Available For Licensing: LKB1 Mutation Status in Non-Small Cell Lung Cancer

MolecularMD is the exclusive licensee of certain pending US patent claims related to use of LKB1 mutation status for diagnostic, prognostic and predictive purposes in non-small cell lung cancer. Such patent rights are jointly-owned by the governing bodies of four institutions: Dana-Farber Cancer Institute, the Massachusetts General Hospital (MGH), the University of North Carolina at Chapel Hill (UNC), and The University of Texas Southwestern Medical Center (UTSW). The inventors named in these patent rights include Drs. Kwok-Kin Wong, Bruce Johnson, Hongbin Ji, and Pasi Janne of Dana-Farber; Dr. Nabeel Bardeesy of MGH; Dr. Norman E. Sharpless of UNC; and Dr. Diego Castrillon of UTSW.

Non-Small Cell Lung Cancer: LKB1 Mutations

Non-small cell lung cancer (NSCLC) accounts for approximately 85% of all lung cancers and over 200,000 new cases of NSCLC are estimated to be diagnosed in the United States in 2013. In recent years, substantial advances have been made in understanding critical molecular and cellular mechanisms driving tumor initiation, maintenance, and progression in NSCLC. Research has shown that the gene named LKB1 (liver kinase B1)/STK11 (serine-threonine kinase 11) is a tumor suppressor encoding a serine/threonine kinase that negatively regulates the mTOR (mammalian target of rapamycin) signaling pathway. LKB1 is mutated in 20-30% of NSCLCs and ranks as the 3rd most frequently mutated gene in lung adenocarcinoma after the p53 tumor suppressor and the Ras proto-oncogene.

LKB1 Mutations: Clinically Significant Information

Loss of LKB1 protein has been shown to predict the aggressiveness of cancer especially in the context of accompanying KRAS mutations. Mutated LKB1 is found preferentially in smokers and concomitantly with alterations in other cancer genes including KRAS, PIK3CA, MYC, CDKN2A and TP53, but not with EGFR mutations. Strikingly, LKB1 loss is associated with greater resistance to single-agent PI3K/Akt and MEK inhibitors, suggesting that LKB1 mutations have potential as predictive biomarkers and warrant further investigation prospectively in clinical trials of PI3K, Akt, mTOR and MEK pathway inhibitors. MolecularMD is developing diagnostic assays for LKB1 status, including immunohistochemistry (IHC) and next generation sequencing (NGS) tests, in support of a variety of clinical trials exploring LKB1 clinical utility. MolecularMD provides comprehensive clinical trial support through its CLIA-certified and CAP-accredited Clinical Reference Laboratory. In addition, MolecularMD provides IVD development and manufacturing capability to support companion diagnostic device commercialization.

Patent-pending Technology: Available for Licensing

Technology associated with LKB1 mutation status in NSCLC is described in US patent 12/449,404 entitled “Methods of Diagnosing and Prognosing Lung Cancer.” MolecularMD will also support further commercialization of LKB1 technology through sublicensing to Clinical Reference Laboratories and diagnostic assay developers and manufacturers.

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References: