FOR IMMEDIATE RELEASE

Caris Life Sciences Launches MI FOLFOXai, Improving Overall Survival by 50% for Metastatic Colorectal Cancer Patients

First AI-powered FOLFOX predictor to guide first-line metastatic colorectal cancer treatment

IRVING, Texas, March 31, 2020 – Caris Life Sciences®, a leading innovator in molecular science focused on fulfilling the promise of precision medicine, today announced the launch of MI FOLFOXai™, the newest addition to the company’s suite of comprehensive molecular science offerings. MI FOLFOXai is an Artificial Intelligence (AI)-based predictor of response to FOLFOX chemotherapy in metastatic colorectal cancer that demonstrated approximately 50 percent improvement in overall survival across two independent validation studies. Using Caris Molecular Intelligence® tumor profiling results, this AI-powered predictor is intended to gauge a patient’s likelihood of benefit from FOLFOX as a first-line regimen in combination with bevacizumab.

MI FOLFOXai was validated using two independent data sets to compare the increased benefit arm to the decreased benefit arm. The first study was a blinded, prospective analysis from retrospectively tested samples from the randomized Phase III TRIBE2 study. This study showed a median overall survival improvement of 6.9 months. The second study involved several hundred cases with real-world evidence that showed a median overall survival increase of 11.8 months.

MI FOLFOXai was developed using a subset of results from the company’s proprietary Caris Molecular Intelligence platform, which includes next generation sequencing for DNA mutations, copy number alterations, insertions/deletions; whole transcriptome sequencing for RNA fusions and variant transcripts; and protein testing via immunochemistry. Machine learning algorithms were then used to create a molecular signature that was validated using the two independent data sets to compare the increased benefit arm to the decreased benefit arm.

“FOLFOX is part of an NCCN Guidelines® recommended first-line treatment regimen for the roughly 35,000 patients in the U.S. newly diagnosed with metastatic colorectal cancer each year, and initiating the most appropriate therapy at this stage can be critical to successfully altering the course of disease,” said W. Michael Korn, M.D., Chief Medical Officer of Caris. “Clinical outcomes from MI FOLFOXai validations represent a mean overall survival of nearly 50%, making it imperative to get this information to patients and their physicians as soon as possible.”
Colorectal cancer is the third most common cancer globally, with more than 1.8 million patients diagnosed with the disease each year\(^1\). As many as 25 percent of colorectal cancer patients will present with Stage IV – or metastatic – disease, where the cancer has spread to other parts of the body, making the choice of treatment critical to the patient’s prognosis.

“We are excited to bring the world’s first fully validated AI based treatment algorithm to patients suffering from CRC. MI FOLFOXai will help physicians better determine the relative benefit patients will receive from the FOLFOX chemotherapy regimen and improve clinical outcomes,” stated David Spetzler, M.S., MBA, Ph.D., President and Chief Scientific Officer. “Precision medicine powered by AI has enormous potential in cancer profiling, as well as other areas of medicine, and we look forward to continuing to release additional AI-based molecular intelligence products in the near future.”

**Caris AI-Driven Molecular Profiling**

MI FOLFOXai represents Caris’ second AI-driven molecular profiling offering. In December 2019 the company launched MI GPSai™, the first-ever molecular AI product used for cancer assessment in a clinical setting. As an AI-driven tumor type biology similarity score to better classify tumors, MI GPSai uses both DNA and RNA analysis along with a machine learning algorithm, which includes more than 6,500 mathematical models, to compare molecular characteristics of a patient’s tumor against Caris’ extensive database. The results provide insights to inform treatment decisions for cancer of unknown primary (CUP) cases, atypical clinical presentation cases and other difficult to treat cancer cases.

**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.

Caris is also advancing precision medicine with Caris 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.

Whole transcriptome sequencing with MI Transcriptome™ provides the most comprehensive and unique RNA analysis available on the market and covers all 22,000 genes, with an average of 60 million reads per patient, to deliver extremely broad coverage and high resolution into the dynamic nature of the transcriptome. Assessing the whole transcriptome allows the ability to dig deeper into the RNA universe to uncover and detect fusions, splice variants, and
expression changes that provide oncologists with more insight and actionable information when determining treatment plans for patients.

Caris Pharmatech™, a pioneer of the original Just-In-Time research system with the largest research-ready oncology network is changing the paradigm from the traditional physician outreach model to a real-time approach where patient identification is completed at the lab and the physician is informed so that the patient can be enrolled days earlier, and remain in the local physician’s care, without having to travel to a large central trial site. This fundamentally redefines how pharmaceutical and biotechnology companies identify and rapidly enroll patients in precision oncology trials by combining Caris’ highest quality industry leading large-scale molecular profiling services with Pharmatech’s on-demand site activation and patient enrollment system.

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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