



## **Rosetta Genomics Receives Final Approval from New York State for First-of-its-kind Thyroid Cancer Diagnostic Assay**

*RosettaGX Reveal™ Available in all 50 States*

**PHILADELPHIA and REHOVOT, Israel (May 4, 2017)** – Rosetta Genomics Ltd. (NASDAQ: ROSG), a genomic diagnostics company that improves treatment decisions by providing timely and accurate diagnostic information to physicians, announces it has received final approval for RosettaGX Reveal™ (Reveal), its novel microRNA classifier for the diagnosis of indeterminate thyroid cases from the New York State Department of Health (NYSDOH) under the Company's Molecular Oncology permit. RosettaGX Reveal is the only molecular test in the thyroid market that has been validated in a multicenter, international, blinded study using convenient, routinely prepared cytology slides.

The Rosetta Laboratory is CLIA-certified, but New York State requires an additional license from the NYSDOH for Lab Developed Tests to be offered to patients in the state. The assay had previously received conditional approval and now that approval has become final.

"We are very pleased to have final approval for this important cancer diagnostic for the benefit of physicians and patients in New York State. The NYSDOH has a very rigorous approval process and this final approval further confirms the overall robust performance of our Reveal assay," stated Kenneth A. Berlin, President and Chief Executive Officer of Rosetta Genomics. "Reveal is a truly differentiated assay being promoted in an established market that has substantial room for further penetration. Reveal's convenience and performance advantages are strongly resonating with clinicians, allowing us to continue to win business from the competition and to expand Reveal sales into untapped parts of the market. Continuing to have access for Reveal to the vast New York market will significantly enhance these efforts."

"It is estimated that nearly 550,000 FNAs are performed on thyroid nodules each year in the U.S. and that approximately 740,000 are performed annually in Europe. Interpretation of FNA samples is not always straightforward, leading to an indeterminate result in up to 30% of the samples. Many patients with indeterminate results undergo surgery as a precaution despite the fact that up to 80% of these cases are benign. This exposes patients to unnecessary surgical risk and costs the healthcare system hundreds of millions of dollars. Through an analysis of our validation study data, we believe we can help prevent up to 75% of unnecessary thyroid surgeries," added Mr. Berlin.

### **About Rosetta Genomics**

Rosetta is pioneering the field of molecular diagnostics by offering rapid and accurate diagnostic information that enables physicians to make more timely and informed treatment decisions to improve patient care. Rosetta has developed a portfolio of unique diagnostic solutions for oncologists, urologists, endocrinologists, cytopathologists and other specialists to

help them deliver better care to their patients. RosettaGX Reveal™, a Thyroid microRNA Classifier for the diagnosis of cancer in thyroid nodules, as well as the full RosettaGX™ portfolio of cancer testing services are commercially available through the Company's Philadelphia, PA- and Lake Forest, CA-based CAP-accredited, CLIA-certified labs.

### **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 creating long term revenue opportunities via Reveal, achieving further market penetration and market acceptance from clinicians, expanding Reveal sales into untapped parts of the market, and growing global interest in this assay and statements containing the words "expect," "believe," "will," "may," "should," "project," "estimate," "anticipated," "scheduled," and like expressions, and the negative thereof, 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 risks and uncertainties, including, but are not limited to the following: we will require substantial additional funds to continue our operations and, if additional funds are not available, we may need to significantly scale back or cease our operations; we have a history of losses and may never be profitable; if we are unable to expand sales of our diagnostic tests in the United States, it would have a material adverse effect on our business and financial condition; the intensely competitive biotechnology market could diminish demand for our tests and products; the market may not be receptive to any diagnostic tests or therapeutic products using our microRNA technology; we currently have limited sales, marketing or distribution experience and may in the future depend significantly on third parties to commercialize microRNA-based diagnostic tests or therapeutic products we may develop; we are largely dependent upon our distributors for the success of commercialization of our current diagnostic tests; health insurers and other third-party payors may decide not to cover our diagnostic products or may provide inadequate reimbursement, which could jeopardize our commercial prospects; because of Medicare billing rules, we may not receive reimbursement for all tests provided to Medicare patients; if we fail to comply with our obligations under any licenses or related agreements, we could lose license rights that may be necessary for developing microRNA-based diagnostics and therapeutics; if we fail to comply with the complex federal, state, local and foreign laws and regulations that apply to our business, we could suffer severe consequences that could materially and adversely affect our operating results and financial condition; we contract with a single manufacturer for the purchase of microarray chips for certain tests, and the failure of this manufacturer to supply sufficient quantities on a timely basis could have a material adverse effect on our business; and other risk factors discussed under the heading "Risk Factors" in 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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