



Regulus Therapeutics Announces Achievement of Interim Enrollment Milestone Under Collaboration with Sanofi

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Regulus to Receive Remaining \$5 Million Payment for Enrollment Milestone

LA JOLLA, Calif., Nov. 2, 2020 /PRNewswire/ -- [Regulus Therapeutics Inc.](#) (Nasdaq: RGLS), a biopharmaceutical company focused on the discovery and development of innovative medicines targeting microRNAs, today announced that it has achieved the remaining \$5 million milestone associated with interim enrollment under its Collaboration and License Agreement (the "Milestone") with Sanofi for its development of miR-21 programs. The Milestone was triggered upon achievement of an enrollment metric by Sanofi in its Phase 2 clinical study evaluating RG-012 for the treatment of patients with Alport Syndrome. The proceeds from this Milestone will be used to pay down the Company's term loan with Oxford LLC. The payment to Oxford will reduce the remaining principal due under the term loan to approximately \$4.7 million and enable the Company to receive an extension of interest-only payments through 2021, an extension of seven months from the previous terms.



"We are very pleased with the commitment of our partner, Sanofi, to this important program," stated Jay Hagan, CEO of Regulus. "This is an important step in advancing a potential treatment for patients with Alport Syndrome, a rare genetic condition affecting the kidneys with no approved therapies."

Previously, the Company announced completion of the Phase 1b renal biopsy study, where patients with Alport Syndrome were dosed every other week for one year. Results from that study demonstrated kidney tissue concentrations that would be predictive of therapeutic benefit based on animal disease models as well as engagement of the target, miR-21. Over the course of the one year open-label study, promising trends in disease markers were observed and RG-012 was generally well tolerated with no serious adverse events. RG-012 has received orphan designation in both the U.S. and Europe.

Under the terms of the Collaboration and License Agreement, the Company is also eligible to receive an additional \$25.0 million upon the successful achievement of a development milestone anticipated in 2023 related to the ongoing Phase 2 HERA study.

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 La Jolla, CA.

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 the achievement of milestone payments from its collaboration partners and paydown of its debt with Oxford LLC. 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. 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. 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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