Regeneron and Tessera Therapeutics to Jointly Develop TSRA-196, an Investigational Gene Editing Therapy for Alpha-1 Antitrypsin Deficiency (AATD)

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- *TSRA-196 is a potential one-time treatment to precisely correct the genetic mutation underlying AATD, with Investigational New Drug filing expected by the end of the year*
- *Tessera to receive $150 million, inclusive of a cash upfront and equity investment from Regeneron; companies to share worldwide development costs and future profits 50:50*
- *Collaboration combines Regeneron's long-standing expertise in genetics, genetic medicines and clinical development with Tessera's pioneering Gene Writing ™ and non-viral delivery platforms*

TARRYTOWN, N.Y. and SOMERVILLE, Mass., Dec. 01, 2025 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ:REGN) and Tessera Therapeutics, Inc., today announced a global collaboration to develop and commercialize TSRA-196, Tessera's lead investigational *in vivo* Gene Writing program for the treatment of alpha-1 antitrypsin deficiency (AATD), an inherited monogenic disease that can affect the lungs, liver, or both organs, and currently impacts approximately 200,000 people in the U.S. and Europe. TSRA-196 is designed to precisely correct the genetic mutation underlying AATD, with the goal of restoring production of functional alpha-1 antitrypsin (AAT) protein through a one-time, durable treatment option for patients. Tessera expects to file an Investigational New Drug and multiple Clinical Trial Applications for TSRA-196 with the U.S. Food and Drug Administration (FDA) by the end of the year.

The collaboration brings together Regeneron's industry-leading capabilities in genetics and proven track record in advancing novel genetic medicines with Tessera's innovative Gene Writing and proprietary non-viral delivery platforms. Under the terms of the agreement, the companies will share worldwide development costs and potential future profits relating to TSRA-196 equally. Tessera will receive $150 million, inclusive of a cash upfront payment and equity investment from Regeneron. Tessera is also eligible to receive additional near and mid-term development milestone payments totaling $125 million. Tessera will lead the initial first-in-human trial, while Regeneron will lead subsequent global development and commercialization.

"At Regeneron, we are strong believers in the power of genetics and genetic medicines to transform patients' lives, and we have a robust portfolio of potential treatments to do just this," said George D. Yancopoulos, M.D., Ph.D., Board co-Chair, President and Chief Scientific Officer of Regeneron. "Alpha-1 antitrypsin deficiency is a serious disease with limited treatment options today and is particularly well suited for Tessera's gene editing approach. Together with Tessera, we have an opportunity to pioneer new frontiers in genetic medicine and redefine what is possible for AATD patients."

"This collaboration underscores what we believe is a medically and commercially important opportunity to deliver transformative outcomes with a one-time, intravenously delivered genetic treatment for patients living with alpha-1 antitrypsin deficiency," said Michael Severino, M.D., Chief Executive Officer of Tessera Therapeutics. "Tessera is on the cusp of a critical inflection point as we prepare to enter the clinic in the near term. We are excited to partner with Regeneron, a global leader in innovative biotechnology and genetic medicine, to accelerate the development of TSRA-196 and broaden its potential impact to patients in need."

The collaboration builds on Tessera's recent progress in advancing TSRA-196, including preclinical data presented at the American Society of Gene & Cell Therapy 28th Annual Meeting, which highlighted durable, high-fidelity genome editing of SERPINA1, the locus responsible for AATD, in mice and non-human primates following a single dose of TSRA-196, with high liver editing specificity, no germline or off-target editing, and favorable safety and tolerability using Tessera's proprietary lipid nanoparticle delivery vehicle. These findings reinforce TSRA-196's potential to correct the underlying genetic cause of AATD and support its advancement into clinical development.

This agreement is subject to customary closing conditions, including applicable regulatory agency clearances under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 in the United States.

