Regulus Therapeutics Strengthens Research & Development Leadership

Appoints Preston S. Klassen, M.D., as President and Head of Research & Development

Curtis A. Monnig, Ph.D., named Vice President of CMC

SAN DIEGO, June 12, 2023 /PRNewswire/ -- Regulus Therapeutics Inc. (Nasdaq: RGLS), a biopharmaceutical company focused on the discovery and development of innovative medicines targeting microRNAs (the "Company" or "Regulus"), today announced the appointment of Preston S. Klassen M.D., M.H.S., to President and Head of Research and Development. Dr. Klassen brings over 20 years of experience in leadership roles in both large and small biopharmaceutical companies. In addition, the Company announced the appointment of Curtis A. Monnig, Ph.D., to Vice President of CMC.

"We are thrilled to welcome Dr. Klassen to the Regulus team," said Jay Hagan, Chief Executive Officer of Regulus Therapeutics. "Preston's considerable leadership experience across a range of therapeutic areas and modalities is a huge addition for Regulus and his particular expertise in both academic and industry settings in the field of kidney disease will be invaluable as we advance our program in ADPKD."

Dr. Preston Klassen is an established nephrologist who brings years of experience in leadership, medical affairs, and research and development across multiple therapeutic areas. Most recently he served as the President and CEO of Metacrine. Prior to that, he was an Executive Vice President and Head of R&D at Arena Pharmaceuticals, CMO and President at SANIFIT, and Senior Vice President and Head of Global Development at Orexigen Therapeutics. Previously, while at Amgen, he held multiple leadership roles, including Executive Medical Director and Therapeutics Area Head for Nephrology. Dr. Klassen earned his M.D. from the University of Nebraska Medical Center and completed both his residency in internal medicine and nephrology as well as his Master's in Health Sciences at Duke University Medical Center.

"I'm excited to be joining a team where I will have a hand in helping to bring novel disease-modifying therapies for kidney and other orphan diseases through the clinic and to patients in need," said Dr. Klassen. "I am particularly looking forward to leading the team as we advance through the Phase 1b MAD study of RGLS8429 for the treatment of ADPKD. We look forward to reviewing the topline data from the first cohort of patients expected later this year and working to advance the pipeline as we execute on upcoming clinical milestones."

Dr. Curtis Monnig comes to Regulus with over 25 years of experience in both pharmaceutical and biotech product development and commercial product support. Most recently, he was Vice President of CMC at January Therapeutics. Prior to this, he held positions at Currax Pharmaceuticals, Allergan, Cardinal Health and Amylin Pharmaceuticals. Dr. Monnig earned his B.S. in biochemistry and M.S. in chemistry from the University of Missouri and his Ph.D. in chemistry from Indiana University.

On June 12, 2023, Dr. Klassen will be granted (i) a stock option under the Company's 2021 Inducement Plan to purchase 250,000 shares of the Company's common stock and (ii) a stock option to purchase 100,000 shares of the Company's common stock under the Company's 2019 Equity Incentive Plan. Each of the options will have an exercise price equal to the fair market value at closing on the date of grant. The option has a 10-year term and vests over a period of four years, with 25% of the option vesting on the first anniversary of the Employment Commencement Date and the balance vesting in equal monthly installments over the following 36 months, subject to Dr. Klassen's continuous service through each vesting date, and subject to the terms and conditions of Regulus' 2021 Inducement Plan, the 2019 Equity Incentive Plan and the stock option grant notices and agreements thereunder. The options were granted under Nasdaq Listing Rule 5635(c)(4) as an inducement material to Dr. Klassen entering into employment with the Company.

About ADPKD

Autosomal Dominant Polycystic Kidney Disease (ADPKD), caused by mutations in the PKD1 or PKD2 genes, is among the most common human monogenic disorders and a leading cause of end-stage renal disease. The disease is characterized by the development of multiple fluid filled cysts primarily in the kidneys, and to a lesser extent in the liver and other organs. Excessive kidney cyst cell proliferation, a central pathological feature, ultimately leads to end-stage renal disease in approximately 50% of ADPKD patients by age 60. Approximately 160,000 individuals are diagnosed with the disease in the United States alone, with an estimated global prevalence of 4 to 7 million.

About RGLS8429

RGLS8429 is a novel, next generation oligonucleotide for the treatment of ADPKD designed to inhibit miR-17

and to preferentially target the kidney. Administration of RGLS8429 has shown robust data in preclinical models, where clear improvements in kidney function, size, and other measures of disease severity have been demonstrated along with a superior pharmacologic profile in preclinical studies compared to Regulus' first-generation compound, RGLS4326. Regulus announced completion of the Phase 1 SAD study in September 2022. The Phase 1 SAD study demonstrated that RGLS8429 has a favorable safety and PK profile. RGLS8429 was well-tolerated with no serious adverse events reported and plasma exposure was approximately linear across the four doses tested and is similar to the PK data from the first-generation compound. In April, Regulus announced completion of enrollment for the first cohort of patients in the Phase 1b MAD study and with the recent review of all available safety data, is advancing to the second cohort where patients will receive 2 mg/kg of RGLS8429 or placebo every other week for three months.

About Regulus

Regulus Therapeutics Inc. (Nasdaq: RGLS) is a biopharmaceutical company focused on the discovery and development of innovative medicines targeting microRNAs. Regulus has leveraged its oligonucleotide drug discovery and development expertise to develop a pipeline complemented by a rich intellectual property estate in the microRNA field. Regulus maintains its corporate headquarters in San Diego, CA.

Forward-Looking Statements

Statements contained in this presentation 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 the Company's RGLS8429 program, including the expected timing for initiating clinical studies, the expected timing for reporting topline data, the safety of RGLS8429 and the timing and future occurrence of other preclinical and clinical activities. 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, and the risk additional toxicology data may be negative. In addition, while Regulus expects the COVID-19 pandemic to adversely affect its business operations and financial results, the extent of the impact on Regulus' ability to achieve its preclinical and clinical development objectives and the value of and market for its common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S. and in other countries, and the effectiveness of actions taken globally to contain and treat the disease. These and other risks are described in additional detail in Regulus' filings with the Securities and Exchange Commission, including under the "Risk Factors" heading of Regulus' most recently filed annual report on Form 10-Q. 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.

SOURCE Regulus Therapeutics Inc.

For further information: Investor Relations Contact: Cris Calsada, Chief Financial Officer, 858-202-6376; Media Contact: Sarah Sutton, Argot Partners, 212-600-1902, regulus@argotpartners.com

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