Latest Dupixent® (dupilumab) and Itepekimab Data at ERS Highlight Scientific Innovation and Leadership in Respiratory Diseases

August 26, 2024 at 1:00 AM EDT

20 abstracts, including 4 oral presentations, offer new treatment insights for chronic obstructive pulmonary disease (COPD), asthma and chronic rhinosinusitis with nasal polyps (CRSwNP)

Data from landmark Phase 3 trials for Dupixent in COPD reinforce exacerbation reduction and improvement in lung function compared to placebo, and provide new assessments on health-related quality of life across patient subgroups

Additional presentations spotlight a novel asthma imaging study showing the early impact of Dupixent on clinical remission, airway remodeling and mucus plugging starting at 4 weeks, as well as data from investigational therapy itepekimab in former smokers with COPD

TARRYTOWN, N.Y., Aug. 26, 2024 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced 20 abstracts across Dupixent® (dupilumab) and investigational therapy itepekimab will be presented at the European Respiratory Society (ERS) Congress 2024 being held from September 7 to 11 in Vienna, Austria. These clinical and real-world abstracts presented in collaboration with Sanofi include four oral presentations and demonstrate the potential of targeting key drivers of type 2 inflammation and other pathways to address respiratory diseases, such as COPD and asthma, and improve patient outcomes.

"The breadth of our presentations at the ERS Congress showcase our commitment to advancing the management of a range of difficult-to-treat respiratory diseases," said George D. Yancopoulos, M.D., Ph.D., Board co-Chair, President and Chief Scientific Officer at Regeneron, and a principal inventor of Dupixent. "Through our Dupixent clinical program, we have gained a deep understanding of the biology of airway diseases. We are now applying those insights to COPD, a complex and heterogenous disease, and are excited by the remarkable potential of our COPD research program investigating Dupixent, as well as our anti-IL-33 antibody itepekimab to support COPD patients regardless of smoking history."

Among the notable Dupixent presentations at ERS is a pooled analysis of the previously reported Phase 3 BOREAS and NOTUS trials in uncontrolled COPD with evidence of type 2 inflammation (i.e., raised blood eosinophils). In the trials, all patients were on background maximal standard-of-care inhaled therapy (with nearly all on triple therapy). BOREAS and NOTUS formed the basis of the recent European Commission approval and regulatory submissions around the world for Dupixent in certain patients with uncontrolled COPD.

As shared in the abstract, the pooled analysis demonstrated that Dupixent patients (n=938) experienced a 31% reduction in the annualized rate of moderate or severe COPD exacerbations over 52 weeks compared to placebo (n=936; nominal $p<0.0001$). Additional COPD data to be presented at the meeting will evaluate the impact of Dupixent on daily symptom frequency and severity, exacerbations and lung function regardless of baseline body mass index, airflow obstruction, dyspnea (shortness of breath) and exercise capacity measures. Safety results were generally consistent with the known safety profile of Dupixent in its approved indications. Adverse events more commonly observed with Dupixent (≥5%) compared to placebo in either COPD trial were back pain, COVID-19, diarrhea, headache and nasopharyngitis.

Additionally, new research will be shared from the Phase 4 VESTIGE trial, a novel imaging study evaluating the effects of Dupixent on airway remodeling in certain adults with asthma. Two poster presentations will show new data on the 4-week impact of Dupixent treatment on airway inflammation, volume, and flow, and mucus plugging, as well as outcomes for clinical remission after 4 and 24 weeks of treatment in adults with uncontrolled moderate-to-severe asthma.

The full list of Regeneron and Sanofi presentations at ERS includes:

