FOR IMMEDIATE RELEASE

Caris Life Sciences Receives FDA Approval for MI Cancer Seek™ as a Companion Diagnostic (CDx) Test

MI Cancer Seek is the first and only simultaneous Whole Exome and Whole Transcriptome-based assay with CDx indications for adults and pediatric patients

IRVING, Texas, November 6, 2024 – Caris Life Sciences® (Caris), a leading next-generation AI TechBio company and precision medicine pioneer, today announced the U.S. Food and Drug Administration (FDA) has approved MI Cancer Seek™ for use as a companion diagnostic (CDx) to identify cancer patients who may benefit from treatment with targeted therapies. The assay includes one pan-cancer and five tumor-specific indications for numerous FDA-approved therapies. MI Cancer Seek is the first and only simultaneous Whole Exome Sequencing (WES) and Whole Transcriptome Sequencing (WTS)-based assay with FDA-approved CDx indications for molecular profiling of solid tumors. MI Cancer Seek is available for adults and pediatric patients, ages 1-22.

"FDA approval of MI Cancer Seek – the first of its kind – further demonstrates Caris' continued leadership in molecular science and our extreme focus on quality," said Caris Chairman, Founder and CEO David Dean Halbert, DSc (h.c.). "We are thrilled to bring MI Cancer Seek to market to ensure patients have access to critical precision medicine tools."

MI Cancer Seek is a next-generation sequencing (NGS) based *in vitro* diagnostic (IVD) device using total nucleic acid (TNA) isolated from formalin-fixed paraffin-embedded (FFPE) tumor tissue specimens for the detection of single nucleotide variants (SNVs) and insertions and deletions (indels) in 228 genes, microsatellite instability (MSI), tumor mutational burden (TMB) in patients with previously diagnosed solid tumors, and copy number amplification (CNA) in one gene in patients with breast cancer. MI Cancer Seek is intended as a companion diagnostic to identify patients who may benefit from treatment with the targeted therapies listed in the Companion Diagnostic Indications table, in accordance with the approved therapeutic product labeling. Additionally, MI Cancer Seek is intended to provide tumor mutational profiling to be used by qualified healthcare professionals in accordance with professional oncology guidelines for cancer patients with previously diagnosed solid malignant neoplasms. Genomic findings other than those listed in the Companion Diagnostic Indications table are not prescriptive or conclusive for labeled use of any specific therapeutic product.

"We are very excited to receive FDA approval for our MI Cancer Seek test. The extensive rigor with which the FDA evaluates new technology ensures patients have access to safe and effective tests," said Caris President David Spetzler, MS, PhD, MBA. "The process of working with the FDA was both collaborative and insightful, and we applaud their expertise in the evaluation of novel technologies."

MI Cancer Seek Companion Diagnostic Indications

Indication	Biomarker	Therapy
Breast Cancer	*PIK3CA* (C420R; E542K; E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R; and H1047L, H1047R, H1047Y)	PIQRAY® (alpelisib)
Colorectal Cancer (CRC)	*KRAS* wild-type (absence of mutations in exons 2, 3, and 4) and *NRAS* wild type (absence of mutations in exons 2, 3, and 4)	VECTIBIX® (panitumumab)
	BRAF V600E	BRAFTOVI® (encorafenib) in combination with ERBITUX® (cetuximab)
Melanoma	*BRAF* V600E	*BRAF* Inhibitors approved by FDA*
	BRAF V600E or V600K	MEKINIST® (trametinib) or *BRAF/MEK* Inhibitor Combinations approved by FDA*
Non-Small Cell Lung Cancer (NSCLC)	*EGFR* exon 19 deletions and exon 21 L858R alterations	*EGFR* Tyrosine Kinase Inhibitors approved by FDA*
Solid Tumors	MSI-H	KEYTRUDA® (pembrolizumab), JEMPERLI (dostarlimab-gxly)
Endometrial Carcinoma	Not MSI-H	KEYTRUDA® (pembrolizumab) in combination with LENVIMA® (lenvatinib)

*For the most current information about the device indications for the therapeutic products in this group, go to: https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools#Group_Labeling

PIQRAY® is a registered trademark of Novartis AG. VECTIBIX® is a registered trademark of Immunex Corporation. BRAFTOVI® is a registered trademark of Array BioPharma Inc. in the United States and various other countries. ERBITUX® is a registered trademark of ImClone LLC, a wholly owned subsidiary of Eli Lilly and Company. MEKINIST® is a registered trademark of Novartis AG Corporation Switzerland. KEYTRUDA® is a registered trademark of Merck. LENVIMA® (lenvatinib) is a registered trademark used by Eisai Inc. under license from Eisai R&D Management Co., Ltd.

Typically, DNA and RNA analysis by NGS requires two separate testing processes, which may require more tissue and time. However, by combining WES and WTS into one workflow, MI Cancer Seek provides a comprehensive molecular blueprint that saves tissue without compromising results. For complete product details, including companion diagnostic information and performance characteristics, please visit www.CarisLifeSciences.com/MICancerSeek.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. The agency is also responsible for the safety of the United States' food supply, cosmetics, and radiation-emitting electronic products and for regulating tobacco products.

About Caris Life Sciences

Caris Life Sciences® (Caris) is a leading next-generation AI TechBio company and precision medicine pioneer that is actively developing and delivering innovative solutions to revolutionize healthcare and improve the human condition. Through comprehensive molecular profiling (Whole Exome and Whole Transcriptome Sequencing) and the application of advanced AI and machine learning algorithms, Caris has created the large-scale, multi-modal database and computing capability needed to analyze and unravel the molecular complexity of disease. This convergence of sequencing power, big data and AI technologies provides an unmatched platform to deliver the next generation of precision medicine tools for early detection, diagnosis, monitoring, therapy selection and drug development.

Caris was founded with a vision to realize the potential of precision medicine in order to improve the human condition, and we value our employees as much as we do our patients of every creed, color, sex, sexual orientation and religion. Headquartered in Irving, Texas, Caris has offices in Phoenix, New York, Cambridge (MA), Tokyo, Japan and Basel, Switzerland. Caris or its distributor partners provide services in the U.S., Europe, Asia and other international markets. To learn more, please visit CarisLifeSciences.com.

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