Regeneron Completes Acquisition of Decibel Therapeutics, Adding Promising Gene Therapy Programs for Hearing Loss

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TARRYTOWN, N.Y., Sept. 25, 2023 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced that it has successfully completed its acquisition of Decibel Therapeutics, Inc., strengthening the company's gene therapy and auditory programs.

The acquisition of Decibel builds on prior collaboration between the companies and includes three ongoing gene therapy programs targeting different forms of congenital, monogenic hearing loss. The most advanced clinical-stage candidate is DB-OTO, which is currently being studied in the global Phase 1/2 CHORD™ clinical trial, and is an investigational cell-selective, adeno-associated virus (AAV) gene therapy designed to provide durable, physiological hearing to individuals with profound, congenital hearing loss caused by mutations of the otoferlin gene. Preclinical programs include AAV.103 for people with GJB2-related hearing loss and AAV.104 for people with stereocilin (STRC)-related hearing loss.

"After several years of successful collaboration, the integration of Decibel's programs, capabilities and accomplished team will further bolster Regeneron's genetic medicines portfolio and advance our mission of helping patients around the globe," said Leonard S. Schleifer, M.D., Ph.D., Board Co-Chair, President and Chief Executive Officer of Regeneron. "We will continue to strategically deploy capital by selectively pursuing deals that secure access to novel technologies and approaches that are complementary to our technologies, portfolio and strengths in research."

"As we advance Regeneron's commitment to genetic medicine, we welcome our new colleagues and their important expertise in the biology of auditory disorders," said George D. Yancopoulos, M.D., Ph.D., Board Co-Chair, President and Chief Scientific Officer of Regeneron. "In addition to DB-OTO, we have worked with Decibel to build a rich pipeline of programs targeting congenital hearing loss caused by single-gene mutations, including the more common GJB2 and STRC mutations. We are actively expanding our expertise in cutting-edge genetic medicine approaches, which currently includes gene silencing, gene editing and gene therapy technologies with the potential to address many serious and hard-to-treat diseases."

The tender offer by Regeneron for shares of Decibel expired one minute after 11:59 p.m., Eastern Time, on Friday, September 22, 2023. Computershare, the depository and paying agent for the tender offer, advised Regeneron that as of the tender offer expiration, a total of 19,797,530 shares had been validly tendered and not validly withdrawn, representing, together with the shares held by Regeneron, approximately 86.1% of the outstanding shares. As a result of the completion of the offer, all holders of shares that were validly tendered become entitled to $4.00 per share (without interest), with an additional non-tradeable contractual contingent value right (CVR) to receive up to $3.50 per share in cash upon achievement of certain clinical development and regulatory milestones for Decibel's lead investigational candidate, DB-OTO, within specified time periods. Subject to the terms of the CVR agreement (including adjustments for CVRs received in exchange for certain options with an exercise price greater than $4.00 per share), CVR holders will become entitled to receive contingent payments as follows: (i) $2.00 in cash, upon the fifth participant being administered with DB-OTO in a clinical trial on or prior to December 31, 2024 (the DB-OTO Milestone); and (ii) $1.50 in cash, upon (a) the first participant being administered with DB-OTO in a registration enabling trial (as defined in the CVR Agreement) or (b) acceptance for review of a Biologics License Application by the U.S. Food and Drug Administration, a Marketing Authorization Application by the European Medicines Agency or the U.K. Medicines and Healthcare Products Regulatory Agency, or an equivalent application by the applicable national regulatory authority in any of Germany, France, Italy or Spain for DB-OTO, whichever occurs first, on or prior to December 31, 2028; provided the DB-OTO Milestone is achieved on or prior to December 31, 2024. There can be no assurance that any payments will be made with respect to the CVR. Following its acceptance of the tendered shares, Regeneron completed its acquisition of Decibel through a second step merger of Symphony Acquisition Sub, Inc., with and into Decibel. Upon consummation of the merger, all holders of shares that were not validly tendered will be converted into the right to receive the same consideration per share paid pursuant to the offer. As a result of the acquisition, Decibel common stock has ceased to be traded on the Nasdaq Global Market.

Any changes to Regeneron's 2023 GAAP and non-GAAP financial guidance as a result of this transaction will be reflected in the guidance update to be provided in conjunction with Regeneron's third quarter 2023 earnings announcement.

Regeneron's legal advisor for the transaction is Wachtell, Lipton, Rosen & Katz. Centerview Partners LLC and Leerink Partners LLC served as Decibel's financial advisors and Wilmer Cutler Pickering Hale and Dorr LLP served as Decibel's legal advisor.

About Regeneron
Regeneron 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, Regeneron's unique ability to repeatedly and consistently translate science into medicine has led to numerous FDA-approved treatments and product candidates in development, almost all of which were homegrown in Regeneron's laboratories. Regeneron's medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, 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 additional information about the company, please visit www.regeneron.com or follow Regeneron on LinkedIn.

Forward-looking Statements
This press release contains forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "propose," "provide," "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. Risks that may cause these forward-looking statements to be inaccurate include, without limitation: risks related to Regeneron's ability to realize the anticipated benefits of the acquisition of Decibel Therapeutics, Inc. ("Decibel"), including the possibility that the expected benefits from the acquisition will not be realized or will not be realized within the expected time period and that Regeneron and Decibel will not be integrated successfully; the effects of the transaction on relationships with employees, other business partners or governmental entities; negative effects of this announcement or the consummation of the acquisition on the market price of Regeneron's common stock and/or Regeneron's operating results; significant transaction costs; unknown liabilities; Regeneron's ability to continue to conduct research and clinical programs; Regeneron's ability to manage its supply chains; Regeneron's ability to manage net product sales of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products"); the nature, timing, and possible success and therapeutic applications of Regeneron's Products, product candidates being developed by Regeneron and/or its collaborators or licensees (including without limitation the investigational gene therapy DB-OTO for the treatment of congenital hearing loss and the other gene therapy programs discussed or referenced in this press release (collectively, "Regeneron's Product Candidates")), the extent to which the results from the research and development programs conducted by Regeneron and/or its respective collaborators or licensees may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; 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; uncertainty regarding each of the contingent value rights milestones referenced in this press release and the possibility that any or all of such milestones will never be achieved and that some or all milestone payments may not be made; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products; 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 and/or its collaborators to manufacture and 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 or Regeneron's Product Candidates; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products or Regeneron's Product Candidates; and the impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on Regeneron's businesses.

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 (the "SEC"), including its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023, and its Annual Report on Form 10-K for the fiscal year ended December 31, 2022. Any forward-looking statements are made based on the current beliefs and judgments of Regeneron's management, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Except as required by law, 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.

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