Regulus Appoints Michael Huang, M.D. as Vice President, Clinical Development

LA JOLLA, Calif., Aug. 25, 2015 /PRNewswire/ -- Regulus Therapeutics Inc. (*NASDAQ:RGLS*), a biopharmaceutical company leading the discovery and development of innovative medicines targeting microRNAs, announced today the appointment of Michael Huang, M.D. as Vice President, Clinical Development. Dr. Huang is an experienced drug developer with proven success in advancing programs through clinical trials that led to commercialization in a wide range of therapeutic areas. At Regulus, Dr. Huang will be responsible for leading the company's global clinical operations and medical affairs and will serve as a key member of the executive leadership team.

"Over the last two and a half years, Regulus has executed well on our 'Clinical Map Initiative' goals and we've advanced our lead microRNA therapeutic programs into important stages of clinical development. RG-101 is being tested in Phase II, RG-012 is being tested in Phase I, and RG-125 is expected to enter the clinic by the end of 2015," said Paul Grint, M.D., President and CEO of Regulus. "To continue to strengthen our clinical capabilities, we are pleased to welcome Mike to Regulus. His expertise in advancing investigational drugs through both early and late-stage development will greatly enhance our ability to bring microRNA therapeutics to patients in need."

"I am excited to join Paul and the Regulus team, who are so enthusiastic and committed to creating a new class of high-impact medicines based on microRNAs," said Dr. Huang, Vice President, Clinical Development of Regulus. "At Regulus, we are uniquely positioned to leverage our oligonucleotide drug discovery and development expertise to treat a wide variety of serious diseases and I feel confident in our ability to make meaningful impacts on patients' lives."

Most recently, Dr. Huang served as Vice President, Clinical Development of Auspex Pharmaceuticals, Inc. (acquired by Teva Pharmaceutical Industries Ltd. in May 2015) and was responsible for providing project and clinical leadership across multiple programs focused on the treatment of central nervous system disorders. Prior to Auspex, Dr. Huang served in medical leadership roles at Santarus, Inc., Spectrum Pharmaceuticals, Inc., Phenomix Corporation and Valeant Pharmaceuticals International. His clinical and medical expertise has resulted in regulatory approvals of Potiga®, Zevalin®, Uceris® and Ruconest®. Dr. Huang received his Bachelor of Arts degree in molecular and cell biology from the University of California, Berkeley and an M.D. from the Chicago Medical School at Rosalind Franklin University. He completed his residency training in family medicine at the University of California, Irvine and is Board Certified in primary care medicine. Dr. Huang is the author or co-author of numerous peer-reviewed journal articles, abstracts and scientific publications.

The Regulus Board of Directors approved the grant of an inducement stock option to purchase 41,948 shares of common stock to Dr. Huang. The stock option has an exercise price per share equal to $6.89, the fair market value on the grant date, and vests ratably over four years, subject to Dr. Huang's continued service relationship with Regulus. The stock option also has a ten year term and is subject to the terms and conditions of Regulus' Inducement Plan and the applicable stock option agreement.

The stock option grant was granted as an inducement material to Dr. Huang entering into employment with Regulus Therapeutics Inc. in accordance with NASDAQ listing Rule 5635(c)(4).

About microRNAs

microRNAs are small RNA molecules, typically 20 to 25 nucleotides in length, that do not encode proteins but instead regulate gene expression. More than 800 microRNAs have been identified in the human genome, and over one-third of all human genes are believed to be regulated by microRNAs. A single microRNA can regulate entire networks of genes. As such, these molecules are considered master regulators of the human genome. microRNA expression, or function, has been shown to be significantly altered or dysregulated in many disease states, including oncology, fibrosis, metabolic diseases, immune-inflammatory diseases and HCV. Targeting microRNAs with anti-miRs, chemically modified, single-stranded oligonucleotides, offers a unique approach to treating disease by modulating entire biological pathways and may become a new and major class of drugs with broad therapeutic application.

About Regulus

Regulus Therapeutics Inc. (*NASDAQ:RGLS*) is a biopharmaceutical company leading the discovery and development of innovative medicines targeting microRNAs. Regulus has leveraged its oligonucleotide drug discovery and development expertise to develop a well-balanced microRNA therapeutics pipeline complemented by a maturing microMarkers^{SM} biomarkers platform and a rich intellectual property estate to retain its leadership in the microRNA field. Under its 'Clinical Map Initiative', Regulus is developing RG-101, a

GalNAc-conjugated anti-miR targeting microRNA-122 for the treatment of chronic hepatitis C virus infection, and RG-012, an anti-miR targeting microRNA-21 for the treatment of Alport syndrome, a life-threatening kidney disease driven by genetic mutations with no approved therapy. In addition, RG-125, a GalNAc-conjugated anti-miR targeting microRNA-103/107 for the treatment of NASH in patients with type 2 diabetes/pre-diabetes, has been selected for clinical development. Regulus is also advancing several programs toward clinical development in orphan disease indications, oncology and fibrosis. Regulus' commitment to innovation has resulted in multiple peer-reviewed publications in notable scientific journals and has resulted in the formation of strategic alliances with AstraZeneca and Sanofi and a research collaboration with Biogen focused on microRNA biomarkers. Regulus maintains its corporate headquarters in La Jolla, CA. For more information, please visit http://www.regulusrx.com.

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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