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PRESS RELEASE

Novartis to acquire Regulus Therapeutics and farabursen, an investigational microRNA inhibitor to treat ADPKD, the most common genetic cause of renal failure

- *Regulus is a clinical-stage biopharmaceutical company developing microRNA therapeutics with a focus on autosomal dominant polycystic kidney disease (ADPKD), a severe renal disease*
- *Lead asset for ADPKD, farabursen, is a novel, next-generation oligonucleotide targeting miR-17 that recently completed a Phase 1b multiple-ascending dose clinical trial*
- *Transaction includes USD 0.8 billion upfront with a potential additional USD 0.9 billion payment upon the achievement of a future regulatory milestone; transaction is expected to close in the second half of 2025, subject to customary closing conditions*

Basel, April 30, 2025 – Novartis today announced that it has entered into an agreement to acquire Regulus Therapeutics, a San Diego-based, publicly traded (Nasdaq: RGLS) clinical-stage biopharmaceutical company focused on developing microRNA therapeutics. Regulus' lead asset, farabursen, is a potential first-in-class, next-generation oligonucleotide targeting miR-17 for the treatment of autosomal dominant polycystic kidney disease (ADPKD). The agreed deal is fully in line with the therapeutic area focus of Novartis and leverages our strength and expertise in renal disease.

"With limited treatment options currently available for patients suffering from ADPKD, farabursen represents a potential first-in-class medicine with a profile that may provide enhanced efficacy, tolerability and safety versus standard of care," said Shreeram Aradhye, President, Development and Chief Medical Officer, Novartis. "ADPKD is the most common genetic cause of renal failure worldwide[1]. The team at Regulus has done meaningful foundational work with farabursen, and we look forward to investigating its potential further as we aim to bring a better treatment option to patients in need."

Farabursen is an investigational microRNA inhibitor designed to target miR-17 with preferential kidney exposure, aiming to reduce the growth of cysts and kidney size, as well as delay progression of disease severity in ADPKD. In March 2025, Regulus announced the successful completion of its Phase 1b multiple-ascending dose clinical trial for farabursen. The Phase 1b trial data showed promising clinical efficacy and safety, including consistent impact on urinary polycystin (PC), a biomarker of mechanistic response, and height-adjusted total kidney volume (htTKV), a measure of progressive disease.

Transaction details
Under the terms of the transaction, which has been unanimously approved by the Boards of Directors of both companies, Novartis will, through an indirect wholly owned subsidiary, commence a tender offer to purchase all outstanding shares of Regulus common stock. Holders of Regulus common stock would receive USD 7 per share in cash at closing and a contingent value right ("CVR") with a value of up to USD 7 per share payable in cash upon the achievement of a regulatory milestone.

Following completion of the tender offer, Novartis expects to merge the acquiring subsidiary with Regulus, resulting in Regulus becoming an indirect wholly owned subsidiary of Novartis.

The transaction is expected to close in the second half of 2025, subject to the satisfaction or waiver of customary closing conditions, including the tender of a majority of the outstanding shares of Regulus common stock and the receipt of regulatory approvals. Until closing, Novartis and Regulus will continue to operate as separate and independent companies.

Novartis in renal disease
Building on a 40-year legacy that began with innovations in transplantation, Novartis is dedicated to transforming kidney health by addressing conditions with significant unmet need. This commitment is reflected in three FDA approvals in renal care within nine months, including Vanrafia® in IgA nephropathy (IgAN) in April 2025, and Fabhalta® for C3 glomerulopathy (C3G) and IgAN in March 2025 and August 2024.

Additional information
This press release is neither an offer to purchase nor a solicitation of an offer to sell any shares of the common stock, par value USD 0.001 (the "Shares"), of Regulus or any other securities. The tender offer for the outstanding Shares described in this press release has not commenced. At the time the tender offer is commenced, Novartis and its indirect wholly owned subsidiary, Redwood Merger Sub Inc. ("Purchaser"), will file, or will cause to be filed, a tender offer statement on Schedule TO, including an offer to purchase, a letter of transmittal and related documents, with the U.S. Securities and Exchange Commission (the "SEC"), and Regulus will file a solicitation/recommendation statement on Schedule 14D-9 with the SEC, in each case with respect to the tender offer.

