Sanofi og Regeneron kunngjør godkjenning av Dupixent® (dupilumab) for behandlig av voksne pasienter med moderat til alvorlig atopisk dermatitt (eksem) i EU.

- Første målrettede biologiske legemiddel som mottar markedsføringstillatelse for behandling av atopisk dermatitt i EU.

Lysaker – 02. oktober 2017 - Sanofi og Regeneron Pharmaceuticals, Inc. kunngjorde 28. September at Europakommisjonen har innvilget markedsføringstillatelse for Dupixent® (dupilumab), til behandling av voksne med moderat til alvorlig atopisk dermatitt (eksem) som er kandidater for systemisk behandling.

Atopisk dermatitt, en form for eksem, er en kronisk inflammatorisk sykdom hvor de vanligste symptomene er utslett på huden.[1,2,3,4] Moderat til alvorlig atopisk dermatitt karakteriseres av utslett som ofte dekker store deler av kroppen. Atopisk dermatitt kan også inkludere intens vedvarende kløe, rød, tørr og sprukken hud, skorpedannelse og væsking.[5,6] Kløe er et av de mest plagsomme symptomene for pasienter, og kan i noen tilfeller være invalidiserende.[7] I tillegg opplever mennesker med moderat til alvorlig atopisk dermatitt redusert livskvalitet, søvnforstyrrelser og økte symptomer på angst og depresjon.[7]

"Mennesker med moderat til alvorlig atopisk dermatitt kan oppleve uutholdelige symptomer som kan påvirke livskvaliteten betydelig. Mange sliter med å opprettholde kontroll over sykdommen med behandlingsalternativene som til nå har vært tilgjengelige», forteller Christine Janus, leder i International Alliance of Dermatology Patient Organizations. *"Vi støtter en rask tilgang til denne nye behandlingen for pasienter med moderat til alvorlig atopisk eksem, slik at de kan få hjelp til å kontrollere og oppnå lindring fra denne livsendrende, ofte invalidiserende sykdommen».*

Dupixent er et humant monoklonalt antistoff som er selektivt rettet mot å hemme forhøyet signalisering via to nøkkelproteiner, IL-4 og IL-13, som antas å være viktige drivende faktorer i den underliggende inflammasjonen ved atopisk dermatitt og visse andre allergiske eller atopiske sykdommer.[8,9] Dupixent vil komme i ferdigfylte sprøyter og kan selvadministreres av pasienter som en subkutan injeksjon annenhver uke etter en oppstartsdose. Dupixent kan brukes med eller uten samtidig behandling med topikale kortikosteroider.[8]

"Denne godkjenningen av Dupixent i Europa viser vår evne til å levere innovative legemidler til de som lever med et stort udekket medisinsk behov, og dagens godkjenning representerer en viktig milepæl for mennesker med moderat til alvorlig atopisk eksem i Europa", sier Elias Zerhouni, M.D., President, Global R&D, Sanofi. *"Dupixent retter seg mot den underliggende årsaken til atopisk eksem, bidrar til oppklaring av huden, reduksjon av vedvarende, invalidiserende kløe og forbedring av den generelle livskvaliteten. Vi fokuserer nå på å raskt gjøre dette nye, viktige legemiddelet tilgjengelig for europeere som lever med denne systemiske sykdommen."*

Etter mottatt markedsføringstillatelse vil Sanofi and Regeneron samarbeide med relevante lokale myndigheter for å gjøre Dupixent tilgjengelig for pasienter i land over hele Europa.

"Dupixent kulminerer tiår av forskning på biologien bak allergiske sykdommer som moderat til alvorlig atopsik eksem", sier George D. Yancopoulos, M.D., Ph.D., President, and Chief Scientific Officer, Regeneron. *"Vi fortsetter å utforske potensialet til dupilumab til behandling av atopisk dermatitt hos barn og ungdom, i tillegg til andre allergiske sykdommer som drives av IL-4/IL-13 signalisering."*

Dupixent er godkjent i USA for behandling av voksne med moderat til alvorlig atopisk dermatitt (eksem) som ikke er godt kontrollert med reseptbelagte topikale behandlinger , eller som ikke kan bruke topikale behandlinger. Dupixent kan brukes med eller uten samtidige topikale kortikosteroider. Det er foreløpig ikke gjort studier på om Dupixent er trygt og effektivt til barn.[10]

«LIBERTY AD» klinisk utprøvingsprogram
Godkjenningen av Dupixent var basert på studier fra det globale kliniske utprøvingsprogrammet LIBERTY AD, hvor nesten 3,000 pasienter har deltatt. LIBERTY AD inkluderte studiene SOLO 1, SOLO 2, CHRONOS, SOLO-CONTINUE og CAFÉ. Studiene undersøkte behandling med Dupixent enten alene (SOLO 1, SOLO 2 og SOLO-CONTINUE) eller i kombinasjon med topikale kortikosteroider (CHRONOS eller CAFÉ) hos pasienter med moderat til alvorlig atopisk eksem der topikal behandling eller immunsuppresjon, f.eks med ciklosporin, ikke ga tilstrekkelig sykdomskontroll eller var uegnet. I alle disse studiene nådde Dupixent alene eller sammen med topikale kortikosteroider de primære studieendepunktene og sentrale sekundære endepunkter. De vanligste uønskede hendelsene som forekom hyppigere med Dupixent enn i placebogruppene (≥ 1 prosent) inkluderte reaksjoner på injeksjonsstedet, øye- og øyelokkinflammasjon, inkludert rødhet, hevelse og kløe, og forkjølelsessår i munnen eller på leppene.

