SANOFI

Nota de prensa

Fuente: Sanofi (EURONEXT: SAN) (NASDAQ: SNY)

Se presentan en ESMO resultados positivos del ensayo EMPOWER en carcinoma basocelular localmente avanzado

- Cemiplimab es el primer producto en investigación que demuestra un beneficio clínico en el carcinoma basocelular avanzado tras el tratamiento con un inhibidor de la vía hedgehog en un ensayo prospectivo.
- Se observó una tasa de respuesta objetiva del 31 % en los pacientes del ensayo y se estimó que el 85 % de las respuestas seguían en curso al cabo de un año.

BARCELONA, 30 de septiembre de 2020. Se han presentado en el Congreso Virtual de la Sociedad Europea de Oncología Médica (ESMO) los resultados positivos del ensayo pivotal fase II del inhibidor de PD-1 cemiplimab en pacientes con carcinoma basocelular (CBC) localmente avanzado que habían progresado con el tratamiento con inhibidores de la vía hedgehog (HHI) o que eran intolerantes a ellos.

Los resultados constituirán la base de las presentaciones del registro, incluidas las de EE. UU. y la Unión Europea.

> *"El carcinoma basocelular avanzado puede ser una enfermedad implacable altamente desfigurativa, y no existe ninguna opción de tratamiento autorizada cuando el paciente progresa o se vuelve intolerante a los inhibidores de la vía de hedgehog",* afirmó el **Dr. Alexander Stratigos**, catedrático de Dermatología en la Facultad de Medicina de la Universidad de Atenas en el Hospital Andreas Sygros y uno de los investigadores del ensayo. *"Es la primera vez que un ensayo prospectivo de un producto investigado ha demostrado un beneficio clínico en esta población de pacientes, y los resultados de cemiplimab aportan esperanza para este cáncer difícil de tratar."*

Según la revisión central independiente, la tasa de respuesta objetiva (TRO) fue del 31 % entre los pacientes tratados con cemiplimab (n = 84; intervalo de confianza [IC] del 95 %: 21-42 %), con una mediana de seguimiento de 15 meses (intervalo: 1-25 meses). Esto incluía una tasa de respuesta completa del 6 % (n = 5) y una tasa de respuesta parcial del 25 % (n = 21). Se trata de un aumento en TRO con respecto al dato comunicado en mayo e incluye dos respuestas que se confirmaron después del análisis inicial de los datos. Se observaron respuestas con independencia de la expresión basal de PDL1 en las células tumorales.

En el momento del corte de datos, la mediana de la respuesta y la mediana de la supervivencia global aún no se había alcanzado. Al año, el 85 % de las respuestas estaban en curso (IC del 95 %; 61-95 %), la probabilidad de supervivencia sin progresión era del 57 % (IC del 95 %: 44-67 %), y la probabilidad de supervivencia global era del 92 % (IC del 95 %: 84-97 %), de conformidad con las estimaciones de Kaplan-Meier.

No se observaron nuevas alertas de seguridad con cemiplimab. Los acontecimientos adversos (AA) relacionados con el tratamiento más frecuentes fueron fatiga (25 %, n = 21), prurito (14 %, n = 12) y astenia (14 %, n = 12). Los AA relacionados con el tratamiento de grado 3 o superior producidos en al menos 2 pacientes fueron colitis (5 %, n = 4), fatiga e insuficiencia suprarrenal (2 %, n = 2 cada uno). Catorce pacientes (17 %) interrumpieron el tratamiento debido a AA aparecidos durante el mismo.

Sanofi y Regeneron están desarrollando cemiplimab de forma conjunta mediante un acuerdo de

colaboración internacional. El uso de cemiplimab para el tratamiento del CBC avanzado está en investigación y no ha sido evaluado totalmente por ninguna autoridad sanitaria.

