FOR IMMEDIATE RELEASE

Caris Life Sciences Submits Two PMA Applications to the FDA for Whole Exome and Whole Transcriptome Sequencing

IRVING, Texas, April 28, 2020 – Caris Life Sciences®, a leading innovator in molecular science focused on fulfilling the promise of precision medicine, today announced the submission of two Pre-Market Approval (PMA) applications for MI Exome™ CDx and MI Transcriptome™ CDx to the U.S. Food and Drug Administration (FDA). MI Exome™ CDx, whole exome sequencing (DNA), and MI Transcriptome™ CDx, whole transcriptome sequencing (RNA), are powerful precision medicine assays that include key companion diagnostic biomarkers with therapy claims, and detect all classes of alterations including genomic signatures for microsatellite instability (MSI), tumor mutation burden (TMB), and loss of heterozygosity (LOH).

“I am very excited about reaching this important regulatory milestone and further advancing our commitment to help cancer patients,” said David D. Halbert, Founder, Chairman and CEO of Caris. “MI Exome™ CDx and MI Transcriptome™ CDx are incredibly sophisticated and comprehensive assays designed to identify the molecular information required to personalize care – they will represent the only clinical offering of their kind and will be run on each and every clinical patient.”

MI Exome™ CDx is a next-generation sequencing-based test utilizing DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens for the qualitative detection of genomic alterations. MI Exome™ CDx can identify genetic variants (single nucleotide variants, insertions and deletions), copy number alterations, MSI, TMB and LOH.

MI Transcriptome™ CDx is a next-generation sequencing-based test that utilizes RNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens for the qualitative detection of genomic and transcriptomic alterations. MI Transcriptome™ CDx is a broad, multi-gene panel utilized to identify gene fusions, transcript variants, genetic variants (single nucleotide variants, insertions and deletions), and gene expression changes. MI Transcriptome™ CDx received Breakthrough Device designation by the FDA in 2019.

“We have been very encouraged by the FDA’s support of precision oncology. They have been a great partner to work with and we look forward to continuing to work with them,” said David
Spetzler, M.S., PhD., MBA, President and Chief Scientific Officer. “MI Exome™ CDx and MI Transcriptome™ CDx will have an immediate impact for patients upon approval, and the molecular data generated from these platforms will create boundless opportunities to inform and innovate in molecular science for many years to come.”

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 assesses DNA, RNA and proteins to reveal a molecular blueprint that helps physicians and cancer patients make more precise and personalized treatment decisions. MI Exome™ whole exome sequencing with 22,000 DNA genes, and MI Transcriptome™ whole transcriptome sequencing with 22,000 RNA genes along with cancer-related pathogens, bacteria, viruses and fungi analysis run on every patient provides the most comprehensive and clinically relevant DNA and RNA profiling available on the market.

Caris is also advancing precision medicine with Caris MAI™ (Molecular Artificial Intelligence) that combines its innovative service offerings, Caris Molecular Intelligence® 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.

Caris Pharmatech is changing the paradigm and streamlines the clinical trial process by assisting biopharma companies with accessing research-ready oncology sites for clinical trials. With over 200 research sites within the Caris Pharmatech JIT Oncology Network, biopharma companies can identify and enroll more patients, faster. Caris Pharmatech Just-In-Time Clinical Trial Solutions focus on rapid site activation and patient enrollment to streamline the drug development process. By implementing a Just-In-Time (JIT) Research System, site activation and patient enrollment is achievable within 14 days for pre-registered locations with pre-qualified patients.

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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