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ASIA EDITION

Invivoscribe LeukoStrat CDx FLT3 Mutation Test approved for treating R/R AML with FLT3 –ITD

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Japanese MHLW approval for Diagnostic Assistant of Daiichi Sankyo's Quizartinib to evolve FLT3 for critically ill patients with AML in Japan

Invivoscribe, announced that on 5 June 2019, the Ministry of Health, Labour and Welfare (MHLW) approved LeukoStrat® CDx *FLT3* Mutation test, as a diagnostic assistant for Daiichi Sankyo's Quizartinib for the treatment of Relapsed/Refractory acute myeloid leukemia (AML) patients with *FLT3* -ITD positive relapse in Japan. At the same time, the Japanese MHLW has added an authorization to use EDTA collection tubes to the existing authorization for the heparin collection tubes used in this test.

The Quantum-R study found that quizartinib resulted in a statistically significant improvement in overall survival (OS) compared to follow-up chemotherapy when patients were selected in the LeukoStrat CDx*FLT3* mutation assay. Mutations in the *FLT3* gene are among the most important motor mutations in AML.

This milestone further enhances the role of the LeukoStrat CDx*FLT3* mutation assay as an absolute international reference in the overall evaluation of *FLT3* for critically ill patients with AML.

This in vitro diagnostic test based on PCR detects tandem internal duplication (DIT) mutations as well as D835 and I836 tyrosine kinase (DTK) domain mutations in the *FLT3* gene in genomic DNA extracted from mononuclear cells obtained from aspirations of peripheral blood or bone marrow from patients with AML. This test, which is available worldwide, includes software that interprets data, generates standardized mutated/wild signal ratios for DIT and DTK mutations, and predicts response to multiple tyrosine kinase inhibitors.

"Once again, our Streamlined CDx® program has proven effective in accelerating filings and approvals for our partners around the world. Invivoscribe welcomes partnership opportunities with global pharmaceutical companies interested in the development and commercialization of diagnostic assistants, regardless of whether their treatments target haematological diseases or solid tumours, "said Dr Jeffrey Miller, director of the security and CEO of Invivoscribe.

The LeukoStrat test is available as a test menu service through Invivoscribe's wholly-owned subsidiaries: LabPMM LLC (San Diego, California, USA), LabPMM GmbH (Martinsried, Germany) and LabPMM GK (Kawasaki, Japan). More than 95% of patient samples tested using the FDA-approved LeukoStrat CDx *FLT3* mutation assay, along with a selection of other PCR-based and CLIA-validated hair tests, provide results within 48 hours receipt of samples in all LabPMM laboratories. The LeukoStrat CDx *FLT3* mutation test kits are currently distributed in Japan, Europe and Australia, and are expected to be distributed in the US and China in the future.