Abstract title	Abstract	Presenting author	Presentation date, time (CEST)
COPD			
Reduction in exacerbations with itepekimab in former smokers with chronic obstructive pulmonary disease (COPD) by prior exacerbation frequency	OA3645 Oral presentation	Rabe, K.F.	Monday, September 9 2:15-3:30 PM
Dupilumab Efficacy and Safety in Patients with Moderate-to-Severe COPD with Type 2 Inflammation: Pooled Analysis of BOREAS and NOTUS Trials	PA4787 Poster Presentation	Bhatt, S.	Tuesday, September 10 12:30-2:00 PM
Dupilumab improves respiratory symptoms in patients with moderate-to-severe COPD with type 2 inflammation in phase 3 BOREAS trial	PA4786 Poster Presentation	Papi, A.	Tuesday, September 10 12:30-2:00 PM
Dupilumab improves quality of life in non-exacerbators with moderate-to-severe COPD and type 2 inflammation: phase 3 BOREAS trial	PA4784 Poster Presentation	Rabe, K.F.	Tuesday, September 10 12:30-2:00 PM
Dupilumab improves lung function in non-exacerbators with moderate-to-severe COPD with type 2 inflammation in phase 3 BOREAS trial	PA4785 Poster Presentation	Rabe, K.F.	Tuesday, September 10 12:30-2:00 PM

Dupilumab efficacy in patients with COPD and type 2 inflammation irrespective of mortality risk score	PA4782 Poster Presentation	Vogelmeier, C.	Tuesday, September 10 12:30-2:00
Asthma			
Clinical remission with dupilumab in children with uncontrolled, moderate-to-severe, type 2 asthma (dupilumab)	RCT3719 Late-Breaking Oral Presentation	Bacharier, L.	Monday, September 9 3:30-5:00 PM
Impact of early transient increase in eosinophils in patients with moderate-to-severe asthma on the long-term efficacy of dupilumab in TRAVERSE	OA2779 Oral Presentation	Pavord, I.	Monday, September 9 9:30-10:45 AM
Dupilumab reduces mucus plugging and volume: phase 4 VESTIGE trial	OA3649 Oral Presentation	Porsberg, C.	Monday, September 9 2:35-3:30 PM
Effectiveness of dupilumab vs omalizumab in patients with severe asthma – The EU-ADVANTAGE study	PA2171 Poster Presentation	Canonica, G.W.	Monday, September 9 8:00-9:30 AM
Characteristics of long-term oral corticosteroid users stratified by blood eosinophil count in the International Severe Asthma Registry	PA439 Poster Presentation	Chan, J.	Sunday, September 8 8:00-9:30 AM
Phenotype and biomarkers in patients who initiated biologic therapy stratified by oral corticosteroids use in the International Severe Asthma Registry	PA438 Poster Presentation	Chan, J.	Sunday, September 8 8:00-9:30 AM
Dupilumab-treated patients with moderate-to-severe asthma are more likely to meet clinical remission criteria: results from the VESTIGE trial	PA1202 Poster Presentation	Lugogo, N.L.	Sunday, September 8 12:30-2:00 PM
Baseline Characteristics of Patients with Asthma Initiating Dupilumab in a Real-World Setting: the RAPID Registry	PA4484 Poster Presentation	Lugogo, N.L.	Tuesday, September 10 8:00-9:30 AM
Early treatment response to dupilumab on airway inflammation, airway dynamics, and mucus plugging in VESTIGE	PA3933 Poster Presentation	Papi, A.	Tuesday, September 10 8:00-9:30 AM
Real-world effectiveness of dupilumab vs benralizumab and vs mepolizumab in severe asthma: The EU-ADVANTAGE study	PA2170 Poster Presentation	Virchow, J.C.	Monday, September 9 8:00-9:30 AM
Dupilumab improves lung function and reduces exacerbations despite withdrawal of inhaled corticosteroids/long-acting beta agonists	PA1172 Late-Breaking Poster Presentation	Wechsler, M.E.	Sunday, September 8 12:30-2:00 PM
Dupilumab Reduces Exacerbations and FeNO Levels and Improves Asthma Control with Inhaled Corticosteroid Withdrawal: a Phase 2 Study	PA5371 Poster Presentation	Wechsler, M.E.	Tuesday, September 10 12:30-2:00 PM
CRSwNP			
Baseline Characteristics of Patients with Chronic Rhinosinusitis with Nasal Polyps and Coexisting Asthma Initiating Dupilumab in the AROMA Global Registry	PA425 Poster Presentation	Heffler, E.	Sunday, September 8 8:00-9:30 AM
Initiation of dupilumab led to reduced use of oral corticosteroids (OCS) and other medications over 12 months in patients with chronic rhinosinusitis with nasal polyps (CRSwNP): A US real-world practice study	PA2177 Poster Presentation	Lee, S.E.	Monday, September 9 8:00-9:30 AM

About Dupixent

Dupixent, which was invented using Regeneron's proprietary *VelocImmune*® technology, is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) pathways and is not an immunosuppressant. The Dupixent development program has shown significant clinical benefit and a decrease in type 2 inflammation in Phase 3 trials, establishing that IL-4 and IL-13 are key and central drivers of the type 2 inflammation that plays a major role in multiple related and often co-morbid diseases.

