effective care of those people who are not malaria positive is only becoming more important.”

Data from the clinical evaluation in India will be available later in 2019.

FIND’s contribution to this initiative was supported by Australian aid and UK aid from the British people.

About SD Biosensor, Inc

SD Biosensor (“SDB”) is a South Korean IVD manufacturer. SD Biosensor offers various product portfolio such as glucometers and strips, ELISA, rapid diagnostic test, fluorescent immunoassay, G6PD point-of-care test etc. SDB is now developing RT-PCR platform that will be launched soon, Infectious and tropical diseases have been SDB’s interest for many years. Especially SDB’s STANDARD™ Q Malaria Pf, STANDARD™ Q Malaria Pf/Pv and STANDARD™ Q Malaria Pf /Pan are under review by WHO for Prequalification process. SDB has been actively developing innovative diagnostics such as STANDARD™ Q Arbo Panel I (Multiplex RDT for detection of different infections by ZIKV, DENV, CHIKV and YFV), STANDARD™ Q HIV/Syphilis Combo (Simultaneous diagnosis of HIV and Syphilis), STANDARD™ G6PD Test (Quantitative Point-of-care test of G6PD and Total Hemoglobin). Further information can be found on the website www.sdbiosensor.com/xe

About FIND

FIND is a global non-profit organization that drives innovation in the development and delivery of diagnostics to combat major diseases affecting the world's poorest populations. Our work bridges R&D to access, overcoming scientific barriers to technology development; generating evidence for regulators and policy-makers; addressing market failures; and enabling accelerated uptake and access to diagnostics in low- and middle-income countries (LMICs). Since 2003, we have been instrumental in the development of 24 new diagnostic tools. Over 50 million FIND-supported products have been provided to 150 LMICs since the start of 2015. A WHO Collaborating Centre, we work with more than 200 academic, industry, governmental, and civil society partners worldwide, on over 70 active projects that cross six priority disease areas. FIND is committed to a future in which diagnostics underpin treatment decisions and provide the foundation for disease surveillance, control and prevention. For more information, please visit www.finddx.org

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