Regeneron to Highlight Pioneering Pipeline Progress Across Multiple Modalities Spanning 10 Types of Blood Cancers and Disorders at ASH

November 13, 2024 at 7:00 AM EST

Oral presentation shares head-to-head results for investigational combination pozelimab plus cemdisiran vs. ravulizumab in paroxysmal nocturnal hemoglobinuria

Initial results for odronextamab in first-line follicular lymphoma showcase compelling monotherapy potential and progress in the confirmatory trial

Additional oral presentations explore odronextamab in areas of high unmet need, including the primary analysis in diffuse large B-cell lymphoma progressing after CAR-T therapy and first results in relapsed/refractory marginal zone lymphoma

TARRYTOWN, N.Y., Nov. 13, 2024 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced new and updated data from its hematology pipeline will be shared across 23 abstracts at the American Society of Hematology (ASH) 2024 Annual Meeting, taking place from December 7-10 in San Diego, CA. The latest research advances demonstrate the potential of Regeneron's diverse pipeline, which aims to address unmet needs in ten types of blood cancers and disorders. These innovative and differentiated approaches include CD3 bispecific antibodies, costimulatory bispecific antibodies, and a pioneering combination of a monoclonal antibody and small interfering RNA (siRNA).

"Our presentations at ASH demonstrate the progress we are making toward transforming care for a range of blood cancers and disorders where advancements are desperately needed," said L. Andres Sirulnik, M.D., Ph.D., Senior Vice President and Hematology Clinical Development Unit Head at Regeneron. "These include new head-to-head data exploring a novel combination that aims to maximize disease control in paroxysmal nocturnal hemoglobinuria compared to a standard-of-care treatment, as well as initial results from our confirmatory odronextamab trial in first-line follicular lymphoma. Together, our presentations underscore our commitment to work towards translating scientific breakthroughs to differentiated medicines for hematology patients."

At ASH, abstracts in blood disorders include an oral presentation from an exploratory cohort of a Phase 3 trial investigating a novel combination of pozelimab with cemdisiran compared to ravulizumab in patients with paroxysmal nocturnal hemoglobinuria (PNH) who were naïve to complement inhibition at baseline. Notably, the presentation will detail interim results from patients who were initially randomized to ravulizumab but crossed over to the combination in an open label extension portion of the trial.

Progress on the odronextamab development program will be featured in twelve abstracts. Among them are initial results in patients with previously untreated follicular lymphoma (FL) from Part 1 of the Phase 3 OLYMPIA-1 confirmatory trial, which consists of a non-randomized safety run-in (Part 1) followed by a randomized efficacy portion (Part 2) comparing odronextamab monotherapy to rituximab plus standard-of-care chemotherapies. Two oral presentations on the ELM-1 and pivotal ELM-2 trials will feature new analyses in settings with significant unmet needs: one in patients with diffuse large B-cell lymphoma (DLBCL) who progressed after CAR-T therapy and the other in relapsed/refractory (R/R) marginal zone lymphoma (MZL).

Other notable abstracts include the latest linvoseltamab efficacy and safety results from the pivotal LINKER-MM1 study in R/R multiple myeloma (MM), preclinical data evaluating a CD38xCD28 costimulatory bispecific antibody in combination with linvoseltamab, and preclinical data on TMPRSS6 inhibition in beta-thalassemia.

The full list of Regeneron presentations at ASH includes:

Abstract Title	Abstract	Presenter	Session Date/Time (PT)
Odronextamab			
Efficacy and Safety of Odronextamab Monotherapy in Patients (Pts) with Diffuse Large B-Cell Lymphoma (DLBCL) Progressing after CAR T-Cell Therapy: Primary Analysis from the ELM-1 Study	Abstract #866 Oral Presentation Session	Matthew Matasar	Monday, December 9, at 2:45-4:15 pm Marriott Marquis San Diego Marina, Pacific Ballroom Salons 15-17
Efficacy and Safety of Odronextamab in Relapsed/Refractory Marginal Zone Lymphoma (R/R MZL): Data from the R/R MZL Cohort in the ELM-2 Study	Abstract #862 Oral Presentation Session	Tae Min Kim	Monday, December 9, at 2:45-4:15 pm Marriott Marquis San Diego Marina, Marriott Grand

