Regeneron Presents New Data at ASH from Advancing Hematology Pipeline across Multiple Blood Cancers and Disorders

November 3, 2022 at 9:00 AM EDT

First Phase 2 data for odronextamab (CD20xCD3) in diffuse large B-cell lymphoma and follicular lymphoma to be presented in two oral sessions

Additional presentations include new data on linvoseltamab (REGN5458; BCMAxCD3) in multiple myeloma

Regeneron will host an investor webcast on Wednesday, December 14 at 8:30 AM ET to provide updates across its hematology portfolio

TARRYTOWN, N.Y., Nov. 3, 2022 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that new data across its hematology pipeline will be highlighted in 17 presentations at the 2022 American Society of Hematology (ASH) Annual Meeting from December 10-13 in New Orleans, LA.

"We've made significant strides toward developing a comprehensive hematology portfolio that has the potential to address diverse and difficult-to-treat blood cancers and blood disorders," said L. Andres Sirulnik, M.D., Ph.D., Senior Vice President, Translational and Clinical Sciences, Hematology at Regeneron. "Our ASH presentations not only showcase some of the many modalities we're exploring – which includes monoclonal antibodies, bispecific antibodies, gene modifying technologies, and siRNA inhibition – but also the depth of research we're conducting in support of our pipeline."

Notable Regeneron blood cancer presentations at ASH include the first interim data from the Phase 2 ELM-2 study of odronextamab (CD20xCD3) in relapsed/refractory (R/R) follicular lymphoma (FL) and R/R diffuse large B-cell lymphoma (DLBCL), which will be shared in two oral sessions. Updated Phase 1/2 data will also be presented for linvoseltamab (REGN5458; BCMAxCD3 bispecific antibody) in patients with heavily pre-treated multiple myeloma. Based on these findings, a recommended dose was selected for the Phase 2 portion of the linvoseltamab trial.

Additionally, first clinical data from two Phase 2 studies evaluating pozelimab (C5 antibody) in combination with Alnylam Pharmaceuticals, Inc.'s cemdisiran (siRNA C5 inhibitor) in patients with paroxysmal nocturnal hemoglobinuria (PNH), a rare blood disorder, will be shared.

Investor Webcast Information
Regeneron will host a conference call and simultaneous webcast to share updates on the company's hematology portfolio on Wednesday, December 14 at 8:30 AM ET. A link to the webcast may be accessed from the 'Investors and Media' page of Regeneron's website at http://investor.regeneron.com/events.cfm. To participate via telephone, please register in advance at this link. Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode and registrant ID that can be used to access the call. A replay of the conference call and webcast will be archived on the company's website for at least 30 days.

Regeneron data at ASH:

Abstract title	Abstract	Presentation date/time, location
Odronextamab		
Odronextamab in patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL): Results from a prespecified analysis of the pivotal Phase II study ELM-2	#444 Oral Presentation	Sunday, December 11 10:45 AM Ballroom AB
Odronextamab in patients with relapsed/refractory (R/R) follicular lymphoma (FL) Grade 1–3a: Results from a prespecified analysis of the pivotal Phase II study ELM-2	#949 Oral Presentation	Monday, December 12 4:30 PM R06-R09
Trial in Progress: Follicular lymphoma outcomes in relapsed/refractory patients treated with systemic therapy in a real-world assessment (FLORA)	#2277 Poster Presentation	Saturday, December 10 5:30-7:30 PM

