

# Sanofi grants Regeneron worldwide exclusive license rights to Libtayo® (cemiplimab)

- Sanofi will receive an upfront payment of \$900 million, and an 11% royalty on worldwide net sales of Libtayo
- Sanofi will also be entitled to a \$100 million regulatory milestone payment as well as sales-related milestone payments of up to \$100 million over the next two years

**Paris, June 2, 2022.** Sanofi restructures its immuno-oncology collaboration with Regeneron Pharmaceuticals, Inc. Under the amended and restated license and collaboration agreement, Regeneron will obtain worldwide exclusive license rights to Libtayo. The Sanofi and Regeneron global immuno-oncology license and collaboration agreement was originally executed in 2015. Prior to today, the companies had split Libtayo's worldwide operating profits equally and co-commercialized Libtayo in the U.S., with Sanofi solely responsible for commercialization in the rest of the world.

### **Bill Sibold**

Executive Vice President of Specialty Care & President of North America, Sanofi

*“Our diverse oncology portfolio doubled between 2019 and 2022 and now includes twelve compounds in clinical trials, each with a unique mechanism of action. Our early steps with Libtayo in immuno-oncology provided a strong foundation for our revitalized oncology efforts. Now, we are focused on leveraging our internal capabilities and advancing a new generation of oncology medicines. We continue to maintain a strong partnership with Regeneron in immunology, and will work closely with them on the seamless transition of Libtayo to ensure there is no impact for patients.”*

Under the terms of the amended and restated immuno-oncology license and collaboration agreement, Sanofi will transfer the rights to develop, commercialize, and manufacture Libtayo entirely to Regeneron, on a worldwide basis, over the course of a defined transition period (to start upon receipt of any required governmental clearances worldwide). In exchange, Sanofi will receive an upfront payment of \$900 million, and an 11% royalty on worldwide net sales of Libtayo. Sanofi will also be entitled to a \$100 million regulatory milestone payment upon the first approval by either the FDA or European Commission of Libtayo in combination with chemotherapy for first-line treatment of certain patients with NSCLC, as well as sales-related milestone payments of up to \$100 million in total over the next two years. The transaction is subject to clearance under competition law and is expected to close in the third quarter of 2022.

Regeneron will also accelerate reimbursement of the development balance associated with Regeneron and Sanofi's separate Antibody Collaboration. Regeneron will increase from 10% to 20% the share of its profits that are paid to Sanofi to reimburse Sanofi-funded development expenses, until Regeneron's share of the total cumulative development costs incurred under the collaboration has been reached.

Sanofi continues to build its considerable expertise in oncology and has increased research and development capabilities, focusing on difficult to treat cancers including breast, blood, and lung. We are committed to translating scientific discoveries into potential new treatments and addressing critical gaps in cancer care.

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### **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 some 100 countries, 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

### *Media Relations*

**Sandrine Guendoul** | + 33 6 25 09 14 25 | [sandrine.quendoul@sanofi.com](mailto:sandrine.quendoul@sanofi.com)

**Sally Bain** | + 1 617 834 6026 | [sally.bain@sanofi.com](mailto:sally.bain@sanofi.com)

**Chrystel Baude** | + 33 6 70 98 70 59 | [chrystel.baude@sanofi.com](mailto:chrystel.baude@sanofi.com)

**Nicolas Obrist** | + 33 6 77 21 27 55 | [nicolas.obrist@sanofi.com](mailto:nicolas.obrist@sanofi.com)

**Victor Rouault** | + 33 6 70 93 71 40 | [victor.rouault@sanofi.com](mailto:victor.rouault@sanofi.com)

### *Investor Relations*

**Eva Schaefer-Jansen** | + 33 7 86 80 56 39 | [eva.schaefer-jansen@sanofi.com](mailto:eva.schaefer-jansen@sanofi.com)

**Arnaud Delépine** | + 33 6 73 69 36 93 | [arnaud.delepine@sanofi.com](mailto:arnaud.delepine@sanofi.com)

**Corentine Driancourt** | + 33 6 40 56 92 21 | [corentine.driancourt@sanofi.com](mailto:corentine.driancourt@sanofi.com)

**Felix Lauscher** | + 1 908 612 7239 | [felix.lauscher@sanofi.com](mailto:felix.lauscher@sanofi.com)

**Priya Nanduri** | +1 617 764 6418 | [priya.nanduri@sanofi.com](mailto:priya.nanduri@sanofi.com)

**Nathalie Pham** | + 33 7 85 93 30 17 | [nathalie.pham@sanofi.com](mailto:nathalie.pham@sanofi.com)

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### **Disclaimers or 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 and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. 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, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, 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, 2021. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.