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ASIA EDITION

Invivoscribe, Astellas sign agreement for companion diagnostics

29 April 2015 | News | By BioSpectrum Bureau

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Invivoscribe Technologies Inc., a US-based company with international experience in commercializing in-vitro diagnostic tests and developing companion diagnostics, has entered into a companion diagnostic agreement with Japanese pharmaceutical company Astellas Pharma Inc.

A companion diagnostic is a medical device, often an in-vitro device, which provides information that is essential for the safe and effective use of a corresponding drug or biological product.

Invivoscribe will develop and commercialize a companion diagnostic for FLT3 and use the internationally harmonized signal ratio test to stratify and enroll acute myeloid leukemia patients for Astellas' investigational trials of its targeted drug ASP2215 in the United States, Europe, Japan and certain other countries. This signal ratio assay is a test for identifying patients with FLT3mutations and an important tool for stratifying cytogenetically normal Acute Myeloid Leukemia (AML).

Invivoscribe will receive an upfront payment, reimbursement for certain development, regulatory and commercialization costs, as well as milestone payments for completion of certain of the development, regulatory and commercialization related goals. Invivoscribe is responsible for development of the companion diagnostic, regulatory submissions, approval of the test in the designated territories, and international commercialization activities, including those in the United States, Europe, and Japan.