

News Release

Rosetta Genomics Enters Research Collaboration using microRNA Biomarkers to Predict Response to Leading Immuno-Oncology Drug Nivolumab in Lung Cancer Patients

PHILADELPHIA and REHOVOT, Israel (November 21, 2016) – Rosetta Genomics Ltd. (NASDAQ: ROSG), a leading developer and provider of microRNA-based and other molecular diagnostics, announces that the Company has entered into a research agreement with Sheba Medical Center at Tel HaShomer, Israel, to develop a microRNA-based signature to predict response to Nivolumab, an immunotherapy drug marketed as Opdivo®, which is approved for the treatment of lung cancer patients.

The prospective study, "Circulating microRNA Biomarkers for Lung Cancer Patient Response to the Drug Nivolumab when Administered as Second Line"," will be led by Jair Bar, M.D., Deputy Director-Institute of Oncology, Sheba Medical Center, and will include collection of whole blood, peripheral blood mononuclear cells (PBMCs) and serum samples. Rosetta will use its proprietary microarray design and qRT-PCR platform to identify miRNAs associated with response. The primary endpoint of the study is prediction of Objective Response Rate (ORR) as measured by tumor radiologic response to the immunotherapy (RECIST 1.1 response rate at 6 months.) The secondary endpoint of the project is to predict survival benefit of advanced non-small cell lung cancer (NSCLC) from immunotherapy as measured by Overall Survival (OS) and OS rate (12 and 24 months).

"Immunotherapy is a promising tool in the treatment of lung cancer. We are still at the early phases of understanding who will benefit from immunotherapy, which is making a big difference for a subgroup of 23-30% of the patients. For this reason, we are excited to be collaborating with Rosetta Genomics to identify blood biomarkers that will predict which patients will benefit from immunotherapy with Nivolumab. Our aim is to develop a test that offers a potentially powerful method of identifying markers to measure the status of the immune system and other biological events. Our goal is to be able to accurately predict which patients should receive immunotherapy and which patients would receive larger benefit from other treatment modalities," concluded Dr. Bar.

"microRNAs are key regulators of immune system and have been shown to directly target and inhibit PD-1 and PDL-1 in various cancers. Their important biological role as well as high stability in the circulation makes them excellent candidates for predicting response to these breakthrough drugs. We have conducted early clinical research that has demonstrated microRNAs' potential as predictive biomarkers in immuno-oncology," stated Dganit Bar, Ph.D., Chief Scientific Officer of Rosetta Genomics. "Our goals for this collaboration with Sheba Medical dovetail with earlier work we conducted in partnership with large pharmaceutical companies that focused on establishing biomarkers to identify responders to certain immunooncology drugs."

"The development of a new microRNA biomarker signature to predict response to Opdivo in lung cancer patients fits well with our comprehensive lung-specific menu that assists in diagnosis, prognosis, and prediction to therapy for lung cancer patients. This menu includes a full array of lung-specific biomarkers via FISH, PCR, and IHC, OncoGxLung (utilizing NGS), and mi-LUNG, a proprietary microRNA diagnostic test for differentiating between the 4 main subtypes of lung cancer. We look forward to advancing this collaboration with Sheba Medical Center on the development of a new microRNA biomarker signature that can better predict patient response to Opdivo and other PD-1 and PD-1 inhibitors in lung cancer patients," noted Kenneth A. Berlin, President and Chief Executive Officer of Rosetta Genomics.

Opdivo® is a registered trademark of Bristol-Myers Squibb.

About Rosetta Genomics

Rosetta develops and commercializes a full range of microRNA-based and other molecular diagnostics. Rosetta's integrative research platform combining bioinformatics and state-of-theart laboratory processes has led to the discovery of hundreds of biologically validated novel human microRNAs. Building on its strong patent position and proprietary platform technologies, Rosetta is working on the application of these technologies in the development and commercialization of a full range of microRNA-based diagnostic tools. Through the acquisition of PersonalizeDx, the Company now offers core FISH, IHC and PCR-based testing capabilities and partnerships in Pathology, Oncology and Urology that provide additional content and platforms that complement Rosetta's microRNA and Next-Gen Sequencing offerings. RosettaGX RevealTM, a Thyroid microRNA Classifier for the diagnosis of indeterminate thyroid FNA smears, as well as the full RosettaGXTM portfolio of cancer testing services are commercially available through the Company's Philadelphia, PA- and Lake Forest, CA-based CAP-accredited, CLIA-certified labs. For more information visit www.rosettagx.com.

Forward-Looking Statement Disclaimer

Various statements in this release concerning Rosetta's future expectations, plans and prospects including, but not limited to statements relating to developing new biomarker signatures, predicting health outcomes, developing diagnostic tests, and partnering with pharmaceutical companies constitute forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including those risks more fully discussed in the "Risk Factors" section of Rosetta's most recently filed Annual Report on Form 20-F, as filed with the SEC. In addition, any forward-looking statements represent Rosetta's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. Rosetta does not assume any obligation to update any forward-looking statements unless required by law.

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