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Value from Innovation

Fujifilm and FIND[*1] to Receive JPY420 Million Additional Funding from Global Health Innovative Technology Fund[*2] for the development of the Highly Sensitive Rapid Tuberculosis Diagnosis Kit for Developing Countries

September 27, 2018

FUJIFILM Corporation (President: Kenji Sukeno) is delighted to announce that the Global Health Innovative Technology Fund (GHIT Fund) has decided to provide JPY420 million in additional funding for the development of highly sensitive rapid tuberculosis (TB) diagnosis kit. Together with joint development partner FIND (Foundation for Innovative New Diagnostics), a Swiss non-profit organization, Fujifilm is working towards the early receipt of a recommendation from the World Health Organization (WHO) through efforts to acquire the European CE marking certification as well as through the accelerated implementation of large prospective clinical evaluations in developing countries.

TB is one of the world's 3 major infectious diseases[*3] infecting 10.4 million people, and causing the death of 1.7 million people[*4] annually around the world. Of all TB patients, 86% are living in developing countries in Africa and Southeast Asia[*4]. TB infections have a serious impact on the societies and economic activities of these countries due to the ongoing spread of the disease and the cost of medical treatment for patients. In parts of Africa, where comparatively large numbers of people are immuno-compromised due to HIV infections, the rates of TB among people living with HIV is between 20 and 30 times greater than among healthy populations, and co-infection with tuberculosis accounts for 40% of deaths among HIV-positive patients[*4]. Furthermore, patients infected with both HIV and TB frequently become seriously ill. As such, timely diagnosis and early drug intervention is crucial.

The most common method for diagnosing TB is to analyze a specimen of the patient's sputum, but data shows that in the case of HIV-positive patients showing symptoms of TB, collection of sputum is not possible in between about 20% and 60% of patients[*5]. In addition, many HIV-positive patients develop extra-pulmonary TB, a TB infection that affects an area other than the lungs. As TB symptoms vary depending on the location of the disease within the body, disease detection relying on sputum known as a typical symptom of pulmonary TB might result in insufficient diagnoses of extra-pulmonary TB.

Under the United Nations' Sustainable Development Goals (SDGs) and End TB Strategy, the United Nations is committed to reducing rates of TB mortality by 90% and rates of TB infection by 80%[*4] by 2030, the year in which the SDGs are set to be achieved. In order to achieve this goal, it is essential to develop a non-sputum based, rapid, effective diagnostic tool which can be used in the lower and middle-income countries that account for more than 95% of TB mortality[*6], and which is, in particular, effective for use with HIV-positive patients.

In April 2016, Fujifilm and FIND, following the receipt of a subsidy of JPY220 million from the GHIT Fund, accelerated the development of a rapid TB diagnosis kit with the aim of detecting LAM (lipoarabinomannan)[*7], a compound characteristically produced by Mycobacterium tuberculosis, in the urine. The kit makes use of high-sensitivity virus detection technology, a technology developed by harnessing Fujifilm's proprietary silver halide amplification

technology[*8]. The kit requires no special equipment. Applying the urine sample to a cartridge is sufficient to achieve a simple on-the-spot[*9] test for the presence or absence of Mycobacterium tuberculosis. As such the kit is suitable for use in developing countries with unstable power transmission infrastructure.

In May this year, FIND and other organizations conducted a clinical study of the kit in South Africa[*10], and the kit achieved the targeted diagnostic performance[*11]. Following these results, the GHIT Fund decided to grant an additional subsidy of JPY420 million to continue research and development of the diagnosis kit. Fujifilm and FIND are committed to continuing with further clinical studies in developing countries, with the aim of accelerating preparation towards mass production of the product in order to acquire the European CE marking certification, and finally recommendation from the WHO.

