

News Release



Study Validating Ability of microRNAs to Predict Progression of Bladder Cancer Published in *British Journal of Urology International*

PHILADELPHIA and REHOVOT, Israel (February 7, 2013)–Rosetta Genomics Ltd. (NASDAQ: ROSG), a leading developer and provider of microRNA-based molecular diagnostics, today announced that data from a study demonstrating the ability of microRNA expression to serve as a biomarker to predict the progression of bladder urothelial carcinoma were published online in the *British Journal of Urology International*, in an article entitled, “Predicting progression of bladder urothelial carcinoma using microRNA expression.” The article can be accessed online at <http://onlinelibrary.wiley.com/doi/10.1111/j.1464-410X.2012.11748.x/abstract> and is expected to be published in the print edition of the *British Journal of Urology International*.

In the study, formalin-fixed, paraffin-embedded samples of 108 non-muscle invasive (“NMI”) bladder carcinomas, and 29 muscle invasive tumors, were collected and highly specific microRNA expression levels were measured by Rosetta Genomics’ microarray technology. Using micro-dissection, specific tumor microRNAs were chosen to be included in the study in order to avoid background contamination derived from surrounding tissue. The study found that the expression level of one microRNA, miR-29c*, was significantly under-expressed in tumors that progressed and could be used to stratify bladder cancer patients into risk groups.

The study showed that significantly higher expression of miR-29c* was detected in NMI bladder tumors that did not progress compared with lesions that did progress. The lower expression of miR-29c* in patients that later progressed was similar to the expression levels seen in patients with muscle invasive disease.

Prediction of recurrence and progression is currently based upon clinical and pathological factors such as: tumor grade, tumor stage, number of lesions, tumor size, prior recurrence rate and presence of concomitant carcinoma in-situ (“CIS”). These factors are not specific enough to predict progression and approximately 50% of patients diagnosed as high risk in fact do not progress within 3 years. The follow up on patients is expensive, and requires invasive procedures that are uncomfortable for the patient and can lead to complications.

Study author Prof. Ofer Nativ, M.D., Department of Urology, Bnei Zion Medical Center in Haifa, Israel, noted, “Despite the utilization of clinical and pathological factors, the ability to assess patient prognosis is not satisfactory, partially due to the subjectivity of grading and staging that causes relatively high inter-observer variability. Since follow-up and treatment regimens depend on prognosis, there is a need for more accurate stratification to increase the predictive values of risk groups. With a reliable diagnostic test for progression, suitable treatment could be tailored to each patient. This study showed that microRNA can be useful biomarkers for prognosis in patients with urothelial carcinoma and that the expression levels of several microRNAs, including miR-29c, identified high- and low-risk groups. These biomarkers show promise for stratification of bladder cancer patients.”

“This publication adds to the growing body of clinical data demonstrating the utility of microRNA expression for predicting progression of disease, and for stratification of patients with bladder cancer,” stated Kenneth A. Berlin, President and CEO of Rosetta Genomics. “According to the American Cancer Society, urothelial cancer of the bladder is the fourth most common cancer in men in the Western world. New treatment options in oncology make it more important than ever to know

the potential risk of disease progression. Our proprietary microRNA technology, with its predictive value, may have a significant impact on treatment and follow-up care for individual patients.”

About Bladder Cancer

Bladder cancer begins when normal cells in the bladder lining, most commonly, urothelial cells, change and grow uncontrollably, forming a mass called a tumor. Most bladder cancers are transitional cell carcinomas (cancer that begins in cells that normally make up the inner lining of the bladder). Other types include squamous cell carcinoma (cancer that begins in thin, flat cells) and adenocarcinoma (cancer that begins in cells that make and release mucus and other fluids). The cells that form squamous cell carcinoma and adenocarcinoma develop in the inner lining of the bladder as a result of chronic irritation and inflammation. Bladder cancer may be described as noninvasive, non-muscle-invasive, or muscle-invasive. Both noninvasive and non-muscle-invasive bladder cancers have the possibility of spreading into the bladder muscle or to other parts of the body. Additionally, all cell types of bladder cancer can metastasize (spread) beyond the bladder.

According to the National Cancer Institute, it is estimated that 73,510 men and women (55,600 men and 17,910 women) will be diagnosed with and 14,880 men and women will die of cancer of the urinary bladder in 2012.

About miRview® Products

miRview® are a series of microRNA-based diagnostic products offered by Rosetta Genomics. miRview® mets² accurately identifies the primary tumor type in primary and metastatic cancer including CUP. miRview®meso diagnoses mesothelioma, a cancer connected to asbestos exposure. miRview® lung accurately identifies the four main subtypes of lung cancer using small amounts of tumor cells. miRview® kidney accurately classifies the four most common kidney tumors: clear cell renal cell carcinoma (RCC), papillary RCC, chromophobe RCC and oncocytoma. miRview® tests 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 miRview® mets² test, 60,000 from miRview®meso, 54,000 from miRview® kidney and 226,000 patients from miRview® lung. 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.mirviewdx.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 miRview® product line is commercially available through its Philadelphia-based CAP-accredited, CLIA-certified lab. Frost & Sullivan recognized Rosetta Genomics with the 2012 North American Next Generation Diagnostics Entrepreneurial Company of the Year Award.

Forward-Looking Statement Disclaimer

Various statements in this release concerning Rosetta’s future expectations, plans and prospects, including without limitation, statements relating to Rosetta’s strategic plan, the market acceptance of Rosetta’s miRview® assays, particularly miRview® mets², Rosetta’s capitalization of its microRNA platform and Rosetta’s development of personalized medicine products 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, 2011 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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