

## **Rosetta Genomics' Novel and Differentiated Thyroid Cancer Assay Moves to Advanced Stages of Development**

*Company remains on track to launch the novel assay by the end of the third quarter of 2015*

**PRINCETON, N.J. and REHOVOT, Israel (February 26, 2015)** – Rosetta Genomics Ltd. (NASDAQ: ROSG), a leading developer and provider of microRNA-based molecular diagnostics, provides an update on the development of its microRNA-based assay for the differential diagnosis of thyroid neoplasia, which has the potential to improve clinical management in a cost-effective manner by reducing the number of unnecessary surgeries.

An estimated 4% to 7% of the general population develops nodules in the thyroid that can be felt upon examination, although fewer than 10% are malignant. A Fine Needle Aspirate (FNA) to obtain tissue from the thyroid nodule for analysis is the standard technique for detecting cancer. It is estimated that nearly 500,000 FNAs are performed each year in the U.S. and 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. Approximately 75% of patients with indeterminate results undergo surgery - despite the fact that less than 50% of these tumors are malignant. This exposes patients to unnecessary surgical risk and costs hundreds of millions of dollars.

Rosetta Genomics has been developing this assay for the past two years and has conducted several discovery studies with more than 500 thyroid FNA and surgical samples, representing various histological subtypes. The samples were analyzed using the Company's proprietary microarray and qPCR platforms, and a subset of the samples was also analyzed by deep sequencing. This approach enabled the discovery of new microRNA biomarkers and allows the profiling of small cytological samples to ensure low failure rates.

Several microRNAs differentially expressed between benign and malignant tumors, as well as microRNA biomarkers of medullary thyroid carcinoma, one of the deadliest forms of thyroid cancer, were identified in these studies. These studies also demonstrated the ability to extract and profile microRNAs from thyroid FNAs in various sample types, such as cytological smears and cellblocks, and in a manner that is consistent with common clinical practices. Rosetta is now conducting training studies and will soon commence blinded validation studies at several leading medical centers in Israel, Europe and the U.S, where the Company already has samples ready for testing.

"We are very pleased with the progress we've made in advancing the development of our thyroid cancer assay. Upon commercialization we believe our thyroid assay will be competitive with current testing methods as we expect it to have the best combination of Negative

Predictive Values and Positive Predictive Values, our turnaround time is expected to be less than half that of the market leaders and our process will spare patients unnecessary needle passages. Our specimen collection process is a competitive differentiator because it can utilize the smear used by the cytologist as part of their standard process rather than taking additional FNAs and preserving them in specialized tubes. The latter process of taking additional FNAs through another needle passage into the patient's neck is required by some currently marketed thyroid tests, also creates the potential for misdiagnosis," stated Kenneth A. Berlin, President and Chief Executive Officer of Rosetta Genomics.

According to Nicole Massoll, M.D., Director of Cytopathology, University of Arkansas for Medical Sciences, Director of FNAPath, "Rosetta's soon to be launched thyroid test brings an innovative new way to help those patients and physicians struggling with an indeterminate result in thyroid nodules utilizing microRNAs. This test uses selected slides from the smears with the previously identified cells in question for molecular testing, while methods that require a separate FNA may not have the cells of interest leaving the potential for misdiagnosis."

"We will soon complete our training and validation studies and we remain on track to launch our microRNA-based thyroid neoplasia assay by the end of the third quarter of 2015. We believe this will be an important product for our portfolio as earlier competitors have already established the market and such testing has already been incorporated into the National Comprehensive Cancer Network's clinical practice guidelines. In addition, the growing body of clinical evidence supporting the medical and economic utility of our thyroid assay has been developed and should support relatively rapid reimbursement coverage. With nearly 30% of FNAs yielding indeterminate results, the annual opportunity in the U.S. alone exceeds \$350 million and currently available tests in this space generated approximately \$50 million in revenues in 2014. We are looking forward to launching our novel and differentiated assay into this fast converting market," added Mr. Berlin.

### **About Rosetta Cancer Testing Services**

Rosetta Cancer Tests are a series of microRNA-based diagnostic testing services offered by Rosetta Genomics. The Rosetta Cancer Origin Test™ can accurately identify the primary tumor type in primary and metastatic cancer including cancer of unknown or uncertain primary (CUP). The Rosetta Lung Cancer Test™ accurately identifies the four main subtypes of lung cancer using small amounts of tumor cells. The Rosetta Kidney Cancer Test™ accurately classifies the four most common kidney tumors: clear cell renal cell carcinoma (RCC), papillary RCC, chromophobe RCC and oncocytoma. Rosetta's assays are designed to provide objective diagnostic data; it is the treating physician's responsibility to diagnose and administer the appropriate treatment. In the U.S. alone, Rosetta Genomics estimates that 200,000 patients a year may benefit from the Rosetta Cancer Origin Test™, 65,000 from the Rosetta Kidney Cancer Test™ and 226,000 patients from the Rosetta Lung Cancer Test™. The Company's assays are offered directly by Rosetta Genomics in the U.S., and through distributors around the world. For more information, please visit [www.rosettagenomics.com](http://www.rosettagenomics.com). Parties interested in ordering the test can contact Rosetta Genomics at (215) 382-9000 ext. 309.

### **About Rosetta Genomics**

Rosetta develops and commercializes a full range of microRNA-based molecular diagnostics. Founded in 2000, Rosetta's integrative research platform combining bioinformatics and state-of-

the-art 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. Rosetta's cancer testing services are commercially available through its Philadelphia-based CAP-accredited, CLIA-certified lab.

#### **Forward-Looking Statement Disclaimer**

Various statements in this release concerning Rosetta's future expectations, plans and prospects, including without limitation, the timing in which Rosetta will commence blinded validation studies, the various aspects of Rosetta's thyroid assay as well as Rosetta's thyroid assay as a whole being competitive with current testing methods, the scope of sales generated by and the market opportunity for Rosetta's thyroid assay, the fact that Rosetta's thyroid assay will launch, as well as the timeline for said launch, Rosetta's thyroid assay being incorporated in the National Comprehensive Cancer Network's clinical practice guidelines, Rosetta's thyroid assay receiving reimbursement coverage, Rosetta's development or commercialization of molecular diagnostics or therapeutics, the market acceptance of Rosetta's cancer testing services, particularly the Rosetta Cancer Origin Test™ and the thyroid assay, Rosetta's development of personalized medicine products and services, 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 Annual Report on Form 20-F for the year ended December 31, 2013 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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