Caris Life Sciences Partners with Debiopharm International SA to Develop Companion Diagnostic for Detection of Rare FGFR Fusions Using Novel Molecular Intelligence (MI) Transcriptome™

Caris to develop CDx for Debiopharm's FUZE Phase II Pivotal Trial of Debio 1347 in solid tumor patients with FGFR fusions

IRVING, Texas, May 30, 2019 – Caris Life Sciences®, a leading innovator in molecular science focused on fulfilling the promise of precision medicine, today announced that it has entered into a strategic collaboration with Debiopharm for the development of a companion diagnostic (CDx) test using its newly-launched Whole Transcriptome Sequencing (WTS) assay for mRNA analysis called MI Transcriptome™. The assay, which was granted Breakthrough Device Designation by the U.S. Food and Drug Administration (FDA) in early May, reliably detects rare fibroblast growth factor receptor (FGFR1, FGFR2 and FGFR3) fusion events.

"This agreement supports our vision for optimizing the detection of rare fusion events using RNA, and building value on our multi-platform tumor profiling approach," said W. Michael Korn, M.D., Chief Medical Officer at Caris Life Sciences. "We continue to develop novel technologies to provide the most comprehensive molecular profiling possible."

Under this agreement, MI Transcriptome™ will be used to identify eligible patients for Debiopharm's FUZE Phase II Pivotal Trial of Debio 1347, a selective FGFR inhibitor that Debiopharm is evaluating for the treatment of patients with non-central nervous system solid tumors that have a specific FGFR gene fusion. Debio 1347 received Fast Track designation from FDA earlier this year.

In addition to developing MI Transcriptome CDx, Caris will use its MI Trials service to improve the identification of patients eligible to enroll in the FUZE trial, analyzing the tens of thousands of patients profiled by Caris Life Sciences each year. The FUZE study is an open-label, blinded, multicenter, pan-cancer international Phase II Basket Trial that plans to enroll 125 patients across more than 20 countries.

"This collaboration represents a key milestone in the advancement of a new tumor-agnostic approach," explained Angela Zubel, Chief Development Officer at Debiopharm International SA. "We believe that a whole transcriptome assay is particularly relevant to detect oncogene fusions and to identify tumor expression profiles that could benefit from Debio 1347 therapy."

"When investigating novel targeted therapies in small, genetically-defined subpopulations which can be found in a broad range of cancers, it is critical that molecular screening be conducted in the broadest possible group of potential trial participants," said Keith Flaherty, Director of Clinical Research at the Massachusetts General Hospital Cancer Center.

"Kinase fusions across multiple histologies have become very important targets in precision oncology but we know that detection methods based purely on DNA can unfortunately miss some patients who might otherwise benefit from these therapies," said David Hyman, Chief of Early Drug Development at Memorial Sloan Kettering Cancer Center. "We are excited to see the increasing adoption of RNA-based, unbiased screening technologies in the clinic."

As opposed to DNA-only based methods, MI Transcriptome™ RNA profiling has the ability to detect any fusion event independent of breakpoint locations and fusion partners. It can distinguish between different fusion or rearrangement types and has the potential to discover previously uncharacterized events, which is critical to identifying every potential patient who may benefit from targeted therapies. MI Transcriptome™ also uses the capabilities of high-throughput transcript sequencing to gain insight into the gene expression profiles of patients' tumors and builds upon Caris' offering of the most comprehensive tumor profiling approach, which assesses DNA, RNA and proteins for every patient.

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).

About Debiopharm
Debiopharm aims to develop innovative therapies that target high unmet medical needs in oncology. Bridging the gap between disruptive discovery products and real-world patient reach, we identify high-potential compounds for in-licensing and clinical development and then select large pharmaceutical commercialization partners to maximize patient access across the globe. Visit us www.debiopharm.com Follow us @DebiopharmNews.

About Debio 1347
Debio 1347 is an investigational novel orally available small molecule highly selective FGFR 1, 2, 3 ATP competitive inhibitor. Results from the phase 1 clinical trial showed that patients with solid tumors with activating alterations in FGFR may benefit from treatment with Debio 1347. Debio 1347 is expected to become a tailored treatment which will be developed with a companion diagnostic. For more information: patients.debiopharm.com/genetic-alterations/

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