INVESTORS AND SECURITY HOLDERS ARE URGED TO CAREFULLY READ BOTH THE TENDER OFFER MATERIALS (INCLUDING AN OFFER TO PURCHASE, A LETTER OF TRANSMITTAL AND RELATED DOCUMENTS) AND THE SOLICITATION/RECOMMENDATION STATEMENT ON SCHEDULE 14D-9 REGARDING THE OFFER, AS THEY MAY BE AMENDED FROM TIME TO TIME, WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION THAT INVESTORS AND SECURITY HOLDERS SHOULD CONSIDER BEFORE MAKING ANY DECISION REGARDING TENDERING THEIR SECURITIES.

An offer to purchase the Shares will only be made pursuant to the offer to purchase, the letter of transmittal and related offer documents filed as a part of the Schedule TO. Those materials and all other documents filed by, or caused to be filed by, Novartis, Purchaser and Regulus with the SEC will be available at no charge on the SEC's website at www.sec.gov/ or by directing such requests to the information agent for the offer, which will be named in the tender offer statement. The offer to purchase and related materials also may be obtained for free under the "Investors – Financial Data" section of Novartis website at www.novartis.com/investors/financial-data/sec-filings. The solicitation/recommendation statement also may be obtained for free under the "Investors" section of Regulus' website at ir.regulusrx.com/overview. In addition, Regulus files annual, quarterly and current reports and other information, and Novartis files annual reports and other information with the SEC, which are also available to the public at no charge at www.sec.gov.

Disclaimer

This press release contains statements that are not statements of historical fact, or "forward-looking statements," including with respect to Novartis's proposed acquisition of Regulus. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "may," "could," "would," "expect," "anticipate," "look forward," "believe," "committed," "investigational," "pipeline," "launch," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for farabursen, regarding the acquisition of Regulus and the expected timetable for completing the acquisition, the benefits sought to be achieved in the proposed acquisition, or regarding potential future revenues from farabursen. You should not place undue reliance on these statements. Such forward-looking statements are based on Novartis's current beliefs and expectations regarding future events and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that farabursen clinical trials will be successful, that farabursen will be submitted for marketing approval or approved for sale or, if approved, receive approval for any additional indications or labeling, in any market, or at any particular time, nor can there be any guarantee that, if approved, farabursen will be commercially successful in the future. Neither can there be any guarantee that the conditions to the closing of the proposed acquisition will be satisfied on the expected timetable or at all or that the expected benefits or synergies from this transaction will be achieved in the expected timeframe, or at all. In particular, expectations regarding farabursen or the transaction described in this press release could be affected by, among other things, the timing of the offer and the satisfaction of customary closing conditions, including the tender of a majority of the outstanding Shares and the receipt of regulatory approvals on acceptable terms or at all; the risk that competing offers or acquisition proposals will be made; uncertainty as to whether the milestone associated with the CVR will be achieved and that holders of CVRs will receive payments in respect thereof; the effects of disruption from the transactions contemplated by the merger agreement and the impact of the announcement and pendency of the transactions on Novartis and/or Regulus' businesses, including their relationships with employees, business partners or governmental entities; the risk that the offer or the merger may be more expensive to complete than anticipated; the risk that stockholder litigation in connection with the offer or the merger may result in significant costs of defense, indemnification and liability; a diversion of management's attention from ongoing business operations and opportunities as a result of the offer, the merger or otherwise; general industry conditions and competition; general political, economic and business conditions, including interest rate and currency exchange rate fluctuations; the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG's and Regulus' filings and reports with the SEC, including Novartis AG's Annual Report on Form 20-F for the year ended December 31, 2024, Regulus' Annual Report on Form 10-K for the year ended December 31, 2024 and any subsequent filings made by either party with the SEC, available on the SEC's website at www.sec.gov. Novartis is providing the information in this press release as of this date and Novartis undertakes any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise, except to the extent required by law.

About Novartis

Novartis is an innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach nearly 300 million people worldwide.

Reimagine medicine with us: Visit us at **https://www.novartis.com** and connect with us on **LinkedIn**, **Facebook**, **X/Twitter** and **Instagram**.

References

1 Muddassar Mahboob, et al. Autosomal Dominant Polycystic Kidney Disease. Available from: https://www.ncbi.nlm.nih.gov/books/NBK532934/

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