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Thermo Fisher Scientific Signs Development Agreement for Next-Generation Sequencing-Based Companion Diagnostic

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Universal test designed for non-small cell lung cancer supports multiple drug development programs

CARLSBAD, Calif. – (Nov. 18, 2015) – Thermo Fisher Scientific, the world leader in serving science, has entered into a long-term agreement with Novartis and Pfizer to develop and commercialize a multi-marker, universal next-generation sequencing (NGS) oncology test that will serve as a companion diagnostic (CDx) for non-small cell lung cancer (NSCLC) across multiple drug development programs.

With many pharmaceutical companies moving toward targeted therapies instead of "one-size-fitsall" drugs, a practical method for matching cancer patients with specific drug candidates is needed to enable the evolution to precision medicine. NGS enables testing of multiple genes simultaneously from a single sample to help identify their unique genetic profile. This information can then be used to guide the appropriate therapy choice among multiple drug candidates.

The streamlined and personalized methodology defined in the development agreement between the companies has the potential to improve safety, effectiveness and health outcome of patients via targeted risk stratification and tailored treatment approaches. The collaboration, focused on a universal testing approach, could also accelerate the development and registration of several new NSCLC drugs and drug indications, with the ultimate goal of providing patients greater access to more targeted treatments and appropriate clinical trials as quickly as possible.

"We look forward to this collaboration and the future potential of this technology to further enhance the ability to connect patients to the right clinical trials and treatments for them, even those patients with less common tumor mutation types," said Alessandro Riva, MD, global head oncology development and medical affairs, Novartis Oncology. "It is our hope that we will be able to take advantage of this new technology as part of our growing lung cancer portfolio to offer even better outcomes for patients."

"We believe that this collaboration will help us get closer to our goal of ensuring that cancer patients are able to benefit from a targeted therapy associated with their tumor's genetic profile," said Hakan Sakul, Ph.D., executive director and head of diagnostics, worldwide R&D, Pfizer. "The Thermo Fisher Scientific NGS panel is aligned with a number of our clinical development programs, providing us with an opportunity to accelerate the development for each of these potential new therapies for NSCLC patients with targetable genetic alterations.

" The NGS-based companion diagnostic test for NSCLC will be developed using Thermo Fisher's Ion PGM Dx System and Oncomine assays. Both the NGS platform and Oncomine reagents leverage the Ion AmpliSeq technology, which enables simultaneous sequencing of hundreds of genes, with high reproducibility and rapid turnaround time. Combined with its uniquely low DNA and RNA sample input requirements from Formalin-Fixed Paraffin-Embedded (FFPE) tissues (as little as 10ng extracted nucleic acid per reaction), the Ion Torrent-

based sequencing platform and reagents offer comprehensive sequence analysis of a wider variety of tumor samples, including limited or compromised specimens derived from FFPE tissue or fine needle aspirates. Incorporating oncology markers relevant to a broad range of cancers, the NGS panel will also provide a universal platform to enable potential new clinical indications for existing drugs and development of possible new therapies for other indications in the future.

“The potential to generate a paradigm shift through this agreement - from one test for one drug, to one test for multiple NSCLC therapies, represents a significant step forward in realizing the promise of precision medicine,” said Mark Stevenson, president of life sciences solutions for Thermo Fisher Scientific. “We look forward to building upon our ongoing collaboration with Novartis and Pfizer to lead the efforts in building potential novel NGS testing approaches to advance the future of cancer care.”

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