Dupixent has received regulatory approvals in more than 60 countries in one or more indications including certain patients with atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), eosinophilic esophagitis (EoE), prurigo nodularis, chronic spontaneous urticaria (CSU), and COPD in different age populations. More than 950,000 patients are being treated with Dupixent globally.

Dupilumab Development Program

Dupilumab is being jointly developed by Regeneron and Sanofi under a global collaboration agreement. To date, dupilumab has been studied across more than 60 clinical trials involving more than 10,000 patients with various chronic diseases driven in part by type 2 inflammation.

In addition to the currently approved indications, Regeneron and Sanofi are studying dupilumab in a broad range of diseases driven by type 2 inflammation or other allergic processes in Phase 3 trials, including chronic pruritus of unknown origin and bullous pemphigoid. These potential uses of

dupilumab are currently under clinical investigation, and the safety and efficacy in these conditions have not been fully evaluated by any regulatory authority.

About Itepekimab
Itepekimab, which was invented using Regeneron's proprietary *VelocImmune* technology, is a fully human monoclonal antibody that binds to and inhibits the signaling of interleukin-33 (IL-33), an initiator and amplifier of airway inflammation.

Itepekimab is currently under clinical investigation in two COPD Phase 3 trials and its safety and efficacy have not been evaluated by any regulatory authority.

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, Libtayo® (cemiplimab-rwlc), Praluent® (alirocumab), Kevzara® (sarilumab), Evkeeza® (evinacumab-dgnb), Inmazeb® (atoltivimab, maftivimab and odesivimab-ebgn) and Veopoz® (pozelimab-bbfg).

U.S. INDICATIONS
DUPIXENT is a prescription medicine used:

- to treat adults and children 6 months of age and older with moderate-to-severe eczema (atopic dermatitis or AD) that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies. DUPIXENT can be used with or without topical corticosteroids. It is not known if DUPIXENT is safe and effective in children with atopic dermatitis under 6 months of age.
- with other asthma medicines for the maintenance treatment of moderate-to-severe eosinophilic or oral steroid dependent asthma in adults and children 6 years of age and older whose asthma is not controlled with their current asthma medicines. DUPIXENT helps prevent severe asthma attacks (exacerbations) and can improve your breathing. DUPIXENT may also help reduce the amount of oral corticosteroids you need while preventing severe asthma attacks and improving your breathing. DUPIXENT is not used to treat sudden breathing problems. It is not known if DUPIXENT is safe and effective in children with asthma under 6 years of age.
- with other medicines for the maintenance treatment of chronic rhinosinusitis with nasal polyposis (CRSwNP) in adults whose disease is not controlled. It is not known if DUPIXENT is safe and effective in children with chronic rhinosinusitis with nasal polyposis under 18 years of age.
- to treat adults and children 1 year of age and older with eosinophilic esophagitis (EoE), who weigh at least 33 pounds (15 kg). It is not known if DUPIXENT is safe and effective in children with eosinophilic esophagitis under 1 year of age, or who weigh less than 33 pounds (15 kg).
- to treat adults with prurigo nodularis (PN). It is not known if DUPIXENT is safe and effective in children with prurigo nodularis under 18 years of age.

IMPORTANT SAFETY INFORMATION

Do not use if you are allergic to dupilumab or to any of the ingredients in DUPIXENT®.

