SANOFI

Press Release

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

European Patent Office rules in favor of Sanofi and Regeneron concerning Praluent® (alirocumab)

- Ruling invalidates Amgen's European patent claims directed to PCSK9 antibodies relevant to Praluent® (alirocumab)
- Praluent® (alirocumab) continues to be available in European countries where it is approved for use and for sale

PARIS – October 29, 2020 – The European Patent Office (EPO) Technical Boards of Appeal has today ruled in Sanofi and Regeneron's favor, invalidating certain claims of Amgen's European patent (EP 2 215 124) directed to PCSK9 (proprotein convertase subtilisin/kexin type 9) antibodies relevant to Praluent® (alirocumab). Praluent will continue to be available in European countries where it is approved for use and for sale.

> *"We are pleased with today's decision by the European Patent Office, which upholds the rigorous standard for pharmaceutical patents that we argued for in this case, affirming that Amgen's asserted claims against Sanofi in Europe are invalid,"* said Karen Linehan, Executive Vice President, Legal Affairs and General Counsel, Sanofi. *"This decision validates our years-long commitment to vigorously defending this case."*

Today's EPO decision follows a ruling in Sanofi and Regeneron's favor in August 2019 by the U.S. District Court for the District of Delaware which found as a matter of law that certain of Amgen's asserted patent claims for antibodies targeting PCSK9 are invalid based on lack of enablement.

Editor's notes

Under a restructured agreement announced in December 2019, Sanofi possesses sole rights for Praluent outside the U.S. Regeneron has sole rights for Praluent inside the U.S. Each party is solely responsible for funding development and commercialization expenses in their respective territories.

Praluent is not available in Germany, following an injunction granted by the Düsseldorf Regional Court in July 2019. Sanofi has appealed this decision, and a hearing for the appeal is scheduled for November 5, 2020.

About Praluent

Praluent® (alirocumab) inhibits the binding of PCSK9 (proprotein convertase subtilisin/kexin type 9) to the low-density lipoprotein (LDL) receptor and thereby increases the number of available LDL receptors on the surface of liver cells to clear LDL, which

lowers LDL cholesterol (LDL-C) levels in the blood. Praluent was developed by Sanofi and Regeneron under a global collaboration agreement.

Sanofi possesses sole rights for Praluent outside the U.S. Regeneron has sole rights for Praluent inside the U.S.

Praluent is approved in more than 60 countries worldwide across the European Union (EU), North and South Americas, Asia, Africa and Australia.

In the European Union (EU), Praluent is approved for use in adults:

- with primary hypercholesterolemia (heterozygous familial and non-familial) or mixed dyslipidemia, as an adjunct to diet:
    - in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin or,
    - alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.
- with established atherosclerotic cardiovascular disease (ASCVD) to reduce cardiovascular (CV) risk by lowering LDL-C, as an adjunct to correction of other risk factors:
    - in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or,
    - alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

The effect of Praluent on CV morbidity and mortality has been recognized and approved by regulatory authorities in the EU, U.S., China and other international markets.

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

Media Relations Contacts
Ashleigh Koss
Tel: +1 (908) 981-8745
Ashleigh.Koss@sanofi.com

Investor Relations Contacts Paris
Eva Schaefer-Jansen
Arnaud Delepine
Yvonne Naughton

Investor Relations Contacts North America
Felix Lauscher
Fara Berkowitz
Suzanne Greco

IR main line:
Tel.: +33 (0)1 53 77 45 45
ir@sanofi.com

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 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, 2019. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.