Kevzara® (sarilumab) Approved by FDA for the Treatment of Active Polyarticular Juvenile Idiopathic Arthritis (pJIA)

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Approval in patients with pJIA weighing 63kg or greater adds to Kevzara's position in treating adult chronic inflammatory conditions of moderately to severely active rheumatoid arthritis and polymyalgia rheumatica

TARRYTOWN, N.Y. and CAMBRIDGE, MA, June 11, 2024 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Sanofi today announced that the U.S. Food and Drug Administration has approved Kevzara® (sarilumab) for the treatment of patients weighing 63 kg or greater with active polyarticular juvenile idiopathic arthritis (pJIA), a form of arthritis that impacts multiple joints at a time.

"Polyarticular juvenile idiopathic arthritis can be a painful disease for children where multiple joints are impacted by this chronic infammation," said George D. Yancopoulos, M.D., Ph.D., Board co-Chair, President and Chief Scientific Officer at Regeneron. "Not only are their daily lives impacted, but their futures can be disrupted without adequate treatment. The approval of Kevzara in polyarticular juvenile idiopathic arthritis provides these vulnerable patients and their families a new FDA-approved treatment option to help navigate this disease."

The FDA approval in this patient population is supported by evidence from adequate and well-controlled studies and pharmacokinetic data from adults with rheumatoid arthritis as well as a pharmacokinetic, pharmacodynamic, dose finding and safety study in pediatric patients with pJIA.

People living with pJIA may experience joint symptoms such as pain, stiffness and swelling, which may restrict their activities and make certain aspects of their day-to-day life incredibly challenging. The disease can lead to an increased risk of permanent joint damage as well as delayed growth and development, due to chronic joint inflammation.

No new adverse reactions (ARs) and safety concerns were identified in the pJIA population compared to the rheumatoid arthritis population. The most common adverse drug reactions for patients with pJIA were nasopharyngitis, neutropenia, upper respiratory tract infection, and injection site erythema. The most common AR that resulted in permanent discontinuation of therapy with Kevzara was neutropenia. Overall, patients treated with Kevzara are at increased risk for developing serious infections that may lead to hospitalization or death.

"This latest approval for Kevzara brings a new treatment option with an established efficacy and safety profile to pediatric patients living with polyarticular juvenile idiopathic arthritis," said Brian Foard, Executive Vice President, Head, Specialty Care at Sanofi. "This milestone highlights our ongoing commitment to bringing medicines to our younger patients living with this chronic condition that can cause debilitating joint pain and inflammation."

Sanofi and Regeneron are committed to helping patients in the U.S. who are prescribed Kevzara gain access to the medicine and receive the support they may need. KevzaraConnect®, a comprehensive and specialized program that provides support services to patients throughout every step of the treatment process, can help eligible patients who are uninsured, lack coverage, or need copay assistance. For more information, please call: 1-844-Kevzara (1-844-538-9272) or visit www.Kevzara.com.

About Kevzara
In addition to pJIA, Kevzara is currently approved in 25 countries to treat adults with moderately to severely active rheumatoid arthritis after at least one other medicine, called a disease modifying antirheumatic drug (DMARD), has been used and did not work well or could not be tolerated. Kevzara is also approved in the U.S. for the treatment of polymyalgia rheumatica – an inflammatory rheumatic disease – in adult patients who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.

Kevzara binds specifically to the IL-6 receptor and has been shown to inhibit IL-6-mediated signaling. IL-6 is an immune system protein produced in increased quantities in patients with rheumatoid arthritis and has been associated with disease activity, joint destruction and other systemic problems.

Sarilumab is being jointly developed by Sanofi and Regeneron under a global collaboration agreement.

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

U.S. Indications and Important Safety Information

KEVZARA® (sarilumab) is an injectable prescription medicine called an interleukin-6 (IL-6) receptor blocker. KEVZARA is used to treat:

- adult patients with moderately to severely active rheumatoid arthritis (RA) after at least one other medicine called a disease-modifying antirheumatic drug (DMARD) has been used and did not work well or could not be tolerated.
- adult patients with polymyalgia rheumatica (PMR) after corticosteroids have been used and did not work well or when a slow decrease in the dose of corticosteroids (taper) cannot be tolerated.
- people with active polyarticular juvenile idiopathic arthritis (pJIA) who weigh 63kg (139 lbs) or more.

It is not known if KEVZARA is safe and effective in children with pJIA under 2 years of age.