Before using DUPIXENT, tell your healthcare provider about all your medical conditions, including if you:

- have eye problems.
- have a parasitic (helminth) infection.
- are scheduled to receive any vaccinations. You should not receive a "live vaccine" right before and during treatment with DUPIXENT.
- are pregnant or plan to become pregnant. It is not known whether DUPIXENT will harm your unborn baby.
    - A pregnancy registry for women who take DUPIXENT during pregnancy collects information about the health of you and your baby. To enroll or get more information call 1-877-311-8972 or go to https://mothertobaby.org/ongoing-study/dupixent/.
- are breastfeeding or plan to breastfeed. It is not known whether DUPIXENT passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the- counter medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you are taking oral, topical, or inhaled corticosteroid medicines; have asthma and use an asthma medicine; or have atopic dermatitis, chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis, or prurigo nodularis and also have asthma. **Do not** change or stop your corticosteroid medicine or other asthma medicine without talking to your healthcare provider. This may cause other symptoms that were controlled by the corticosteroid medicine or other asthma medicine to come back.

DUPIXENT can cause serious side effects, including:

- **Allergic reactions. DUPIXENT can cause allergic reactions that can sometimes be severe.** Stop using DUPIXENT

and tell your healthcare provider or get emergency help right away if you get any of the following signs or symptoms: breathing problems or wheezing, swelling of the face, lips, mouth, tongue or throat, fainting, dizziness, feeling lightheaded, fast pulse, fever, hives, joint pain, general ill feeling, itching, skin rash, swollen lymph nodes, nausea or vomiting, or cramps in your stomach-area.

- **Eye problems.** Tell your healthcare provider if you have any new or worsening eye problems, including eye pain or changes in vision, such as blurred vision. Your healthcare provider may send you to an ophthalmologist for an exam if needed.
- **Inflammation of your blood vessels.** Rarely, this can happen in people with asthma who receive DUPIXENT. This may happen in people who also take a steroid medicine by mouth that is being stopped or the dose is being lowered. It is not known whether this is caused by DUPIXENT. Tell your healthcare provider right away if you have: rash, chest pain, worsening shortness of breath, a feeling of pins and needles or numbness of your arms or legs, or persistent fever.
- **Joint aches and pain.** Some people who use DUPIXENT have had trouble walking or moving due to their joint symptoms, and in some cases needed to be hospitalized. Tell your healthcare provider about any new or worsening joint symptoms. Your healthcare provider may stop DUPIXENT if you develop joint symptoms.

The most common side effects include:

- **Eczema:** injection site reactions, eye and eyelid inflammation, including redness, swelling, and itching, sometimes with blurred vision, dry eye, cold sores in your mouth or on your lips, and high count of a certain white blood cell (eosinophilia).
- **Asthma:** injection site reactions, high count of a certain white blood cell (eosinophilia), pain in the throat (oropharyngeal pain), and parasitic (helminth) infections.
- **Chronic Rhinosinusitis with Nasal Polyposis:** injection site reactions, eye and eyelid inflammation, including redness, swelling, and itching, sometimes with blurred vision, high count of a certain white blood cell (eosinophilia), gastritis, joint pain (arthralgia), trouble sleeping (insomnia), and toothache.
- **Eosinophilic Esophagitis:** injection site reactions, upper respiratory tract infections, cold sores in your mouth or on your lips, and joint pain (arthralgia).
- **Prurigo Nodularis:** eye and eyelid inflammation, including redness, swelling, and itching, sometimes with blurred vision, herpes virus infections, common cold symptoms (nasopharyngitis), dizziness, muscle pain, and diarrhea.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of DUPIXENT. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Use DUPIXENT exactly as prescribed by your healthcare provider. It's an injection given under the skin (subcutaneous injection). Your healthcare provider will decide if you or your caregiver can inject DUPIXENT. **Do not** try to prepare and inject DUPIXENT until you or your caregiver have been trained by your healthcare provider. In children 12 years of age and older, it's recommended DUPIXENT be administered by or under supervision of an adult. In children 6 months to less than 12 years of age, DUPIXENT should be given by a caregiver.

Please see accompanying full Prescribing Information including Patient Information.

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.

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 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 Dupixent® (dupilumab) and itepekimab; 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 (such as Dupixent) and Regeneron's Product Candidates (such as itepekimab); the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new

indications for Regeneron's Products, including itepekimab for the treatment of chronic obstructive pulmonary disease as well as Dupixent for the treatment of chronic pruritus of unknown origin, bullous pemphigoid, and other potential indications; 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 (such as Dupixent) and Regeneron's Product Candidates (such as itepekimab) 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 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 June 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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