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New Data on IntegraGen's miR-31-3p Biomarker Featured in Presentation at 2016 ESMO Congress

Data presented concludes that miR-31-3p expression is predictive of anti-EGFR therapy effect on objective response, depth of response, and early tumor shrinkage in patients with metastatic colorectal cancer enrolled in prospective, randomized FIRE-3 Trial

Copenhagen, Denmark, (**October 10, 2016**) – IntegraGen, a company specializing in the transformation of data from biological samples to actionable genomic information and developer of diagnostic tools for oncology, today announced the presentation of new clinical data demonstrating the benefits of its miR-31-3p biomarker during the 2016 European Society of Medical Oncology (ESMO) Congress being held in Copenhagen. The new data, which was featured as an oral presentation during a proffered plenary session during the meeting, demonstrates that IntegraGen's proprietary miR-31-3p biomarker is predictive of anti-EGFR therapy effect on objective response, depth of response, and early tumor shrinkage in wild-type (WT) metastatic colorectal cancer (mCRC) patients. The miR-31-3p biomarker identifies patients who have better efficacy from anti-EGFR therapy (cetuximab) than with anti-VEGF therapy (bevacizumab). These results are based on an analysis of the expression of miR-31-3p in tumors from 370 *RAS* wild-type (WT) metastatic colorectal cancer (mCRC) patients enrolled in the FIRE-3 clinical trial (AIO KRK-0306).

The data presented on miR-31-3p during the 2016 ESMO Congress builds upon data from a separate analysis of patients enrolled in the FIRE-3 trial that was presented at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting earlier this year which demonstrated that patients with a miR-31-3p expression below a pre-defined threshold treated with FOLFIRI plus cetuximab had a one year longer median overall survival and a 40% reduction in mortality risk compared to patients treated with FOLFIRI plus bevacizumab. These results reconfirm that testing miR-31-3p expression in *RAS* WT mCRC patients can help to identify which 1st line biologic therapy may be most beneficial and support a personalized, precision medicine approach to the care of cancer patients.

"These new results show that miR-31-3p can identify which patients with metastatic colorectal cancer will have improved outcomes when treated in first line with cetuximab compared to bevacizumab when combined with FOLFIRI therapy," stated Professor Pierre Laurent-Puig, M.D., Ph.D. from the Department of Genetics and Head of the Clinical Oncogenetic Unit at the European Georges Pompidou Hospital (HEGP) in Paris, France, Director of the INSERM UMR-S 1147 Research Unit at the Paris Descartes University Medical School, and lead author for the present study. "Having the ability to proactively identify patients who will have a better treatment efficacy with cetuximab when used in first line will enable physicians to better select the most appropriate therapy which provides the greatest clinical benefit for this patient population."

"We have shown that superior response outcome parameters such as early tumor shrinkage and depth of response clearly correlate with overall survival benefit in metastatic colorectal cancer patients treated with biologic therapies," said Professor Volker Heinemann, from the Department of Medical Oncology and Comprehensive Cancer Center at University Hospital Grosshadern in Munich, Germany and lead investigator for the FIRE-3 study. "The present study demonstrated that the nearly two-thirds of the patients with *RAS* wild-type tumors enrolled in the FIRE-3 study had low miR-31-3p expression levels and

would therefore have overall survival and response benefits when treated with cetuximab versus bevacizumab as first line therapy for metastatic colorectal cancer."

"The results from this study provide yet more clinical evidence that IntegraGen's miR-31-3p biomarker can guide the appropriate choice of first line biologic therapy for patients with metastatic colorectal cancer," stated Dr. Bernard Courtieu, IntegraGen's CEO. "The data featured during an oral presentation at this year's ESMO Congress further demonstrates that patients would benefit from the analysis of miR-31-3p expression prior to the determination of which biologic agent to utilize as first line therapy. This aligns with a more personalized approach to cancer care and contributes to the ability to tailor therapies to patients who are more likely to have clinical benefit of these therapies."

Dr. Courtieu also added that "IntegraGen plans to make a miR-31-3p test available in 2017 to cancer specialists and biologists in both Europe and the United States. We estimate that the market for this test represents a $100 million annual revenue opportunity worldwide."

ABOUT THE FIRE-3 CLINICAL TRIAL

The FIRE-3 clinical trial is an independent, randomized, controlled Phase III trial conducted in Europe and led by Ludwig-Maximilians University in Munich, Germany. The study compares outcomes of KRAS Exon 2 wild-type (WT) stage IV colorectal cancer patients randomized to receive FOLFIRI therapy (5-FU, folinic acid and irinotecan) in combination with either cetuximab or bevacizumab.

ABOUT INTEGRAGEN

IntegraGen is a company specializing in deciphering the human genome and producing relevant and easily interpretable data for academic and private laboratories. IntegraGen's oncology efforts provide researchers and clinicians with sophisticated tools for analysis and therapeutic individualization of treatment approaches allowing them to tailor therapy to the genetic profiles of patients. As of December 31, 2015, IntegraGen had 37 employees and had generated revenue of €5.6 million in 2015. Based in Evry Genopole, IntegraGen also has an U.S. office in Cambridge, Massachusetts. IntegraGen is listed on Alternext of Euronext Paris (ISIN: FR0010908723 - Ticker: ALINT - PEA-SME).
For more information on IntegraGen visit www.integragen.com.

CONTACTS

INTEGRAGEN

Bernard COURTIEU
President and CEO

Laurence RIOT LAMOTTE
Chief Financial Officer

contact@integragen.com
Tel: +33 (0)1 60 91 09 00

NewCap
Investors relations
Emmanuel HUYNH
Louis-Victor DELOUVRIER
integragen@newcap.eu
Tel.: +33 (0)1 44 71 98 53

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