Regeneron and Sonoma Biotherapeutics Announce Collaboration to Discover, Develop and Commercialize Treg Cell Therapies for Autoimmune Diseases

March 28, 2023

Sonoma Biotherapeutics to receive $75 million upfront, inclusive of $45 million cash and $30 million equity investment; potential for an additional $45 million development milestone payment

TARRYTOWN, N.Y., and SOUTH SAN FRANCISCO, Calif., March 28, 2023 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Sonoma Biotherapeutics, Inc. today announced a collaboration to apply their scientific and clinical expertise and respective technology platforms to the discovery, development and commercialization of novel regulatory T cell (T_{reg}) therapies for autoimmune diseases. The collaboration will bring together Regeneron's industry-leading *VelociSuite*® technologies for the discovery and characterization of fully human antibodies and T cell receptors (TCRs) with Sonoma Biotherapeutics' pioneering approach to developing and manufacturing gene-modified T_{reg} cell therapies.

Under the terms of the agreement, Sonoma Biotherapeutics will receive $75 million in upfront payments, which includes a $30 million equity investment in Sonoma by Regeneron. Sonoma is also eligible to receive a $45 million development milestone payment. Regeneron and Sonoma will jointly research and develop T_{reg} cell therapies for ulcerative colitis, Crohn's disease and two other undisclosed indications, with a Regeneron option for a fifth indication. The parties will equally co-fund research and development for all potential products and share equally any future commercial expenses and profits. Regeneron will have the option to lead late-stage development and commercialization on all products globally, with Sonoma retaining rights to co-promote all such products in the United States. Sonoma will also retain full ownership of its lead cell therapy candidate, SBT-77-7101, and other programs in development.

"We are thrilled to collaborate with Regeneron with the goal of developing best-in-class T_{reg} therapies for ulcerative colitis, Crohn's, and other diseases," said Jeff Bluestone, Ph.D., Co-founder and Chief Executive Officer of Sonoma Biotherapeutics. "Regeneron has a track record of seeking out pioneers in their fields and forging successful partnerships. This collaboration will combine Regeneron's proven technology and clinical expertise with Sonoma Bio's proprietary T_{reg} platform and T_{reg} research enterprise to develop therapies that restore balance to the immune system and potentially cure disease."

"Regeneron's investigational pipeline includes a diverse range of cutting-edge scientific approaches, and we are pleased to expand this toolkit further through a partnership with Sonoma to explore the potential of engineered T_{reg} cell therapies with enhanced functionality and the ability to target specific tissues," said George D. Yancopoulos, M.D., Ph.D., Co-Founder, President and Chief Scientific Officer of Regeneron. "Both Regeneron and Sonoma have strong foundations in basic scientific research, and by bringing together our complementary expertise, we hope to harness the power of T_{regs} to make further progress in the treatment of autoimmune and inflammatory diseases."

T_{reg} cells act as sentinels that survey the body for unwanted immune attacks and rebalance the immune system. T_{regs} as a therapeutic modality potentially possess multiple therapeutic effects, within a single medicine, helping overcome the multifaceted nature of autoimmune and inflammatory disease. Emerging research shows that enhanced T_{reg} cells work directly at the site of inflammation and have the potential to create a durable response. This paradigm-shifting approach could possibly transform treatments for autoimmune and inflammatory diseases.

About Regeneron
Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents, develops and commercializes life-transforming medicines for people with serious diseases. Founded and led for 35 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to nine FDA-approved treatments and numerous product candidates in development, almost all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, hematologic conditions, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*® technologies, such as *VelocImmune*®, which uses unique genetically humanized mice to produce optimized fully human antibodies and bispecific antibodies, and through ambitious research initiatives such as the Regeneron Genetics Center, which is conducting one of the largest genetics sequencing efforts in the world.

For more information, please visit www.Regeneron.com or follow @Regeneron on Twitter.

About Sonoma Biotherapeutics
Sonoma Biotherapeutics is a clinical-stage biotechnology company developing engineered regulatory T cell (T_{reg}) therapies to treat serious autoimmune and inflammatory diseases by restoring balance to the immune system. Founded by pioneers in T_{reg} biology and cell therapy, the company is employing proprietary platform technologies and approaches to develop a new generation of targeted and durable T_{reg} cell therapies. Sonoma Biotherapeutics is based in South San Francisco and Seattle. For more information visit sonomabio.com and follow on Twitter and LinkedIn.

Regeneron Forward-Looking Statements and Use of Digital Media

This press release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements

concern, and these risks and uncertainties include, among others, the impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron's business and its employees, collaborators, and suppliers and other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation any regulatory T cell (T_{reg}) therapies for autoimmune diseases contemplated under Regeneron's collaboration with Sonoma Biotherapeutics, Inc. ("Sonoma") discussed in this press release; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees (including based on Regeneron's collaboration with Sonoma discussed in this press release) may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; the potential for any license, collaboration, or supply agreement, including Regeneron's agreements with Sanofi and Bayer (or their respective affiliated companies, as applicable), as well as Regeneron's collaboration with Sonoma discussed in this press release, to be cancelled or terminated; the potential of utilizing Sonoma's approach to developing and manufacturing gene-modified T_{reg} cell therapies in combination with Regeneron's VelociSuite® technologies as discussed in this press release; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on any of the foregoing or any potential regulatory approval of Regeneron's Products and Regeneron's Product Candidates; the ability of Regeneron's collaborators, licensees, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates; the ability of Regeneron to manage supply chains for multiple products and product candidates; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's Products and Regeneron's Product Candidates; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; the availability and extent of reimbursement of Regeneron's Products from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payers and new policies and procedures adopted by such payers; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; and risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA® (aflibercept) Injection, Praluent® (alirocumab), and REGEN-COV® (casirivimab and imdevimab)), other litigation and other proceedings and government investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2022. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (http://newsroom.regeneron.com) and its Twitter feed (http://twitter.com/regeneron).

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Source: Regeneron Pharmaceuticals, Inc.