

European Patent Office Confirms Grant of New ICE COLD-PCR Patent Exclusively Licensed to Transgenomic

OMAHA, Neb.--(BUSINESS WIRE)-- Transgenomic, Inc. (TBIO) today reported that the European Patent Office (EPO) has confirmed its intention to grant a patent covering multiplexed ICE COLD-PCR (MX-ICP) technology in the European Union (EU). This Dana-Farber Cancer Institute patent is exclusively licensed to Transgenomic.

Paul Kinnon, President and CEO of Transgenomic, commented, “We are delighted that the EPO has decided to grant this important patent for our ICE COLD-PCR (ICP) technology. We have been anticipating the approval of this patent in the EU, which fully opens up a major new market for the company to commercialize its MX-ICP products. This new patent allows us to build on our initial presence in Europe to implement a full-scale EU-wide commercialization campaign and also complements our expansion plans for Asia. These initiatives will be a focus of the post-merger business plan.”

Mr. Kinnon continued, “As everyone is aware, we see MX-ICP is a valuable technology because it enables the accelerated adoption of non-invasive liquid biopsies that allow the analysis of tumor DNA in patient blood or plasma. The growing importance of this approach was evident in the large number of presentations on liquid biopsies at the recently-completed 2017 ASCO Annual Meeting. This new patent further strengthens our proprietary position in the major European market, and equivalent MX-ICP patents are pending in the U.S. and Canada as well.”

Cancer is increasingly being treated based on the genetic makeup of tumors rather than their location in the body, fueling a growing demand for genomic testing from drug developers and oncologists and their patients. MX-ICP helps make this testing feasible by enabling the timely and cost-effective analysis of pan-cancer profiling panels covering multiple mutations in multiple genes, using either tissue or liquid patient samples.

Ilan Danieli, CEO of Precipio Diagnostics, which is in the process of completing a merger with Transgenomic, noted, “This new patent is significant because we see the European market for clinical diagnostic testing as a key area for the expansion and adoption of ICP technology and products outside of the US market. In the past Transgenomic has received interest in the MX-ICP technology from various European players, but it had limited ability to provide MX-ICP products to this market. This new patent will support our plans for the merged company to expand its activities into major new markets.”

MX-ICP is an ultra-high sensitivity DNA amplification technology that allows for the simultaneous detection of mutations in multiple genes from either tumor or liquid samples, such as blood or urine, in a single test tube or well. Multiplexing decreases time and costs, improves workflow and reduces the risks of cross-contamination. MX-ICP panels have the added advantage of enabling the user to detect unexpected rare and novel mutations. Importantly, MX-ICP is platform agnostic--it works on all the sequencing platforms found in laboratories today. MX-ICP is easy to use, highly reliable and easily implemented, requiring minimal disruption to current sequencing processes and procedures.

EPO Patent App. No. 12764286.6; “Methods and Compositions to Enable Multiplex COLD-PCR,” is expected to issue in the next few months. Transgenomic’s development of MX-ICP assays is supported by a \$1.6 million grant from the National Institutes of Health.

MX-ICP, which provides amplified sensitivity for mutation detection down to 0.01%, achieves its ultra-high sensitivity through selective amplification of mutant DNA. The result is up to a 500-fold increase in sensitivity in identifying mutations with the most precise sequence alteration detection rates available. ICE COLD-PCR was originally developed by the laboratory of Dr. Mike Makrigiorgos at the Dana-Farber Cancer Institute, which has exclusively licensed rights to the technology to Transgenomic.

About Transgenomic

Transgenomic, Inc. is a global biotechnology company advancing personalized medicine in oncology and inherited diseases through advanced diagnostic technologies, such as its revolutionary ICE COLD-PCR, which enables use of liquid biopsies for mutation detection. The company also provides specialized clinical and research services to biopharmaceutical companies developing targeted therapies. Transgenomic’s diagnostic technologies are designed to improve medical diagnoses and patient outcomes.