About Alpha-1 Antitrypsin Deficiency (AATD)

AATD is an inherited monogenic disease that can affect the lungs, liver, or both organs. It is most often caused by mutations in the *SERPINA1* gene, which encodes alpha-1 antitrypsin (AAT), a protein produced in the liver and secreted into the bloodstream to protect lung tissue from enzymes such as neutrophil elastase. In individuals with severe AATD, mutations in the Z allele cause AAT protein to misfold and accumulate in the liver, leading to toxic effects such as inflammation and fibrosis. At the same time, insufficient circulating AAT leaves the lungs vulnerable to progressive damage consistent with chronic obstructive pulmonary disease (COPD) and emphysema. An estimated 200,000 people in the U.S. and Europe carry two copies of the Z allele (PiZZ genotype), typically resulting in only about 15 percent of normal serum AAT levels. There are currently no FDA-approved therapies

that address the underlying genetic cause of AATD, and treatment options remain limited to weekly intravenous augmentation therapy for patients with lung disease.

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 by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous approved treatments and product candidates in development, most 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, neurological diseases, hematologic conditions, infectious diseases and rare diseases.

Regeneron pushes the boundaries of scientific discovery and accelerates drug development using our proprietary technologies, such as *VelociSuite*®, which produces optimized fully human antibodies and new classes of bispecific antibodies. We are shaping the next frontier of medicine with data-powered insights from the Regeneron Genetics Center® and pioneering genetic medicine platforms, enabling us to identify innovative targets and complementary approaches to potentially treat or cure diseases.

For more information, please visit www.Regeneron.com or follow Regeneron on LinkedIn, Instagram, Facebook or X.

About Tessera Therapeutics

Tessera Therapeutics is pioneering a new approach to genome engineering through the development of its Gene Writing™ and delivery platforms, with the aim to unlock broad new therapeutic frontiers. Our Gene Writing platform is designed to write therapeutic messages into the genome by efficiently changing single or multiple DNA base pairs, precisely correcting insertions or deletions, or adding exon-length sequences and whole genes. Our proprietary lipid nanoparticle delivery platform is designed to enable the *in vivo* delivery of RNA to targeted cell types. We believe our Gene Writing and delivery platforms will enable transformative genetic medicines to not only cure diseases that arise from errors in a single gene, but also modify inherited risk factors for common diseases and create engineered cells to treat cancer and potentially autoimmune and other diseases. Tessera Therapeutics was founded in 2018 by Flagship Pioneering, a life sciences innovation enterprise that conceives, creates, resources, and develops first-in-category bioplatform companies to transform human health and sustainability.

For more information about Tessera, please visit www.tesseratherapeutics.com.

Regeneron Forward-Looking Statements:

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 nature, timing, and possible success and therapeutic applications of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "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, such as the planned clinical program in collaboration with Tessera Therapeutics, Inc. for TSRA-196, an investigational gene editing therapy for the treatment of alpha-1 antitrypsin deficiency, as discussed in this press release; the likelihood, timing, and scope of achieving any of the anticipated milestones described in this press release, including the filing of regulatory applications and the initiation of clinical trials for TSRA-196 as discussed in this press release; 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 Tessera Therapeutics, Inc. discussed in this press release, to be cancelled or terminated; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees (including those to be conducted as part of the collaboration with Tessera Therapeutics, Inc. 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; 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), including the planned studies discussed in this press release, on any of the foregoing; 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 and risks associated with tariffs and other trade restrictions; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates (such as TSRA-196) 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 or copay assistance for Regeneron's Products from third-party payors and other third parties, including private payor 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 payors and other third parties and new policies and procedures adopted by such payors and other third parties; changes to drug pricing regulations and requirements and Regeneron's pricing strategy; other changes in laws, regulations, and policies affecting the healthcare industry; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates (including biosimilar versions of Regeneron's Products); 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; the impact of public health outbreaks, epidemics, or pandemics on Regeneron's business; and risks associated with litigation and other proceedings and government investigations relating to the Company and/or its operations (including the pending civil proceedings initiated or joined by the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts), 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), 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, 2024, and its Form 10-Q for the quarterly period ended September 30, 2025. 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 (https://investor.regeneron.com) and its LinkedIn page (https://www.linkedin.com/company/regeneron-pharmaceuticals).

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