

Cell Signaling Technology Granted Patent for PCR Methods for Detection of a Subset of Treatable Non-Small Cell Lung Cancers

The Associated Press

DANVERS, Mass.--(BUSINESS WIRE)--Jan 7, 2013--Cell Signaling Technology, Inc. (CST) of Danvers, MA, announced today the issuance of US Patent No. 8,288,102, relating to PCR-based methods for the detection of EML4-ALK (anaplastic lymphoma kinase) polynucleotides in patient samples. The presence of the fusion kinase EML4-ALK has been reported in a subset of patients with breast, colon, and non-small cell lung cancer (NSCLC). Pfizer's XALKORI® (crizotinib) is approved in the US for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with ALK fusions as detected by an FDA-approved test.

Cell Signaling Technology Granted Patent for PCR Methods for Detection of a Subset of Treatable Non-Small Cell Lung Cancers (Photo: Business Wire) The methods disclosed in the patent, entitled "Gene defects and mutant ALK kinase in human solid tumors", include the amplification of DNA or RNA fusion polynucleotides from patient blood, tissue, or cells and the determination of a therapeutic regimen based on the presence of the fusion in the sample. Lung cancer is the world's leading cause of cancer death with more than 1.6 million new cases diagnosed each year. About 85 percent of lung cancer patients are of the non-small cell type and are usually diagnosed with advanced disease with a very low survival rate. Preliminary epidemiology suggests that approximately 3-5 percent of NSCLC patients have tumors positive for the ALK fusion gene.

Cell Signaling Technology, Inc., a leader in the development and manufacture of high performance antibody products for the medical research market, discovered the abnormal gene rearrangement EML4-ALK in NSCLC. The presence of the ALK fusion gene in lung cancer was also reported by a Japanese researcher in 2007. CST's patent portfolio includes other methods of detecting the EML4-ALK fusions, including detection by FISH (fluorescence in situ hybridization) and antibody-based assays for the detection of polypeptides (e.g., US Patent Nos. 7,700,339, 8,168,383, and 8,232,060). Additionally, CST and Astellas Pharma, Inc. have pooled their respective worldwide intellectual property estates relating to the fusion kinase EML4-ALK.

"Cell Signaling Technology's growing patent portfolio and dominant intellectual property directed to the detection of EML4-ALK translocations is very important to our company mission," said Michael J. Comb, Ph.D., President and CEO of CST. "We are thrilled that the strategic R&D and intellectual property investments we've made in the area of EML4-ALK translocation detection are being applied to significant unmet needs in the diagnosis and treatment of cancer patients, and are pursuing all avenues of commercialization." Cell Signaling Technology, Inc. has also entered into a license agreement with Ventana Medical Systems, Inc., a member of

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the Roche Group, who, in collaboration with Pfizer Inc., is developing the first fully automated and standardized immunohistochemistry (IHC) companion diagnostic test for ALK gene rearrangements using CST's D5F3 antibody.

About Cell Signaling Technology, Inc. Cell Signaling Technology, Inc. is dedicated to delivering the world's highest quality research, diagnostic, and therapeutic products to accelerate biological understanding and enable personalized medicine. Through its proprietary monoclonal antibody technology, NG-XMT™, and PTMScan® proteomics technology, CST continues to be at the forefront of applied systems biology research, promoting greater understanding of biochemical aberrations that underlie critical diseases, including cancer. CST has made significant discoveries in cancer research through its internal research group, and from this has built an intellectual property portfolio around biomarkers relevant to non-small cell lung cancer.

Photos/Multimedia Gallery

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