



Regeneron Completes Purchase of Sanofi's Stake in Libtayo® (cemiplimab)

July 1, 2022

Company provides anticipated impact to second quarter 2022 financial results due to recently completed business development transactions

TARRYTOWN, N.Y., July 1, 2022 /PRNewswire/ -- [Regeneron Pharmaceuticals, Inc.](#) (NASDAQ: REGN) today announced that it has completed the acquisition of Sanofi's stake in Libtayo® (cemiplimab), providing Regeneron with exclusive worldwide development, commercialization, and manufacturing rights to the medicine originally discovered in Regeneron's laboratories. The intent to purchase Libtayo was [announced](#) on June 2, 2022.

In 2015, Regeneron and Sanofi entered into the Immuno-oncology License and Collaboration Agreement whereby the companies split Libtayo's worldwide operating profits equally and co-commercialized Libtayo in the U.S., with Sanofi solely responsible for commercialization outside the U.S. With today's closing, Regeneron will now record 100% of global net sales and expenses for Libtayo.

Regeneron intends to update its full year 2022 financial guidance to reflect the Libtayo purchase during its second quarter 2022 earnings announcement in early August.

Anticipated Impact to Second Quarter 2022 Financial Results from Recently Completed Business Development Transactions

There is no financial or accounting impact to second quarter 2022 financial results as a result of the Libtayo transaction.

On May 31, 2022, Regeneron announced that it had successfully acquired Checkmate Pharmaceuticals, Inc. for a total equity value of approximately \$250 million. As a result of the Checkmate acquisition, Regeneron expects to record in the second quarter of 2022 an acquired in-process research and development (IPR&D) charge of approximately \$195 million, which would negatively impact GAAP and non-GAAP diluted earnings per share by approximately \$1.70. This acquired IPR&D charge and its resultant impact on diluted earnings per share represent unaudited estimates that have not been subject to Regeneron's quarterly financial statement closing procedures, and therefore actual amounts could differ from what the Company currently anticipates.

About Regeneron

Regeneron (NASDAQ: **REGN**) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for nearly 35 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to nine FDA-approved treatments and numerous 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, pain, 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 additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

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. Risks that may cause these forward-looking statements to be inaccurate include, among others: risks related to the Company's ability to realize the anticipated benefits of the restructuring (the "Restructuring") of the Company's Immuno-oncology Collaboration with Sanofi related to Libtayo® (cemiplimab-rwlc) and/or the acquisition (the "Acquisition") of Checkmate Pharmaceuticals, Inc. ("Checkmate") discussed in this press release, including the possibility that the expected benefits from the Restructuring and/or the Acquisition will not be realized or will not be realized within the expected time period and that Checkmate will not be integrated successfully; the impact of the Restructuring on Regeneron's business, operating results, and financial condition, as well as effects of the consummation of the Restructuring on the market price of the Company's common stock; future costs associated with the Restructuring and/or integration of Checkmate; 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 or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products, 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 Libtayo; 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) on any of the

foregoing or any potential regulatory approval of Regeneron's Products and Regeneron's Product Candidates; 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 Libtayo); 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; 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 and/or its collaborators to manufacture and manage supply chains for multiple products and product candidates; safety issues resulting from the administration of Regeneron's Products 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; 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, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be cancelled or terminated; 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® (afibercept) Injection, Dupixent® (dupilumab), Praluent® (alirocumab), and REGEN-COV® (casirivimab and imdevimab)), 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, 2021 and its Form 10-Q for the quarterly period ended March 31, 2022. 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 (<http://newsroom.regeneron.com>) and its Twitter feed (<http://twitter.com/regeneron>).

Non-GAAP Financial Measures

This press release includes non-GAAP net income per share, which is a financial measure that is not calculated in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). This non-GAAP financial measure is computed by excluding certain non-cash and/or other items from the related GAAP financial measure. The Company also includes a non-GAAP adjustment for the estimated income tax effect of reconciling items. The Company makes such adjustments for items the Company does not view as useful in evaluating its operating performance. Management uses this and other non-GAAP measures for planning, budgeting, forecasting, assessing historical performance, and making financial and operational decisions, and also provides forecasts to investors on this basis. Additionally, such non-GAAP measures provide investors with an enhanced understanding of the financial performance of the Company's core business operations. However, there are limitations in the use of such non-GAAP financial measures as they exclude certain expenses that are recurring in nature. Furthermore, the Company's non-GAAP financial measures may not be comparable with non-GAAP information provided by other companies. Any non-GAAP financial measure presented by Regeneron should be considered supplemental to, and not a substitute for, measures of financial performance prepared in accordance with GAAP.

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