December 2, 2016

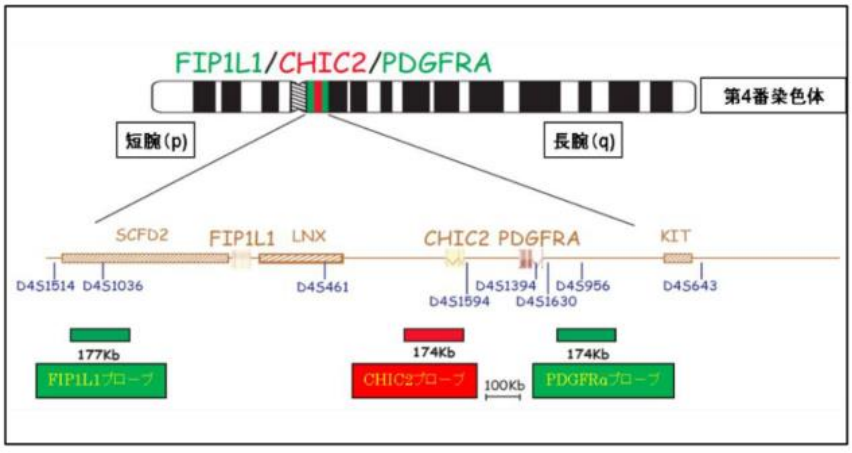
To the press

Riken Genesis Co., Ltd.
President&CEO, Naoto Kondo

Notice of Reimbursement and Launch of In Vitro Diagnostics "OncoGuide® F-P Fusion Gene Detection FISH Kit"

Riken Genesis Co., Ltd. (Head Office: Taito-ku, Tokyo; President&CEO: Naoto Kondo) has got NHI points and launched OncoGuide® F-P Fusion Gene Detection FISH Kit in Japan on December 2, 2016, which in this April, Riken Genesis Co., Ltd. received manufacturing and marketing approval as an in vitro diagnostic agent from the Ministry of Health, Labour and Welfare for "OncoGuide® F-P Fusion Gene Detection FISH Kit" (manufactured by Cytocell Ltd.) that detects *FIP1L1-PDGFRα* fusion gene in chronic eosinophilic leukemia (CEL) and eosinophilia syndrome (HES).

Imatinib mesylate, a tyrosine kinase inhibitor (brand name: Gleevec Tablets 100 mg/Novartis Pharma K.K.) was approved as with drug therapy for CEL and HES positive of *FIP1L1-PDGFRα* fusion gene patients in Japan; it was approved under the condition of "Precautions for Indications" that is "used in patients who have been confirmed to be positive for *FIP1L1-PDGFRα* by chromosomal or genetic testing". Therefore, *FIP1L1-PDGFRα* fusion gene testing is required for imatinib mesylate treatment. This product is an in vitro diagnostics that detects the *FIP1L1-PDGFRα* fusion gene in peripheral blood or bone marrow-derived cells by fluorescence in situ hybridization (FISH).



Chromosome 4 and FISH probe for detection of FIP1L1-PDGFRα fusion gene
Of the *FIP1L1-PDGFRα* fusion gene by the CHIC2 gene located at 12(4q12) of the long arm of chromosome 4. The deletion results in the fusion of the *FIP1L1* gene with the PDGFRα gene. The results show that PDGFRα tyrosine kinase is constitutively activated and CEL/HES develops.

Product Overview

Product name: OncoGuide® F-P Fusion Gene Detection FISH Kit

Generic name: FIP1L1-PDGFRα fusion gene detection kit (87003000)

Approval No. 22800EZX00023000

Approved Timing: On April 19th, 2016

Reimbursement: 3,300 NHI points

Product Specifications:

Components	Product NO.A064 (For 5 tests)	Product NO.A065 (For 10 tests)
Prove mix	50 μL×1	100 μL×1
Counterstain solution	150 μL×1	150 μL×1

Manufacturer

Cytocell Limited, United Kingdom

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