			Ballroom 11-13
Odronextamab Monotherapy in Previously Untreated Patients with High-Risk Follicular Lymphoma (FL): Results of the Safety Lead-in of the Phase 3 OLYMPIA-1 Study	Abstract #4411 Poster Presentation Session	Elizabeth Brem	Monday, December 9, at 6:00-8:00 pm San Diego Convention Center, Halls G-H
Efficacy and Safety of Odronextamab in Rare Subtypes of Relapsed/Refractory Aggressive B-Cell Non-Hodgkin Lymphoma (B-NHL): Data from a Dedicated Cohort of Other B-NHLs in the ELM-2 Study	Abstract #4502 Poster Presentation Session	Emmanuel Bachy	Monday, December 9, at 6:00-8:00 pm San Diego Convention Center, Halls G-H
Treatment Duration and Risk of Fatal Infections in Patients with B-Cell Non-Hodgkin Lymphoma Achieving Complete Response with Odronextamab	Abstract #3080 Poster Presentation	Gottfried von Keudel	Monday, December 9, at 6:00-8:00 pm San Diego Convention Center, Halls G-H
Dynamics of Complete Responses in Patients with Relapsed or Refractory Diffuse Large B Cell Lymphoma Treated with Odronextamab in the ELM-2 Study	Abstract #4486 Poster Presentation Session	Sabarish Ayyappan	Monday, December 9, at 6:00-8:00 pm San Diego Convention Center, Halls G-H
Long-Term Efficacy and Safety of Odronextamab in Relapsed/Refractory Diffuse Large B-Cell Lymphoma (DLBCL): Pooled Analysis from ELM-1 and ELM-2 Studies	Abstract #3118 Poster Presentation Session	John N. Allan	Sunday, December 8, at 6:00-8:00 pm San Diego Convention Center, Halls G-H
Evaluation of CAR-HEMATOTOX Scoring as a Predictor of Infection Risk following Treatment with Odronextamab (a CD20×CD3 Bispecific Antibody) in Relapsed/Refractory Diffuse Large B-Cell Lymphoma	Abstract #3076 Poster Presentation Session	Mathew Matasar	Sunday, December 8, at 6:00-8:00 pm San Diego Convention Center, Halls G-H
Evaluation of Baseline CAR-HEMATOTOX Scores to Predict Increased Severe Infection Risk in Patients with Relapsed/Refractory Follicular Lymphoma Treated with Odronextamab	Abstract #1650 Poster Presentation Session	Matthew Matasar	Saturday, December 7, at 5:30-7:30 pm San Diego Convention Center, Halls G-H
Dynamics of Complete Responses in Patients with Relapsed or Refractory Follicular Lymphoma Treated with Odronextamab in the ELM-2 Study	Abstract #1628 Poster Presentation Session	Stefano Luminari	Saturday, December 7, at 5:30-7:30 pm San Diego Convention Center, Halls G-H
Trial in Progress: Odronextamab for the Treatment of Patients with Relapsed/Refractory Mantle Cell Lymphoma following Prior BTK Inhibitor Therapy - A Cohort of the ELM-2 Study	Abstract Publication Only	Srikanth Ambati	N/A
Matching-Adjusted Indirect Comparisons (MAICs) of Odronextamab Versus Mosunetuzumab and Epcoritamab for the Treatment of Patients with Relapsed/Refractory Follicular Lymphoma (R/R FL) after Two or More Lines of Systemic Therapy	Abstract Publication Only	Deepa Jagadeesh	N/A
Linvoseltamab			
Linvoseltamab in Patients with Relapsed/Refractory Multiple Myeloma: Longer Follow-Up and Selected High-Risk Subgroup Analyses of the LINKER-MM1 Study	Abstract #3369 Poster Presentation	Mansi R. Shah	Sunday, December 8, at 6:00-8:00 pm San Diego Convention Center, Halls G-H
Soluble BCMA Dynamics in Patients with Relapsed/Refractory Multiple Myeloma (RRMM) Treated with Linvoseltamab in LINKER-MM1	Abstract #3310 Poster Presentation	Anasuya Hazra	Sunday, December 8, at 6:00-8:00 pm San Diego Convention Center, Halls G-H