Fujifilm has already developed a "highly sensitive immunochromatography[*12] influenza diagnosis system" capable of detecting the influenza virus with a high sensitivity. This product was launched in Japan in October 2011. This system uses two different types of antibodies in order to identify whether or not the influenza virus is present. The system is easy to operate and produces results within 3.5 to 15 minutes. By harnessing the sliver amplification technology originally developed by Fujifilm for processing photographs, this technique allows for approximately 100 times increased sensitivity compared with visual diagnostic kit[*13]. The development of this proprietary technology for detecting extremely small volumes of the influenza vaccine very soon after the onset of infection has received praise from healthcare professionals, and the introduction of this technology into medical institutions is already underway. This technology has been applied to detect other viruses such as adenovirus, the RS virus and the mycoplasma virus.

Fujifilm considers the resolution of various social issues to represent an opportunity for the growth of its medical business. The company is therefore determined to engage actively in research and development in order to expand its business and work towards the improvement of medical treatment around the world through the provision of innovative pharmaceuticals, contributing to the maintenance and improvement of human health.

*1 FIND is an international non-profit organization headquartered in Geneva, Switzerland. Established in 2003, the organization provides support to join development partners through the provision of blood samples, diagnostic agents and information, in order to promote the development and usage of new technologies that can meet diagnostic needs in developing countries for conditions including tuberculosis, malaria and AIDS.

*2 The Global Health Initiative Technology (GHIT) Fund was established jointly by the Japanese government, Japanese pharmaceutical companies, the Bill and Melinda Gates Foundation, and the United Nations Development Program. A joint government-private sector partnership, the fund aims to produce innovative pharmaceutical treatments, vaccines and diagnostics in Japan in order to reduce rates of infectious diseases in the developing world.

*3 Tuberculosis, AIDS, Malaria

*4 Data from the World Health Organization (WHO) factsheet
(http://www.who.int/en/news-room/fact-sheets/detail/tuberculosis)

*5 Huerga H et al. PLoS ONE 12(1): e0170976. https://doi.org/10.1371/journal.pone.0170976 (accessed 14 August 2018).Lawn SD et al. BMC Medicine 2017;15:67. https://doi.org/10.1186/s12916-017-0822-8 (accessed 14 August 2018).

*6 Approximately 80 countries where Gross National Income (GNI) per capita is below or equal to USD3955.

*7 LAM is found in the cell walls of mycobacterium tuberculosis. It is the most common lipoglycan (polysaccharide containing lipids) characteristic of mycobacterium tuberculosis, and is said to be necessary for the survival of the mycobacterium tuberculosis and the pathological development of tuberculosis.

*8 This proprietary Fujifilm technology harnesses the silver halide amplification technology developed by Fujifilm for the development of photographic film in an immune-chromatography process, amplifying the virus marker included in the collective specimen (gold colloid) to increase its size, greatly increasing the visibility of the marker.

*9 Diagnosis complete within 60 minutes.

*10 In the near future, FIND, which carried out the clinical study, plans to present a paper on the results of the assessment.

*11 Required specifications, including target sensitivity, specificity, measurement periods and sales price are determined under the Target Program Profile (TPP) included in the report released by the World Health Organization (WHO). Further details are included in Table 2 of the report 'Delphi survey results for seven proposed key characteristics of a rapid biomarker-based non-sputum-based test for detecting TB. 1. Diagnostic sensitivity for pulmonary TB in Adults.'

*12 If the target of detection (such as viruses or bacteria) are present within the sample dropped onto the agent (such as fluid wiped from the nostril), then the identification marker antibody within the reagent combines with the target, producing an antigen-antibody complex. When this complex is captured by an antibody which has been applied in advance along the detection line, the line changes color, becoming visible and showing a positive result(antigen present). As results can be obtained in a simple and rapid manner, this method is used frequently in the diagnosis of infections such as influenza where rapid action is required.

*13 This refers to rapid diagnostic tests among In-Vitro Diagnostic products which detects virus or bacteria antigens using the collected specimens and enables to see the result with the naked eye. These tests are widely used at hospitals and clinics; notable examples are products that detect seasonal influenza antigen with immunochromatography.

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