

H.U. Group Holdings, Inc.
FUJIREBIO INC.
SRL, Inc.
Shizuoka Cancer Center

Manufacturing and Marketing Authorization Granted for “Fujinokuni HOPE Onco Panel” Comprehensive Genomic Profiling System

Shizuoka and Tokyo, Japan, March 31, 2026 --- SRL, Inc. (President & CEO: Makoto Matsumoto; Head Office: Minato-ku, Tokyo; hereinafter “SRL”)*¹, Shizuoka Cancer Center (President: Katsuhiko Uesaka; located: Nagaizumi-cho, Sunto-gun, Shizuoka Prefecture), SRL & Shizuoka Cancer Center Collaborative Laboratories, Inc. (Head Office: Shizuoka Cancer Center Research Institute)*², FUJIREBIO INC. (President & CEO: Takeshi Fujita; Head Office: Minato-ku, Tokyo; hereinafter “FUJIREBIO”)*³ announce today that they obtained manufacturing and marketing authorization from the Ministry of Health, Labour and Welfare on March 24, 2026 for the “Fujinokuni HOPE Onco Panel” (hereinafter “the system”), a comprehensive genomic profiling (CGP) system. In addition, this system is the first Software as a Medical Device (SaMD) product within the H.U. Group to receive manufacturing and marketing authorization.

This system is one of the outcomes from the “Project HOPE” (High-tech Omics-based Patient Evaluation)*⁴, a joint research initiative between the Shizuoka Cancer Center and SRL, which has been developed as the first achievement in Japan solely based on the data from Japanese cancer patients (5,143 cases). Through performing matched-pair analysis comparing tumor tissue and blood samples from the same patient, the system analyzes alterations in 410 cancer-related genes and drug-metabolizing enzyme-related genes*^{5,6}. As it obtains the analysis results comprehensively in a single assay, the system will be used as a helpful tool for cancer diagnosis and determination of treatment strategies.

The regulatory approval was obtained with the cooperation of FUJIREBIO, which possesses expertise in pharmaceutical and regulatory affairs. The system represents the outcome from the concerted efforts by the whole H.U. Group in collaboration with the Shizuoka Cancer Center. Preparations are currently underway to apply for the national health insurance coverage. Once it is approved, SRL will accept the test orders from medical institutions, and the testing will be performed by the SRL & Shizuoka Cancer Center Collaborative Laboratories, Inc.

The H.U. Group and the Shizuoka Cancer Center will continue working in collaboration to contribute to the broader adoption and advancement of cancer genomic medicine, with the aim of realizing optimal personalized medicine for each individual patient, by leveraging research and development outcomes obtained through initiatives such as

Project HOPE, together with SRL's advanced specimen testing technologies and extensive expertise in contracted clinical laboratory testing.

Product Overview

Generic Name: Gene Mutation Analysis Program (for Cancer Genomic Profiling Tests)

Product Name: Fujinokuni HOPE Onco Panel

Manufacturing and Marketing Approval Number: 30800BZX00090000

Marketing Authorization Holder: FUJIREBIO INC.

*1 SRL, Inc.:

SRL, Inc. is a consolidated subsidiary of the H.U. Group Holdings, Inc. (hereinafter referred to as "H.U. Group HD").

*2 The SRL & Shizuoka Cancer Center Collaborative Laboratories, Inc.:

The SRL & Shizuoka Cancer Center Collaborative Laboratories, Inc. was established on September 10, 2018, through joint investment by the Shizuoka Cancer Center and SRL, Inc., with ownership ratios of 22.2% and 77.8%, respectively. The company operates as a registered clinical laboratory officially certified by Shizuoka Prefecture, and has obtained accreditation from both the College of American Pathologists (CAP) and the Clinical Laboratory Improvement Amendments (CLIA) of the United States. Its principal business activities include:

1. Contracted and commissioned services for clinical testing and research testing, as well as related management and support services
2. Contracted testing services related to pharmaceuticals and in vitro diagnostics
3. Support services for drug discovery targets and biomarker exploration

As a company established under the policy "the Fujinokuni Advanced Medical Comprehensive Special Zone" (launched in fiscal year 2011), it represents the first case to obtain the regulatory approval for a highly controlled medical device (Class III).

References (Press Releases)

1. [October 3, 2018: "Establishment of a new company for cancer clinical sequencing jointly by the Shizuoka Cancer Center and SRL" \(Japanese\)](#)
2. [March 10, 2023: "Our clinical testing laboratory obtained CLIA accreditation — genomic medicine testing at a globally standardized level of quality" \(Japanese\)](#)

*3 Fujirebio Inc.:

Fujirebio Inc. is a consolidated subsidiary of the H.U. Group HD.

*4 Project HOPE:

Project HOPE is a comprehensive, multidisciplinary research project launched in January, 2014, jointly promoted by the hospital and the research institute of the Shizuoka Cancer Center as an integrated initiative. As of March, 2026, more than 14,000 cases, one of the largest cohorts for a single medical institution in Japan, have been registered. The project utilizes clinical specimens obtained from Japanese cancer patients undergoing surgeries, including tumor tissues excised during surgeries, adjacent normal tissues, and blood samples, forming a large-scale, high-precision biobank. These valuable clinical samples are subjected to multi-omics analyses, such as whole-genome analysis, whole-exome analysis, transcriptome analysis, spatial transcriptome analysis, proteomics, and metabolomics, which are then integratively analyzed together with clinical information. Through this approach, the project aims to elucidate the fundamental nature of cancer and to realize holistic medicine tailored to each individual patient.

- ["Project HOPE \(High-tech Omics-based Patient Evaluation\)" \(multi-omics analysis of cancer\) \(Japanese\)](#)

*5 Types of Variants and Biomarkers Detectable by the "Fujinokuni HOPE Onco Panel":

- Single Nucleotide Variants (SNV)
- Insertions
- Deletions
- Copy Number Variations (CNV)
- Structural Variants (SV), such as gene fusions, etc.

*6 Breakdown of the Target Genes Analyzed by the "Fujinokuni HOPE Onco Panel "(410 genes):

- Genes analyzed for somatic alterations such as base substitutions, insertions, deletions, and copy number variations: 381 genes
- Genes and regions analyzed for structural variants, such as gene fusions: 72 genes/regions (Of these, 43 genes are also analyzed for somatic alterations.)

• Genes analyzed for genetic polymorphisms related to drug-metabolizing enzymes: 22 genes (All of these are also analyzed for somatic alterations.)

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