		Hall D
Trial in Progress: Outcomes in patients with relapsed/refractory DLBCL treated with systemic therapy from real-world experience (ORCHID)	#3601 Poster Presentation	Sunday, December 11 6:00-8:00 PM Hall D
Selection of odronextamab pediatric dosing regimens for aggressive non-Hodgkin lymphoma via a modeling and simulation approach	#3992 Poster Presentation	Monday, December 12 6:00-8:00 PM Hall D
Optimization of intravenous Odronextamab step-up dosing regimen for reducing the risk of high-grade cytokine release syndrome	#5245 Publication Number	Online publication
Modeling and simulation in support of odronextamab subcutaneous dose selection for adult patients with indolent or aggressive non-Hodgkin lymphoma	#5257 Publication Number	Online publication
Evaluate dynamics of IL-6 release during step-up dosing of subcutaneous administration of odronextamab via a quantitative systems pharmacology modelling approach	#5424 Publication Number	Online publication
A quantitative systems pharmacology modelling framework for evaluation of cytokine release syndrome mediated by intravenous odronextamab monotherapy in patients with B-cell non-Hodgkin lymphoma	#5433 Publication Number	Online publication
Linvoseltamab (formerly REGN5458)		
Updated safety and efficacy of REGN5458, a BCMAxCD3 bispecific antibody, treatment for relapsed/refractory multiple myeloma: A Phase 1/2 first-in-human study	#4555 Poster Presentation	Monday, December 12 6:00-8:00 PM Hall D
Trial in Progress: REGN5458, a BCMAxCD3 bispecific antibody, in a Phase Ib multi-cohort study of combination regimens for patients with relapsed/refractory multiple myeloma	#1936 Poster Presentation	Saturday, December 10 5:30-7:30 PM Hall D
Trial in Progress: A Phase II window of opportunity study of the BCMAxCD3 bispecific antibody REGN5458 in previously untreated patients with symptomatic multiple myeloma	#4551 Poster Presentation	Monday, December 12 6:00-8:00 PM Hall D
Real-world study of patients with triple-class exposed relapsed or refractory multiple myeloma: Analysis across a spectrum of advanced disease stage patients in the U.S.	#2321 Poster Presentation	Saturday, December 10 5:30-7:30 PM Hall D
Prevalence of ocular comorbidities in elderly patients with multiple myeloma in the U.S.: An Analysis of 100% Medicare sample data during 2007-2020	#2310 Poster Presentation	Saturday, December 10 5:30-7:30 PM Hall D
Incidence of second primary malignancies (SPMs) in patients in the U.S. with triple-class-exposed (TCE) relapsed or refractory multiple myeloma (RRMM)	#4896 Poster Presentation	Monday, December 12 6:00-8:00 PM Hall D
Pozelimab + Cemdisiran		
Long-term efficacy and safety of pozelimab monotherapy in patients with paroxysmal nocturnal hemoglobinuria	#2326 Poster Presentation	Sunday, December 11 6:00-8:00 PM Hall D
A Phase 2, randomized trial evaluating the safety and efficacy of pozelimab and cemdisiran in patients with paroxysmal nocturnal hemoglobinuria	#3651 Poster Presentation	Monday, December 12 6:00-8:00 PM Hall D

Patient-reported outcomes from a Phase 2, randomized trial evaluating the safety and efficacy of pozelimab and cemdisiran in patients with paroxysmal nocturnal hemoglobinuria	#4873 Poster Presentation	Monday, December 12 6:00-8:00 PM Hall D
A Phase 2, open-label study evaluating the safety and efficacy of combination pozelimab and cemdisiran therapy in patients with paroxysmal nocturnal hemoglobinuria who switch from eculizumab	#3652 Poster Presentation	Monday, December 12 6:00-8:00 PM Hall D
REGN7257 (IL-2Rg antibody)		
Blockade of common gamma chain cytokine signaling with REGN7257, an interleukin 2 receptor gamma (IL2RG) monoclonal antibody, protected mice from inflammatory and autoimmune diseases	#194 Oral Presentation	Saturday, December 10 2:15 PM 260-262
Evaluation of common gamma chain cytokine signaling blockade with REGN7257, an interleukin 2 receptor gamma (IL2RG) monoclonal antibody, on immune cell populations in monkey and human	#1249 Poster Presentation	Saturday, December 10 5:30-7:30 PM Hall D

The potential uses of odronextamab, linvoseltamab, pozelimab, cemdisiran and REGN7257 described above are investigational, and their safety and efficacy have not been fully evaluated by any 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 combination with each other 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.

If you are interested in learning more about our clinical trials, please contact us (clinicaltrials@regeneron.com or 844-734-6643) or visit our clinical trials website.

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 approximately one in five of all original, FDA-approved or authorized fully human monoclonal antibodies. This includes REGEN-COV® (casirivimab and imdevimab), Dupixent® (dupilumab), Libtayo® (cemiplimab-rwlc), Praluent® (alirocumab), Kevzara® (sarilumab), Evkeeza® (evinacumab-dgnb) and Inmazeb™ (atoltivimab, maftivimab and odesivimab-ebgn).

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 nearly 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.

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 odronextamab (a CD20xCD3 bispecific antibody), linvoseltamab (a BCMAxCD3 bispecific antibody), and other of Regeneron's Product Candidates 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 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 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 diffuse large B-cell lymphoma and follicular lymphoma and linvoseltamab for the treatment of multiple myeloma; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates (such as odronextamab and linvoseltamab) 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; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees (including those discussed or referenced in this press release) may be replicated in other studies and/or lead to advancement of product candidates to clinical trials or therapeutic applications; the ability of Regeneron to manufacture and manage supply chains for multiple products and 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; 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 or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer (or their respective affiliated companies, as applicable), to be cancelled or terminated; 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, 2021 and its Form 10-Q for the quarterly period ended September 30, 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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