FOR IMMEDIATE RELEASE

Caris Life Sciences Receives FDA Breakthrough Device Designation for MI Transcriptome™ Companion Diagnostic Test

This is the first companion diagnostic to detect gene fusions across all solid tumors; Caris expects to submit for Pre-Market Approval later this year

IRVING, Texas, May 3, 2019 – Caris Life Sciences®, a leading innovator in molecular science focused on precision medicine, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device designation for the company’s MI Transcriptome™ companion diagnostic (CDx) test. Designed to detect gene fusions in solid tumors, the test is intended to assist clinicians in identifying patients who may benefit from treatment with specific targeted therapies. Caris plans to submit the assay for Pre-Market Approval in late 2019.

“The FDA Breakthrough Device designation for the MI Transcriptome CDx assay is a significant step in advancing precision cancer care for individuals with specific genetic profiles who could benefit from targeted treatment options,” said W. Michael Korn, MD, Chief Medical Officer of Caris. “This also is an incredible milestone for Caris and the company’s efforts to advance molecular science and cancer care by employing cutting edge technology for the detection of highly actionable molecular alterations.”

MI Transcriptome™ CDx is a next-generation sequencing-based in vitro diagnostic test that uses RNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue to detect all classes of structural rearrangements, including fusions, deletions, inversions, and duplications, as well as measuring expression and splice variants in patients diagnosed with cancer. It has received Breakthrough Device designation for detection of novel FGFR biomarkers including gene fusions in solid tumors.

Gene fusions are genetic alterations frequently driving tumor progression and, as a result, are promising therapeutic targets for cancer patients. MI Transcriptome™ CDx can distinguish between different fusion types and can differentiate fusions from other rearrangements. It also has the potential to discover previously uncharacterized events, which is important when identifying patients who could have strong response to targeted therapy.

The MI Transcriptome™ CDx assay can also provide additional tumor profiling data to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with cancer. Additionally, MI Transcriptome™ CDx would be the first companion diagnostic for use in identifying patients with fusions potentially eligible for pan-cancer treatment.

“RNA-based sequencing analysis is emerging as the best method to detect clinically relevant fusions,” said David Spetzler, MS, MBA, PhD, President and Chief Scientific Officer of Caris. “MI Transcriptome™
CDx, which is enabled by Whole Transcriptome Sequencing, provides information on all genes that are expressed in the cancer, which allows the most complete assessment of a patient’s tumor to inform more targeted treatment. We are delighted to have received Breakthrough Device designation and look forward to accelerating development of this assay.”

Earlier this year, Caris launched the newest addition to its comprehensive genomic profiling offering, MI Transcriptome™, which enables Whole Transcriptome Sequencing (WTS). MI Transcriptome uses the capabilities of high-throughput sequencing to gain insight into the RNA profiles of patients’ tumors and builds upon Caris’ offering of the most comprehensive tumor profiling approach, which assesses DNA, RNA and proteins to ensure patients receive the right therapies.

The Breakthrough Devices Program is a program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

About Caris Life Sciences
Caris Life Sciences® is a leading innovator in molecular science focused on fulfilling the promise of precision medicine through quality and innovation. The company’s suite of market-leading molecular profiling offerings assess DNA, RNA and proteins to reveal a molecular blueprint that helps physicians and cancer patients make more precise and personalized treatment decisions. Caris is also advancing precision medicine with Next Generation Profiling™ that combines its innovative service offerings, Caris Molecular Intelligence® and ADAPT Biotargeting System™, with its proprietary artificial intelligence analytics engine, DEAN™, to analyze the whole exome, whole transcriptome and complete cancer proteome. This information, coupled with mature clinical outcomes on thousands of patients, provides unmatched molecular solutions for patients, physicians, payers and biopharmaceutical organizations. Headquartered in Irving, Texas, Caris Life Sciences offers services throughout the U.S., Europe, Asia and other international markets. To learn more, please visit www.CarisLifeSciences.com or follow us on Twitter (@CarisLS).

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