Acerca del ensayo pivotal del CBC

En este ensayo internacional en curso, de fase II, se estudiaron dos cohortes de pacientes: CBC localmente avanzado y CBC metastásico. Todos los pacientes recibieron cemiplimab 350 mg por vía intravenosa cada tres semanas durante un máximo de 93 semanas o hasta la progresión de la enfermedad. El objetivo principal es la TRO, y los objetivos secundarios principales incluyen supervivencia global, supervivencia libre de progresión, duración de la respuesta, seguridad y tolerabilidad. La mediana de la duración de la respuesta y la mediana de la supervivencia global se calcularon mediante el método de Kaplan-Meier. Está previsto que los resultados provisionales del CBC metastásico se presenten en un futuro congreso médico.

Acerca del carcinoma basocelular (CBC)

El CBC es el cáncer de piel no melanoma más frecuente. Aunque la gran mayoría de los CBC se detectan pronto y se curan fácilmente con cirugía y radiación, una pequeña proporción de tumores pueden llegar a progresar y penetrar en los tejidos circundantes (localmente avanzado) o extenderse a otras partes del cuerpo (metastásico), lo que es más difícil de tratar. Solo en EE. UU., se diagnosticarán aproximadamente 2 millones de nuevos casos de CBC cada año, 20.000 pacientes estadounidenses tendrán CBC avanzado y 3.000 pacientes morirán a causa de esta enfermedad.

Acerca de Cemiplimab

Cemiplimab es un anticuerpo monoclonal completamente humano dirigido al receptor del punto de control inmunitario PD-1 en los linfocitos T. Al unirse a PD-1, cemiplimab ha demostrado bloquear las células cancerosas usando la vía PD-1 para suprimir la activación de los linfocitos T.

Cemiplimab es la primera inmunoterapia autorizada en EE. UU., la UE y otros países para adultos con carcinoma cutáneo de células escamosas (CCCE) metastásico o localmente avanzado que no son tributarios de cirugía o radioterapia curativas. También se le puede llamar carcinoma epidermoide cutáneo (CEC).

El amplio programa clínico de cemiplimab se centra en el tratamiento de cánceres difíciles de tratar. En el cáncer de piel, esto incluye ensayos en CCCE en adyuvancia y neoadyuvancia además de ensayos en CBC avanzados. Cemiplimab también se está investigando en ensayos de CPNM y cáncer de cuello uterino, así como en ensayos que combinan cemiplimab con enfoques terapéuticos convencionales o novedosos para tumores sólidos y neoplasias hemáticas. Estos posibles usos están en fase de investigación y su seguridad y eficacia no han sido evaluadas por ninguna autoridad sanitaria.

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 over 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to seven FDA-approved treatments and numerous product candidates in development, 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, 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 additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

Acerca de Sanofi

Sanofi se dedica a apoyar a las personas abordando desafíos en el campo de la salud. Somos una compañía biofarmacéutica mundial centrada en la salud humana. Evitamos enfermedades con vacunas y proporcionamos tratamientos innovadores para combatir el dolor y aliviar el sufrimiento. Estamos al lado de los que sufren enfermedades raras y de los millones de personas que conviven con enfermedades crónicas.

Sanofi, con más de 100 000 personas en 100 países, está transformando la innovación científica en soluciones sanitarias en todo el mundo.

Sanofi, potenciando la vida

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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 fact that pro duct 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 COVID-19 will 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. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. 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, 2019. 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 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 by Regeneron and/or its collaborators (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and Regeneron's product candidates and research and clinical programs now underway or planned, including without limitation Cemiplimab® (cemiplimab); 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 Cemiplimab for the treatment of basal cell carcinoma, non-small cell lung cancer, adjuvant and neoadjuvant cutaneous squamous cell carcinoma, and cervical cancer (as well as in trials combining Cemiplimab with either conventional or novel therapeutic approaches for both solid tumors and blood cancers, as applicable); 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; safety issues resulting from the administration of Regeneron's Products (such as Cemiplimab) and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and 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 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 product candidates; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators may be replicated in other studies and/or lead to advancement of product candidates to clinical tria ls, therapeutic applications, or regulatory approval; 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 (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regenero n'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 and other related proceedings relating to EYLEA® (aflibercept) Injection, Dupixent® (dupilumab), and Praluent® (alirocumab)), 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, 2019 and its Form 10-Q for the quarterly period ended June 30, 2020. 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).