IMPORTANT SAFETY INFORMATION

KEVZARA can cause serious side effects including:

- **SERIOUS INFECTIONS: KEVZARA is a medicine that affects your immune system. KEVZARA can lower the ability of your immune system to fight infections. Some people have had serious infections while using KEVZARA, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections. Your healthcare provider should test you or your child for TB before starting KEVZARA. Your healthcare provider should monitor you closely for signs and symptoms of TB during treatment with KEVZARA.**
- Before starting KEVZARA, tell your healthcare provider if you:
    - think you have an infection or have signs or symptoms of an infection, with or without a fever such as: sweats or chills, muscle aches, a cough, shortness of breath, blood in your phlegm, weight loss, warm, red, or painful skin or sores on your body, diarrhea or stomach pain, burning when you urinate or urinating more often than normal, if you feel very tired, or if you are being treated for an infection, get a lot of infections or have repeated infections.
    - have diabetes, HIV, or a weakened immune system.
    - have TB, or have been in close contact with someone with TB.
    - live or have lived, or have traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance of getting certain fungal infections (histoplasmosis, coccidioidomycosis, or blastomycosis).
    - have or have had hepatitis.
- After starting KEVZARA, call your healthcare provider right away if you have any symptoms of an infection.
- **CHANGES IN CERTAIN LABORATORY TEST RESULTS**: Your or your child's healthcare provider should do blood tests before and after starting KEVZARA to check for low neutrophil (white blood cells that help the body fight off bacterial infections) counts, low platelet (blood cells that help with blood clotting and stop bleeding) counts, and an increase in certain liver function tests. Changes in test results are common with KEVZARA and can be severe. You may also have changes in other laboratory tests, such as your blood cholesterol levels. Your or your child's healthcare provider should do blood tests 4 to 8 weeks after starting KEVZARA and then every 6 months during treatment to check for an increase in blood cholesterol levels.
- **TEARS (PERFORATION) OF THE STOMACH OR INTESTINES**: Tell your healthcare provider if you have had a condition known as diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines. Some people using KEVZARA get tears in their stomach or intestine. This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDS), corticosteroids, or methotrexate. Call your healthcare provider right away if you have fever and stomach (abdominal) pain that does not go away.
- **CANCER**: KEVZARA may increase your risk of certain cancers by changing the way your immune system works. Tell your healthcare provider if you have ever had any type of cancer.
- **SERIOUS ALLERGIC REACTIONS:** Serious allergic reactions can happen with KEVZARA. Get medical attention right away if you or your child have any of the following signs: shortness of breath or trouble breathing; feeling dizzy or faint; swelling of your lips, tongue, or face; moderate or severe stomach (abdominal) pain or vomiting; or chest pain.
- Do not use KEVZARA if you or your child are allergic to sarilumab or any of the ingredients of KEVZARA.
- Before you or your child use KEVZARA, tell your healthcare provider if you or your child:
    - have an infection.
    - have liver problems.
    - have had stomach (abdominal) pain or a condition known as diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines.
    - recently received or are scheduled to receive a vaccine. People who take KEVZARA should not receive live vaccines.

        - All vaccines should be brought up-to-date before starting KEVZARA, unless urgent treatment initiation is required.
    - plan to have surgery or a medical procedure.
    - are pregnant or plan to become pregnant. It is not known if KEVZARA will harm your unborn baby.
    - are breastfeeding or plan to breastfeed. Talk to your healthcare provider about the best way to feed your baby if you use KEVZARA. It is not known if KEVZARA passes into your breast milk.
    - take prescription or nonprescription medicines, vitamins, or herbal supplements. It is especially important to tell your healthcare provider if you or your child use.
        - any other medicines to treat your RA, PMR, or pJIA. Using KEVZARA with these medicines may increase your risk of infection.
        - medicines that affect the way certain liver enzymes work. Ask your healthcare provider if you are not sure if your medicine is one of these.
- The most common side effects include:
    - injection site redness
    - injection site itching
    - upper respiratory tract infection
    - urinary tract infection
    - nasal congestion, sore throat, and runny nose

These are not all of the possible side effects of KEVZARA. Tell your doctor about any side effect that bothers you or does not go away. You are encouraged to report side effects of prescription drugs to the FDA at http://www.fda.gov/medwatch or call 1-800-FDA-1088.

To learn more, talk about KEVZARA with your healthcare provider or pharmacist. The FDA-approved Medication Guide and Prescribing Information can be found at www.KEVZARA.com or by calling 1-844- KEVZARA.

Please click here to see full Prescribing Information including risk of SERIOUS SIDE EFFECTS and Medication Guide.

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 for over 35 years by physician-scientists, our 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 our laboratories. Our 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 more information, please visit www.Regeneron.com or follow Regeneron on LinkedIn.

About Sanofi
We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across the world, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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 Kevzara® (sarilumab) for the treatment of children and adolescents two years and older with active polyarticular-course juvenile idiopathic arthritis; 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; 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 Kevzara for for the treatment

of children and adolescents 1 year and older with systemic juvenile idiopathic arthritis; 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 Kevzara) 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 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 March 31, 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).

Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates regarding the marketing and other potential of the product, or regarding potential future revenues from the product. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the fact that product may not be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic and market conditions, and the impact that pandemics or other global crises may have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2023. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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