

# Caris Diagnostics Providing KRAS Mutational Analysis for Colon Cancer Patients

## Providing Information on Response to Erbitux and Vectibix

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IRVING, Texas and PHOENIX, Arizona; June 24, 2008 – Caris Diagnostics (Caris Dx), a leading provider of the highest quality diagnostic, translational development and pharmaceutical services encompassing anatomic pathology and molecular testing, announced that it is now offering KRAS mutation analysis, designed to provide information on which colon cancer patients are most likely to respond to cetuximab (Erbitux) co-marketed by ImClone and Bristol-Myers Squibb or panitumumab (Vectibix) developed by Amgen.

This assay, which can be performed on biopsies taken for the initial cancer diagnosis, identifies those patients who have somatic mutations in KRAS, which is associated with a lack of response to Erbitux or Vectibix. This prognostic information has recently been validated in a number of retrospective studies and will help better suggest which patients are most likely not going to respond to Erbitux or Vectibix, two chemotherapies widely being utilized to treat colon cancer. Caris Dx's KRAS assay is comprehensive in that it detects any and all nucleotide changes at the three validated KRAS codons (12, 13, and 61) that alter amino acids at these positions, offering a distinct advantage over other laboratories that may only screen for a few specific mutations in codons 12 and 13.

"Responding to oncologists needs for more and better information at the bedside, we are proud to be at the forefront of providing the newest, valuable molecular tests with the consistent quality and reproducibility that physicians have come to expect from Caris Dx," said Dr. Robert Penny, CEO of Caris MPI, the molecular profiling arm of Caris Dx. "We are excited to provide this vital information to clinicians at the time of their initial diagnosis to improve the likelihood of success with the patient's first therapy."

A recent *Journal of Clinical Oncology* study found that none of the 24 patients with confirmed KRAS mutations responded to Erbitux, whereas tumors shrank in 40% of those patients with the wild type (normal) KRAS gene. In another research study conducted in Belgium and published in March, Erbitux was ineffective in treating any of the 42 patients with a mutation, but proved effective in 27 of 66 patients with wild type KRAS. Amgen has also published a study noting that their drug Vectibix only works in patients with wild type KRAS. In Europe, Vectibix is only approved for patients who have wild type KRAS.

"The data are very compelling; research has clearly implicated KRAS as a vital biomarker for the assessment of response to Erbitux and Vectibix," said Dr. Daniel Von Hoff, Executive Director of Caris MPI's Pharmaceutical Services division, TGen Physician in Chief, and Chief Scientific Officer of US Oncology. "I think the oncology community is looking forward to having this type of information available in order to continue to develop more targeted, personalized treatment plans for patients."

KRAS mutation analysis is also being offered as part of Caris Dx's Target Now™ testing program. Target Now is an oncology testing service that utilizes cutting-edge molecular profiling techniques, including DNA microarray, advanced immunohistochemistries (IHC), fluorescent in-situ hybridization (FISH) and sequencing analysis, to provide molecular profiling information about a malignancy as an aid to a patient's oncologist. Each test report provides information on

the molecular targets present in the cancer specimen for which there are believed to be associated therapies based on published literature. Furthermore, the report provides other additional information on the molecular profile of the patient's cancer.

At the beginning of 2008, Caris Diagnostics acquired Caris MPI in order to offer a single source solution to physicians seeking the highest quality medical opinions coupled with the most advanced molecular information available on a patient's tumor. The Company currently receives, processes and provides medical opinions on over one thousand GI biopsies per day. Caris MPI developed the KRAS mutation analysis so that it can be performed on these same biopsies without any need for additional coordination, or delay, and with the highest quality standards.

"Given our leading position in gastrointestinal pathology, it is not only natural, but also imperative for us to offer our clinicians this critical information for their treatment decisions," concluded David D. Halbert, Chairman of Caris Dx. "We have been predicting the convergence of anatomic pathology and molecular testing for some time. With our ability to perform the KRAS analysis on the biopsies that we receive for initial cancer diagnosis each week, the paths of anatomic and molecular test are now united. We look forward to adding further analyses to our Target GI testing panel in the future."

Physicians who are seeking additional information for their patients when considering treatment with Erbitux and/or Vectibix can order mutation analysis for KRAS by contacting 1-800-901-5177.

### **About Caris Diagnostics**

Caris Diagnostics (Caris Dx) is a leading provider of the highest quality diagnostic, translational development and pharmaceutical services encompassing anatomic pathology and molecular testing. Caris Diagnostics provides world-class pathology services to physicians who treat patients in the community setting. The company provides academic-caliber medical consults through its industry-leading team of subspecialty fellowship and expert-trained pathologists in gastrointestinal and liver pathology, dermatopathology and hematopathology. Caris Diagnostics provides the highest levels of service to its customers and their patients through its state-of-the-art laboratories; proprietary, advanced clinical and technology solutions; and rigorous quality assurance programs. Through the molecular testing expertise of the Caris Molecular Profiling Institute (Caris MPI) at Caris Dx, the company also offers advanced molecular analyses of patient samples through prognostic testing services and genomic and proteomic profiling to provide critical information to physicians treating cancer and other complex diseases. In addition, Caris MPI supports pharmaceutical companies and other researchers in their clinical trials for targeted therapeutics with custom genomic and proteomic analyses, analyte preservation, tissue procurement and comprehensive reporting services. The company has strategic relationships with the International Genomics Consortium, US Oncology, the Translational Genomics Research Institute, and the Bidesign Institute of Arizona State University. More than 1,500 physicians nationally use Caris Diagnostics. Formed in 1996, the company is headquartered in Irving, Texas and operates four laboratories: Irving, Texas; Phoenix, Arizona (2 sites); Newton, Massachusetts. Additional information is available at [www.carisdx.com](http://www.carisdx.com).

### **Contacts**

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