**Press Release**

# *Update on Cialis® Rx-to-OTC Switch Actual Use Trial*

**Paris**. **May 30, 2022.** The U.S. Food and Drug Administration has informed Sanofi that its planned Actual Use Trial (AUT) to support the Rx-to-OTC switch for Cialis® (tadalafil) has been placed on clinical hold due to matters surrounding the protocol design. Sanofi's AUT has not yet recruited any patients. Sanofi continues to work with FDA to move the Cialis® program forward and will engage the Agency in upcoming meetings as we determine next steps.

## About Cialis

Currently only available with a prescription, Cialis is a tablet taken to treat erectile dysfunction (ED), the signs and symptoms of benign prostatic hyperplasia (BPH), and both ED and the signs and symptoms of BPH. Cialis is the only PDE-5 inhibitor treatment that offers men a choice when it comes to treatment for erectile dysfunction - Cialis for use as needed and Cialis for once daily use. To learn more about Cialis, visit www.cialis.com.

Cialis is not for women or children. It is important to note that Cialis is not to be taken with medicines called "nitrates" such as isosorbide dinitrate or isosorbide mononitrate which are often prescribed for chest pain; or with recreational drugs called "poppers" like amyl or butyl nitrite, as the combination may cause an unsafe drop in blood pressure; or if allergic to Cialis or Adcirca® (tadalafil), or any of its ingredients. Anyone who experiences any symptoms of an allergic reaction, such as rash, hives, swelling of the lips, tongue or throat, or difficulty breathing or swallowing, should call a healthcare provider or get help right away.

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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


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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 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.