

## Opella reaches study milestone for Cialis

**Paris, January 21, 2025.** Opella, Sanofi's Consumer Healthcare business, announced that the US Food and Drug Administration (FDA) has lifted a clinical hold on its planned actual use trial (AUT) to support the switch of Cialis (tadalafil) from a prescription to an over-the-counter medicine. This decision allows for the initiation of the AUT and makes Cialis the first PDE-5 inhibitor to achieve this milestone.

AUTs evaluate the use of the medicine under real-world conditions to identify any issues that have not previously been identified and to confirm that consumers can self-diagnose and treat themselves appropriately without the help of a healthcare provider.

### **Julie Van Ongevalle**

President and CEO, Opella

*"We are pleased that the FDA has completed their review and is allowing us to initiate this important study. The actual use trial is not only a significant opportunity to gain insights into how Cialis is used by consumers without a prescription, but it also underscores our commitment to advancing self-care solutions. It represents a crucial step towards our commitment to make self-care as simple as it should be."*

### **Dr. Josephine Fubara**

Chief Science Officer, Opella

*"FDA's decision marks a significant step forward in Opella's data-driven efforts to switch a PDE-5 inhibitor like Cialis. Now that the FDA has completed their thorough review of our data, we can move into the next phase of this program; the actual use trial, which is pivotal in ensuring the safety and proper self-selection of Cialis for over-the-counter use. We look forward to continuing our work to bring safe and expanded access to the many consumers who will benefit from nonprescription Cialis."*

Opella remains committed to advancing its development program and bringing a new self-care solution with proven effectiveness for people living with erectile dysfunction. The company is completing the clinical and regulatory activities necessary to initiate the pivotal AUT. Information about the study will become available on [clinicaltrials.gov](https://clinicaltrials.gov).

On October 21, 2024 Sanofi and CD&R announced the intention to transfer a 50% controlling stake in Opella to CD&R with Sanofi to remain a significant shareholder.

### **About Cialis**

Cialis (tadalafil) in the US is 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 ED - Cialis for use as needed and Cialis for once daily use. To learn more about Cialis, visit [www.cialis.com](https://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.

## 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 the world, 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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