Oversikt over Dupilumab utviklingsprogram
Dupilumab gjennomgår for tiden et omfattende utviklingsprogram innenfor atopisk dermatitt. Dette inkluderer studier for barn med alvorlig atopisk dermatitt (6 måneder til 11 års alder) og ungdom med moderat til alvorlig atopisk dermatitt (12 til 17 års). Disse potensielle bruksområdene er under utforskning. Sikkerhet og effekt er ikke fullstendig vurdert eller bekreftet av noen regulatorisk myndighet.

Dupilumab blir også undersøkt i behandling av andre inflammatoriske tilstander som antas å være drevet av IL-4/IL-13-signalisering, inkludert ukontrollert persistent astma (fase 3), nasal polypose (fase 3) og eosinofil øsofagitt (fase 2). Disse potensielle bruksområdene er under utforskning. Sikkerhet og effekt er ikke fullstendig vurdert eller bekreftet av noen regulatorisk myndighet. Dupilumab utvikles gjennom et globalt samarbeid mellom Regeneron og Sanofi.

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About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi is organized into five global business units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Consumer Healthcare. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi Genzyme focuses on developing specialty treatments for debilitating diseases that are often difficult to diagnose and treat, providing hope to patients and their families.

About Regeneron Pharmaceuticals, Inc.

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for nearly 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to six FDA-approved treatments and over a dozen product candidates in development, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye disease, heart disease, allergic and inflammatory diseases, pain, cancer, and infectious and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through its unique *VelociSuite*® technologies and ambitious initiatives such as The Regeneron Genetics Center, one of the largest genetics sequencing efforts in the world.

For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

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 absence of guarantee that the product will 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 litigation and the ultimate outcome of such litigation, and volatile economic conditions, as well as those risks 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, 2016. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Regeneron Forward-Looking Statements and Use of Digital Media

This news 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 Regeneron's products, product candidates, and research and clinical programs now underway or planned, including without limitation Dupixent® (dupilumab) Injection; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products, such as Dupixent for the treatment of uncontrolled moderate-to-severe atopic dermatitis in other potential jurisdictions, as well as other potential indications; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators may be replicated in later studies and lead to therapeutic applications; unforeseen safety issues and possible liability resulting from the administration of products and product candidates in patients, including without limitation Dupixent; serious complications or side effects in connection with the use of Regeneron's products and product candidates (such as Dupixent) in clinical trials; coverage and reimbursement determinations by third-party payers, including Medicare, Medicaid, and pharmacy benefit management

companies; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business, including those relating to the enrollment, completion, and meeting of the relevant endpoints of post-approval studies; 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 product candidates, such as Dupixent; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's products and product candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the commercial success of Regeneron's products and product candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its sales or other 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, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto, including without limitation the patent litigation relating to Praluent® (alirocumab) Injection, the permanent injunction granted by the United States District Court for the District of Delaware that, if upheld on appeal, would prohibit Regeneron and Sanofi from marketing, selling, or manufacturing Praluent in the United States, the outcome of any appeals regarding such injunction, the ultimate outcome of such litigation, 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 United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2016 and its Form 10-Q for the quarterly period ended June 30, 2017. 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 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).

[1] Schneider et al, AAAI 2013, Practice Parameter Update, page 296
[2] Eichenfield et al, AAD 2014, Guidelines of Care for Atopic Dermatitis, page 118
[3] Guideline to treatment, European Dermatology Forum. http://www.euroderm.org/edf/index.php/edf-guidelines/category/5-guidelines-miscellaneous?download=36:guideline-treatment-of-atopic-eczema-atopic-dermatitis. Accessed December 23, 2016
[4] Gelmetti and Wolleberg, BJD 2014, Atopic dermatitis- all you can do from the outside. Page 19
[5] National Institutes of Health (NIH). Handout on Health: Atopic Dermatitis (A type of eczema) 2013. http://www.niams.nih.gov/ Health_Info/Atopic_Dermatitis/default.asp. Accessed October 31, 2016.
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[7] Zuberbier, T et al. Patient perspectives on the management of atopic dermatitis. *J Allergy Clin Immunol* vol. 118, pp. 226-232, 2006.
[8] Dupixent Summary of Product Characteristics.
[9] Simpson et al. Two Phase 3 Trials of Dupilumab versus Placebo in Atopic Dermatitis. *NEJM*, vol. 375, pp. 2335-2348, 2016.
[10] Dupixent Prescribing Information 2017. https://www.regeneron.com/sites/default/files/Dupixent_FPI.pdf. Accessed July 2017.