Characterization of Linvoseltamab's BCMA Binding Epitope and Efficacy Against BCMA Mutations in Relapsed/Refractory Multiple Myeloma	Abstract #3265 Poster Presentation	Ken Lee & Yi Zhou	Sunday, December 8, at 6:00-8:00 pm San Diego Convention Center, Halls G-H
A CD38xCD28 Costimulatory Bispecific Antibody Demonstrates Potent Preclinical Combinatorial Activity with a BCMAxCD3 T Cell-Engager	Abstract #3283 Poster Presentation	Kara Olson & David J. DiLillo	Sunday, December 8, at 6:00-8:00 pm San Diego Convention Center, Halls G-H
Reducing Time Toxicity for Anti-B-Cell Maturation Antigen (BCMA) Bispecific Treatment: Evidence from Pivotal Single-Arm Trial Data on Teclistamab, Elranatamab, and Linvoseltamab for Triple-Class Exposed (TCE) Relapsed/Refractory Multiple Myeloma (RRMM)	Abstract #2271 Poster Presentation Session	Sikander Ailawadh	Saturday, December 7, at 5:30-7:30 pm San Diego Convention, Halls G-H
Exposure-Response Analyses of Various Efficacy and Safety Endpoints in Support of Registrational Dose Selection of Linvoseltamab in Patients with Relapsed/Refractory Multiple Myeloma	Abstract Publication Only	Oleg Milberg	N/A
Comparative Effectiveness of Linvoseltamab Versus Current Real-World Standard-of-Care Therapies in Triple-Class Exposed Relapsed/Refractory Multiple Myeloma Treated at IMWG Sites	Abstract Publication Only	Shaji Kumar	N/A
Comparative Effectiveness of Linvoseltamab Versus Current Real-World (RW) Standard-of-Care (SOC) Therapies in Triple-Class Exposed Relapsed/Refractory Multiple Myeloma (RRMM): Key Subgroups Analysis	Abstract Publication Only	Shaji Kumar	N/A
Additional Presentations			
Efficacy and Safety of Pozelimab Plus Cemdisiran vs Ravulizumab in Patients with Paroxysmal Nocturnal Hemoglobinuria who are Naïve to Complement Inhibition*	Abstract #306 Oral Presentation Session	Christopher Patriquin	Saturday, December 7, at 4 – 5:30 pm San Diego Convention Center, Room 11
TMPRSS6 Inhibition Rapidly Reverses Liver Iron Overload and Prevents an Increase of Splenic Pro-Inflammatory Macrophages in a Mouse Model of Beta-Thalassemia	Abstract #2473 Poster Presentation Session	Heinrich E. Lob	Sunday, December 8, at 6:00-8:00 pm San Diego Convention Center, Halls G-H
The Reality of Beta Thalassemia and Iron Chelation Therapy – A Qualitative Study Unveiling the Patient Burden	Abstract Publication Only	Chris Hartford	

*Agreement with Alnylam Pharmaceuticals, Inc.

Linvoseltamab as well as the combination of pozelimab and cemdisiran are investigational, and the potential uses of odronextamab in R/R MZL and rare subtypes of R/R aggressive B-cell non-Hodgkin lymphoma are also investigational and have not been approved by any regulatory authority. Odronextamab is approved in the European Union as Ordspono™ to treat R/R FL or DLBCL after two or more lines of systemic therapy, but the safety and efficacy of odronextamab have not been fully evaluated by any other regulatory authority.

About Regeneron in Hematology

At Regeneron, we're applying more than three decades of biology expertise with our proprietary *VelociSuite*® technologies to develop medicines for patients with diverse blood cancers and rare blood disorders.

Our blood cancer research is focused on bispecific antibodies that are being investigated both as monotherapies and in various combinations and emerging therapeutic modalities. Together, they provide us with unique combinatorial flexibility to develop customized and potentially synergistic cancer treatments.

Our research and collaborations to develop potential treatments for rare blood disorders include explorations in antibody medicine, gene editing and gene-knockout technologies, and investigational RNA-approaches focused on depleting abnormal proteins or blocking disease-causing cellular signaling.

About Regeneron's *VelocImmune*® Technology

Regeneron's *VelocImmune* technology utilizes a proprietary genetically engineered mouse platform endowed with a genetically humanized immune system to produce optimized fully human antibodies. When Regeneron's Co-Founder, President and Chief

Scientific Officer George D. Yancopoulos was a graduate student with his mentor Frederick W. Alt in 1985.They were the first to envision making such a genetically humanized mouse, and Regeneron has spent decades inventing and developing *VelocImmune* and related *VelociSuite* technologies. Dr. Yancopoulos and his team have used *VelocImmune* technology to create a substantial proportion of all original, FDA-approved or authorized fully human monoclonal antibodies. This includes REGEN-COV® (casirivimab and imdevimab), Dupixent® (dupilumab), Libtayo®, Praluent® (alirocumab), Kevzara® (sarilumab), Evkeeza® (evinacumab-dgnb), Inmazeb® (atoltivimab, maftivimab and odesivimab-ebgn) and Veopoz® (pozelimab-bbfg).

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.

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 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, including without limitation pozelimab in combination with cemdisiran, odronextamab, linvoseltamab, and the other programs discussed or referenced 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, such as odronextamab for the treatment of follicular lymphoma in the United States, linvoseltamab for the treatment of relapsed/refractory multiple myeloma in the United States and/or European Union, and the other programs discussed or referenced in this press release; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates (such as those referenced above) and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), including the studies discussed or referenced in this press release, 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 (such as those referenced above) 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 (including biosimilar versions of Regeneron's Products); the extent to which the results from the research and development programs conducted by Regeneron and/or its 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; 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 potential for any license, collaboration, or supply agreement, including Regeneron's agreements with Sanofi and Bayer (or their respective affiliated companies, as applicable), to be cancelled or terminated; the impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on Regeneron's business; 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), other 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), 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, 2023 and its Form 10-Q for the quarterly period ended September 30, 2024. 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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