

## Biogen Idec and Regulus Therapeutics Form Collaboration to Explore microRNA Biomarkers for Disease Monitoring and Response to Therapy

*- Initial focus on discovery of microRNAs as biomarkers for multiple sclerosis (MS) -*

LA JOLLA, Calif., Aug. 15, 2012 /PRNewswire/ -- Regulus Therapeutics Inc., a biopharmaceutical company leading the discovery and development of innovative medicines targeting microRNAs, announced today that it has entered into a collaboration with Biogen Idec (NASDAQ: BIIB) to identify microRNAs as biomarkers for multiple sclerosis (MS). Under the transaction, Biogen Idec will make an investment in Regulus in addition to upfront and milestone payments. The key objective of the collaboration is to identify microRNA biomarkers in the blood of patients with MS. Regulus believes that microRNA biomarkers may be used to select optimal patient segments in clinical trials, to develop companion diagnostics, and to monitor disease progression or relapse.

"Utilizing innovative technology such as biomarkers can help us make more informed decisions earlier in clinical development and is key to our overall company strategy to enhance early-stage discovery efforts," said Steven Holtzman, Executive Vice President, Corporate Development of Biogen Idec. "We're excited to collaborate with Regulus to seek to identify biomarkers in MS patients, and are hopeful it can speed the work we're doing to bring new, effective treatments to market for patients with MS."

"Regulus is delighted to form a collaboration with Biogen Idec, a biotechnology pioneer with more than thirty years of innovative contributions to the industry," said Garry E. Menzel, Ph.D., Chief Operating Officer and Executive Vice President of Finance of Regulus Therapeutics Inc. "This collaboration allows us to further explore our proprietary microRNA biomarker platform with Biogen Idec's additional resources and expertise. We believe that identification of microRNAs as biomarkers for multiple sclerosis may advance the treatment of this devastating disease."

### **About microRNAs and microRNAs as Biomarkers**

The discovery of [microRNAs](#) 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, like MS.

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 comprehensive intellectual property estate and oligonucleotide technology know-how and believes that microRNA biomarkers may be used to select optimal patient segments in clinical trials, to develop companion diagnostics, and to monitor disease progression or relapse.

### **About Multiple Sclerosis**

Multiple sclerosis (MS) is a chronic, unpredictable, and progressive disease of the central nervous system that causes inflammation and destruction of nerve fibers as well as the myelin sheath, the protective layer that surrounds the body's nerve fibers. Symptoms of MS vary and may include cognitive impairment, loss of vision, weak limbs, unsteadiness in walking, and fatigue. According to the Multiple Sclerosis International Foundation, MS is one of the most common diseases of the central nervous system, and there are more than 2 million people around the world living with the disease.

### **About Biogen Idec**

Through cutting-edge science and medicine, Biogen Idec discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hemophilia and autoimmune disorders. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company. Patients worldwide benefit from its leading multiple sclerosis therapies, and the company generates more than \$5 billion in annual revenues. For product labeling, press releases and additional information about the company, please visit [www.biogenidec.com](http://www.biogenidec.com).

### **About Regulus Therapeutics Inc.**

Regulus Therapeutics is a biopharmaceutical company leading the discovery and development of innovative

medicines targeting microRNAs. Regulus is using a mature therapeutic platform based on technology that has been developed over 20 years. The company works with a broad network of academic collaborators and leverages the oligonucleotide drug discovery and development expertise of its founding companies, Alnylam Pharmaceuticals (*NASDAQ:ALNY*) and Isis Pharmaceuticals (*NASDAQ:ISIS*). Regulus is advancing microRNA therapeutics toward clinical development in several areas, including oncology, fibrosis, hepatitis C and metabolic diseases. Regulus has formed strategic alliances with AstraZeneca, GlaxoSmithKline and Sanofi and entered into a research collaboration with Biogen Idec.

For more information, please visit <http://www.regulusrx.com>. Regulus is also on YouTube at <http://www.youtube.com/user/RegulusRx#p/f> and on Twitter at [www.twitter.com/regulusrx](http://www.twitter.com/regulusrx).

### **Biogen Idec Safe Harbor Statement**

This press release contains forward-looking statements, including statements about product development and commercialization. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "estimate," "expect," "forecast," "intend," "may," "plan," "will" and other words and terms of similar meaning. You should not place undue reliance on these statements. Drug development and commercialization involve a high degree of risk. Factors which could cause actual results to differ materially from current expectations include the risk that adverse safety events may occur, regulatory authorities may require additional information or may fail to approve any potential new therapy, product reimbursement may be limited or unavailable, there may be problems with manufacturing processes, intellectual property rights may not be adequately protected, and the other risks and uncertainties that are described in the Risk Factors section of Biogen Idec Inc.'s most recent annual or quarterly report and in other reports Biogen Idec Inc. has filed with the SEC. These statements are based on current beliefs and expectations and speak only as of the date of this press release. Biogen Idec Inc. does not undertake any obligation to publicly update any forward-looking statements.

### **Forward-Looking Statements**

This press release includes forward-looking statements regarding the future therapeutic and commercial potential of Isis', Alnylam's and Regulus' business plans, technologies and intellectual property related to microRNA therapeutics being discovered and developed by Regulus, including statements regarding expectations around the newly formed relationship between Regulus and Biogen Idec. Any statement describing Isis', Alnylam's or Regulus' goals, expectations, financial or other projections, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those inherent in 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. Such parties' forward-looking statements also involve assumptions that, if they never materialize or prove correct, could cause their results to differ materially from those expressed or implied by such forward-looking statements. Although these forward-looking statements reflect the good faith judgment of the management of each such party, these statements are based only on facts and factors currently known by Isis, Alnylam or Regulus, as the case may be. As a result, you are cautioned not to rely on these forward-looking statements. These and other risks concerning Regulus', Alnylam's, and Isis' programs are described in additional detail in Alnylam's and Isis' annual reports on Form 10-K for the year ended December 31, 2011 and its most recent quarterly report on Form 10-Q, which are on file with the SEC. Copies of these and other documents are available from Alnylam or Isis.

SOURCE Regulus Therapeutics Inc.

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