

## DUPIXENT GODKJENT I BESLUTNINGSFORUM FOR BEHANDLING AV ALVORLIG ASTMA

**LYSAKER – 21. NOVEMBER 2019** – Beslutningsforum avgjorde 18. november at Dupixent (dupilumab) kan innføres til voksne og ungdom som er 12 år og eldre som tillegg til vedlikeholdsbehandling av alvorlig astma<sup>1</sup>.

Dupilumab er et humant monoklonalt antistoff som hindrer signalering fra IL-4 og IL-13, to proteiner som aktiverer Type 2-inflammasjon. I lungene vil høy grad av Type 2-inflammasjon kunne forårsake alvorlig astma. Denne typen inflammasjonsprosess karakteriseres hos astmapasienter av forhøyet nivå av eosinofile celler i blod, forhøyet nitrogenoksid i utpust (FeNO) eller at astmasymptomene er klinisk allergidrevet<sup>2</sup>.

Ved astma er dupilumab indisert (EMA-godkjent 7. mai 2019) hos «voksne og ungdom  $\geq 12$  år som tillegg til vedlikeholdsbehandling av alvorlig astma med type 2-inflammasjon karakterisert ved forhøyede eosinofile celler i blod og/eller forhøyet FeNO, og som er utilstrekkelig kontrollert med høydose ICS i tillegg til et annet legemiddel for vedlikeholdsbehandling».

Pasienter med alvorlig astma har ofte ukontrollerte, vedvarende symptomer til tross for optimalisert standard behandling. Symptomene omfatter hoste, piping og tetthet i brystet, tungpust eller surkling, med forverring om natten eller ved lett aktivitet og anstrengelse. Pasientene med Type 2-inflammasjon har økt risiko for alvorlige astmaanfall (eksaserbasjoner) som kan resultere i legevaktbesøk og/eller sykehusinnleggelse<sup>3</sup>.

*«Vi er glad for at man har kommet til en rask og positiv beslutning for Dupixent for alvorlig astma, og håper denne innovative behandlingen kan bli til nytte for pasienter og lungeleger»*

*Britt Moe Flatla, daglig leder, Sanofi Norge*

Dupilumab er et innovativt biologisk legemiddel med flere indikasjoner som representerer gjennombrudd i pasientbehandlingen innenfor ulike terapiområder.

For den første indikasjonen, alvorlig atopisk eksem hos voksne (EMA-godkjent 28. september 2017), venter man fortsatt på en løsning. Dupilumab er den første målrettede, biologiske behandlingen mot atopisk eksem - en kronisk inflammatorisk hudsykdom preget av intenst kløende, rødt utslett som kan føre til betydelig nedsatt livskvalitet, søvnmangel, angst og depresjon.

Sanofi Genzyme håper at den positive beslutningen og enigheten om betingelsene for Dupilumab ved alvorlig astma, også vil bidra til en snarlig løsning for pasienter med alvorlig atopisk eksem.

Referanser:

- 1: <https://nyemetoder.no/metoder/dupilumab-dupixent-indikasjon-ii> (18. nov. 2019)
2. GINA pocket guide for asthma management and prevention, GINA 2019
3. Castro M, Corren J, Pavord ID, et al. Dupilumab Efficacy and Safety in Moderate-to-Severe Uncontrolled Asthma. N Engl J Med 2018; 378:2486-2496.

GZNO.DUP.19.11.0305 (Nov. 2019)

## About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

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## 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 future 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, 2017. 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**

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 Regeneron’s products, product candidates, and research and clinical programs now underway or planned, including without limitation Dupixent® (dupilumab) Injection; the impact of the opinion adopted by the European Medicine Agency’s Committee for Medicinal Products for Human Use discussed in this news release on the European Commission’s decision regarding the Marketing Authorization Application for Dupixent for use as an add-on maintenance treatment for adults and adolescents (12 years and older) who have severe asthma with type 2 inflammation and who are inadequately controlled with medium-to-high dose inhaled corticosteroid plus another medicinal product for maintenance treatment, and for the treatment of oral corticosteroid-dependent asthma regardless of type 2 inflammatory biomarkers; 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, including possible regulatory approval of Dupixent in the European Union discussed in this news release and possible regulatory approval of Dupixent in other jurisdictions and indications (such as for the treatment of pediatric and adolescent atopic dermatitis, pediatric asthma, chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis, grass allergy, food allergy (including peanut), chronic obstructive pulmonary disease, and other potential indications (as well as in combination with REGN3500)); unforeseen safety issues resulting from the administration of products and product candidates (such as Dupixent) in patients, including serious complications or side effects in connection with the use of Regeneron’s product candidates in clinical trials; ongoing regulatory obligations and oversight impacting Regeneron’s marketed products (such as Dupixent), research and clinical programs, and business, including those relating to patient privacy; 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, including without limitation Dupixent; the availability and extent of reimbursement of the Company’s products (such as Dupixent) 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; uncertainty of market acceptance and commercial success of Regeneron’s products and product candidates (such as Dupixent) and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the commercial success of any such products and product candidates; competing drugs and product candidates that may be superior to Regeneron’s products and product candidates; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators may be replicated in other studies and lead to therapeutic applications; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; the ability of Regeneron’s collaborators, suppliers, or other third parties to perform filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron’s products and 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, 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 proceedings relating to EYLEA® (afibercept) Injection, Dupixent, and Praluent® (alirocumab) Injection, the ultimate outcome of any such litigation proceedings, 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-Q for the quarterly period ended September 30, 2018. 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>).