



Foundation Medicine, Inc. Chugai Pharmaceutical Co., Ltd.

# Foundation Medicine and Chugai Announce Partnership with National Cancer Center for the Use of FoundationOne® Liquid in the Third Stage of SCRUM-Japan

 SCRUM-Japan aims to apply blood-based genomic insights to inform and accelerate the development of precision medicine approaches for patients with advanced cancers

CAMBRIDGE, Mass., USA, TOKYO, Japan – February 13, 2020 – Foundation Medicine, Inc. and Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) have entered into an agreement with the National Cancer Center (NCC) for the use of FoundationOne® Liquid, Foundation Medicine's laboratory-developed liquid biopsy test, in the third stage of SCRUM-Japan, the largest cancer genomic screening consortium in Japan. The multinational program provides genomic screening in collaboration with hospitals on a regional scale in Japan and other countries in Asia, and aims to accelerate the development of innovative biomarker-driven precision medicine cancer therapies.

The third stage of SCRUM-Japan is structured in two programs – LC-SCRUM-Asia and MONSTAR-SCREEN. LC-SCRUM-Asia is investigating genomic changes with the aim of delivering precision medicine to lung cancer patients. MONSTAR-SCREEN is investigating genomic changes across all types of advanced solid tumors, expanding beyond gastrointestinal cancer which was the focus of the second stage.

"The SCRUM-Japan program is a model of how collaboration between industry and academia is making precision medicine a reality for people in need of new treatment approaches," said Brian Alexander, chief medical officer of Foundation Medicine. "Utilization of FoundationOne Liquid in this program underscores its value in informing potential therapy selection for advanced-stage cancer patients. We look forward to continuing to expand access to comprehensive genomic profiling through this collaboration."

"SCRUM-Japan is a groundbreaking program to find therapies for patients with advanced cancer. There is an increasing need for blood-based genomic testing in patients who cannot give tissue samples including those who are unable to undergo invasive tumor biopsy," said Dr. Minoru Watanabe, Vice President, head of Chugai's Foundation Medicine Unit. "We believe that this collaboration with the NCC, which has led a genome screening in Japan will pave the way to realize true precision medicine across the country."

"With the aim of delivering optimal treatments to patients, SCRUM-Japan was started with a view to

detect cancer genomic alterations. The important achievements we saw from the first two stages include registration of over 10,000 patients' clinical and genomic data, and approval of five therapeutic drugs and six *in vitro* diagnostics products based on clinical studies conducted by utilizing the data," said Atsushi Ohtsu, M.D., Ph.D. Director of National Cancer Center Hospital East and Representative of SCRUM-Japan. "Cancers remain leading causes of deaths in Japan and lung cancer has been ranked as the first leading cause of death among all cancer types. By incorporating FoundationOne Liquid into LC-SCRUM-Asia and MONSTAR-SCREEN, we believe the third stage of SCRUM-Japan will further prove the benefit of comprehensive genomic profiling tests such as FoundationOne Liquid."

Lung and gastrointestinal cancers are among the leading causes of cancer-related deaths in Japan, accounting for over 72 percent of cancer deaths in 2018 according to the World Health Organization. Through this collaboration, Foundation Medicine and Chugai will provide FoundationOne Liquid to academic centers participating in LC-SCRUM-Asia and MONSTAR-SCREEN.

In April 2018, Foundation Medicine received Breakthrough Device Designation from the U.S. Food and Drug Administration (U.S. FDA) on a forthcoming version of Foundation Medicine's liquid biopsy test, which is currently under U.S. FDA review. Chugai and Foundation Medicine are preparing for the regulatory filing of this version of the test in Japan with the intention that the product will be approved for use under the National Health Insurance coverage in Japan. The parties intend that both LC-SCRUM-Asia and MONSTAR-SCREEN will transition from the existing FoundationOne Liquid test to the forthcoming version of Foundation Medicine's liquid biopsy test following its anticipated approval by the U.S. FDA and subject to the terms of the agreement.

#### **About SCRUM-Japan**

SCRUM-Japan is the largest cancer genomic screening consortium in Japan and aims to accelerate the development of innovative biomarker-driven precision medicine cancer therapies. Since its launch in 2015, more than 10,000 patients with advanced cancers have participated in SCRUM-Japan. The third stage of SCRUM-Japan started in June 2019, and includes two programs – LC-SCRUM-Asia and MONSTAR-SCREEN. LC-SCRUM-Asia is investigating genomic changes with the aim of delivering precision medicine to lung cancer patients. More than 200 hospitals in Japan and Taiwan have joined the program and its scope area is expanding across Asia. MONSTAR-SCREEN is investigating genomic changes across all types of advanced solid tumors including gastrointestinal cancer. 28 hospitals have registered in Japan, and it aims for patients with various types of cancer to participate in the program.

#### **About Foundation Medicine**

Foundation Medicine is a molecular information company dedicated to a transformation in cancer care in which treatment is informed by a deep understanding of the genomic changes that contribute to each patient's unique cancer. The company offers a full suite of comprehensive genomic profiling assays to identify the molecular alterations in a patient's cancer and match them with relevant targeted therapies, immunotherapies and clinical trials. Foundation Medicine's molecular information platform aims to improve day-to-day care for patients by serving the needs of clinicians, academic researchers

and drug developers to help advance the science of molecular medicine in cancer. For more information, please visit <a href="www.FoundationMedicine.com">www.FoundationMedicine.com</a> or follow Foundation Medicine on Twitter (@FoundationATCG).

## **About Chugai**

Chugai Pharmaceutical is one of Japan's leading research-based pharmaceutical companies with strengths in biotechnology products. Chugai, based in Tokyo, specializes in prescription pharmaceuticals and is listed on the 1st section of the Tokyo Stock Exchange. As an important member of the Roche Group, Chugai is actively involved in R&D activities in Japan and abroad. Specifically, Chugai is working to develop innovative products which may satisfy the unmet medical needs. Additional information is available at <a href="https://www.chugai-pharm.co.jp/english/">https://www.chugai-pharm.co.jp/english/</a>.

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