

PRESS RELEASE – FOR IMMEDIATE DISTRIBUTION

## **IntegraGen Announces CE-IVD Marking of miRpredX 31-3p Kit Which Predicts Patient Response to anti-EGFR Therapy in RAS Wild-Type Metastatic Colorectal Cancer**

**ÉVRY, FRANCE (7 September 2017)** - IntegraGen, a company specializing in the transformation of data from biological samples into genomic information and diagnostic tools for oncology, today announced the CE-IVD marking and commercial launch of its miRpredX 31-3p test kit in the E.U., the first positive theranostic test for patients with metastatic colorectal cancer.

“The utilization of the miRpredX test can identify metastatic colorectal cancer patients who will likely achieve a better response to anti-EGFR drugs like cetuximab and its use will enable clinicians to better individualize treatment approaches,” said Professor Michel Ducreux, Head of the Gastro-enterology Unit at the Gustave Roussy Cancer Center in Villejuif, France. “As such, the results of this test will enable oncologists to select, the therapy likely to provide the greater clinical benefit for a given patient”.

“Achieving CE-IVD for the miRpredX 31-3p kit is a significant milestone for IntegraGen after over 5 years of test development and clinical validation,” stated Yann Gaston-Mathé, Director of Molecular Diagnostics at IntegraGen. “We anticipate strong interest for this test as a result of the demand by oncologists for better tools to personalize treatment approaches for cancer patients. We are extremely pleased to execute this critical step in our corporate strategy and to launch our commercial efforts for miR-31-3p in a worldwide market worth we estimate to be \$150 million.”

The miRpredX kit will be marketed as a CE-IVD product under the Directive 98/79/EC for in vitro diagnostic medical devices. CE-IVD Marking of the kit follows the successful technical validation of the test and completion of several studies which documented the clinical performance of the test.



### **About the miRpredX 31**

The miRpredX 31-3p test is the first positive theranostic test for patients with metastatic colorectal cancer (mCRC). The test is available as a simple, ready to use kit designed to quantify the expression of the miR-31-3p in formalin-fixed, paraffin-embedded (FFPE) tumor samples using standard quantitative reverse transcription PCR (RT-qPCR). The miRpredX 31-3p test predicts the potential clinical benefits associated with first-line anti-EGFR therapy compared to anti-VEGF therapy or when second or further lines of treatment with anti-EGFR therapy is beneficial versus chemotherapy alone

for patients with RAS wild type (WT) mCRC. A recent study demonstrated that expression of the miR-31-3p is a predictive marker of both overall survival and response to treatment with anti-EGFR therapy.<sup>1</sup> The study also demonstrated that patients whose expression level is measured below the pre-defined threshold treated with FOLFIRI plus cetuximab have a one year longer median overall survival, a 40% reduction in mortality risk, and a better treatment response compared to patients treated with FOLFIRI plus bevacizumab.

For more information on the miRpredX 31-3p test visit [www.miRpredX.com](http://www.miRpredX.com).

### About Metastatic Colorectal Cancer

Colorectal cancer is third most common cancer in men and second most common in women with over 1.3 million new cases annually on a worldwide basis. This includes over 345,000 new cases in Europe and 135,000 new cases in the United States on an annual basis.<sup>2</sup> An estimated 25% of patients with colorectal cancer will present with metastatic disease at the time of diagnostic with up to an additional 50% of patients developing mCRC following initial diagnosis.<sup>3</sup> An estimated 694,000 deaths from CRC occur worldwide every year, accounting for 8.5% of all cancer deaths and making it the fourth most common cause of death from cancer.<sup>2</sup> Approximately 50% of patients with metastatic colorectal cancer, representing 347,000 patients worldwide, have RAS wild-type tumors.<sup>4</sup>

1. Laurent-Puig P, Grisoni ML, Heinemann V, et al. MiR-31-3p as a predictive biomarker of cetuximab efficacy effect in metastatic colorectal cancer (mCRC) patients enrolled in FIRE-3 study. *J Clin Oncol*. 2016; 34 (suppl; abstr 3516).
2. World Health Organization – International Agency for Research on Cancer, 2017
3. Van Cutsem E, Cervantes A, Nordlinger B, Arnold D for the ESMO Guidelines Working Group. Metastatic colorectal cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Ann Oncol*. 2014; 25 Suppl 3:iii1-9.
4. Peeters M, et al. Prevalence of RAS mutations and individual variation patterns among patients with metastatic colorectal cancer: A pooled analysis of randomised controlled trials. *Eur J Cancer*. 2015; 51:1704-13.

### 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, 2016, IntegraGen had 38 employees and had generated revenue of €6.0 million in 2016. Based in Evry Genopole, IntegraGen also has an U.S. office in Cambridge, Massachusetts. IntegraGen is listed on Euronext Growth (ISIN: FR0010908723 - Ticker: ALINT - PEA-SME).

For more information, visit [www.integragen.com](http://www.integragen.com)



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