Regulus Appoints Head of Regulus microMarkers[™] R&D Division

-Martin Beaulieu, Ph.D. Brings Extensive Diagnostic Assay Development Experience--Regulus microMarkers ™ Designed to Support Regulus' Therapeutic Pipeline, its Collaborators and Strategic Partners-

LA JOLLA, Calif., Feb. 13, 2014 /<u>PRNewswire</u>/ -- <u>Regulus Therapeutics Inc</u>. (*NASDAQ:RGLS*), a biopharmaceutical company leading the discovery and development of innovative medicines targeting microRNAs, announced today the appointment of Martin Beaulieu, Ph.D. as the head of Regulus *micro*Markers[™], a research and development division of Regulus designed to support the expansion of its innovative biomarkers platform aimed at identifying microRNAs as biomarkers for disease. Regulus *micro*Markers[™] utilizes a clinically-validated, highly reproducible, proprietary technology platform to extract, profile, and analyze microRNAs as potential biomarkers for disease and Regulus controls key intellectual property and know-how related to the division.

"The work we are conducting in our Regulus *micro*Markers[™] division is very important," said Neil W. Gibson, Ph.D., Chief Scientific Officer of Regulus. "We believe our innovative technology platform and know-how may help us and others make more informed decisions earlier in drug development, such as utilizing microRNA biomarkers to select optimal patient segments in clinical trials and developing prognostic and predictive markers that can help monitor disease progression or relapse."

David Szekeres, Chief Business Officer and General Counsel of Regulus added, "We are extremely pleased to welcome Dr. Beaulieu to lead Regulus *micro*Markers[™]. His experience will enhance our collective expertise and will provide guidance as we continue to expand our efforts in identifying microRNAs as biomarkers for disease."

Dr. Beaulieu brings over 15 years of diagnostic assay development and biomarker research experience within the life science industry to Regulus. Prior to joining Regulus, Dr. Beaulieu held positions of increasing responsibility at Abbott Point of Care Inc., DiagnoCure, Inc., Gen-Probe, Inc., and Sequenom, Inc. During his tenure in these positions, Dr. Beaulieu was responsible for leading teams in the development of molecular applications and diagnostic assays including novel high value molecular oncology prognostic tests.

Regulus believes that microRNA biomarkers are of significant value and may provide opportunities to develop prognostic and predictive markers that can help monitor disease progression or relapse for its therapeutic candidates that may be developed and any drugs developed by other companies. In 2012, Regulus formed a research collaboration with Biogen Idec focused on the discovery of microRNAs as biomarkers for multiple sclerosis. More recently, Regulus has entered into an arrangement with another leading, commercial-stage pharmaceutical company to explore microRNAs as biomarkers for specific patient populations.

About microRNAs and microRNAs as Biomarkers

The discovery of <u>microRNAs</u> in humans during the last decade is one of the most exciting scientific breakthroughs in recent history. microRNAs are small RNA molecules, typically 20 to 25 nucleotides in length, that do not encode proteins but instead regulate gene expression. More than 500 microRNAs have been identified in the human genome, and over one-third of all human genes are believed to be regulated by microRNAs. microRNA expression, or function, has been shown to be significantly altered or dysregulated in many disease states, including oncology, fibrosis and metabolic diseases. Regulus believes that microRNAs are clinically relevant therapeutic targets and may be ideally suited as biomarkers for these disease states and others.

microRNAs have been detected in bodily fluids such as blood, and emerging data has demonstrated that microRNA signatures in blood can mimic the expression profile observed in disease tissues. Regulus has a rich intellectual property estate and oligonucleotide technology know-how and believes that microRNA biomarkers may be used to select optimal patient segments in clinical trials and to develop prognostic and predictive markers that can help monitor disease progression or relapse.

About Regulus

Regulus Therapeutics Inc. (*NASDAQ:RGLS*) is a biopharmaceutical company leading the discovery and development of innovative medicines targeting microRNAs. Regulus is uniquely positioned to leverage a mature therapeutic platform that harnesses the oligonucleotide drug discovery and development expertise of Alnylam Pharmaceuticals, Inc. and Isis Pharmaceuticals, Inc., which founded the company. Regulus has a well-balanced microRNA therapeutic pipeline entering clinical development, an emerging microRNA biomarkers platform to support its therapeutic programs, and a rich intellectual property estate to retain its leadership in the microRNA field. Regulus intends to focus its proprietary efforts on developing microRNA therapeutics for oncology indications and orphan diseases and is currently advancing several programs toward clinical development in

oncology, fibrosis and metabolic diseases. Regulus is also developing RG-101, a GalNAc-conjugated anti-miR targeting microRNA-122, for the treatment of chronic hepatitis C virus infection. Regulus' commitment to innovation and its leadership in the microRNA field have enabled the formation of strategic alliances with AstraZeneca, GlaxoSmithKline and Sanofi. In addition, the Company has established Regulus *micro*Markers[™], a research and development division focused on identifying microRNAs as biomarkers of human disease, which is designed to support its therapeutic pipeline, collaborators and strategic partners.

For more information, please visit <u>http://www.regulusrx.com</u>.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements associated with Regulus' expectations regarding future therapeutic and commercial potential of Regulus' business plans, technologies and intellectual property related to microRNA therapeutics being discovered and developed by Regulus. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Regulus' current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. These and other risks concerning Regulus' programs are described in additional detail in Regulus' SEC filings. All forward-looking statements contained in this press release speak only as of the date on which they were made. Regulus undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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