September 3, 2025

# Achieve Life Sciences Announces FDA Acceptance of Cytisinicline New Drug Application for Treatment of Nicotine Dependence for Smoking Cessation

*Filing based on pivotal Phase 3 ORCA-2 and ORCA-3 clinical trials demonstrating statistically significant and clinically meaningful smoking cessation*

*FDA acceptance starts the review process and sets timing for potentially the first new FDA-approved pharmacotherapy in two decades*

*PDUFA targeted date set for June 20, 2026*

SEATTLE and VANCOUVER, British Columbia, Sept. 03, 2025 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a late-stage specialty pharmaceutical company focused on the global development and commercialization of cytisinicline for treatment of nicotine dependence, today announced that the U.S. Food and Drug Administration (FDA) has accepted the cytisinicline New Drug Application (NDA) for a new treatment for smoking cessation in adults. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) targeted action date of June 20, 2026.

“The FDA’s acceptance of our NDA validates the totality of our product development program,” said Dr. Cindy Jacobs, President and Chief Medical Officer of Achieve Life Sciences. “Our application is supported by a decade of rigorous research and comprehensive data from thousands of participants. We've built compelling scientific and clinical results as a foundation that, if approved, positions cytisinicline to potentially address a significant medical need. We’re eager to engage constructively with the FDA as we progress through the NDA review process.”

The company’s NDA details a comprehensive clinical development program, with more than 2,000 clinical trial participants contributing to the body of evidence. The ORCA-2 and ORCA-3 Phase 3 trials showed cytisinicline administered for either 6 or 12 weeks, alongside standard behavioral support, demonstrated significantly greater smoking abstinence rates by the end of treatment and in long-term abstinence through week 24 as compared to placebo.

In addition, safety data will include over 400 participants who have received at least six months of cumulative cytisinicline exposure and over 200 participants receiving at least 1 year of cumulative cytisinicline exposure, with no new safety concerns as reported by the Data Safety Monitoring Committee.

“Smoking is the leading cause of preventable death and disease, claiming the lives of nearly half a million Americans each year, and costing the American economy more than an estimated $600 billion a year,” said Rick Stewart, Chief Executive Officer of Achieve Life Sciences. “The FDA's acceptance of our NDA filing underscores nicotine dependence as an important public health need that demands action. We're energized by this milestone and remain laser-focused on our mission, working toward commercial readiness for the second half of 2026, pending FDA approval. Each year, an estimated 15 million Americans attempt to quit smoking, and we're committed to providing those who are ready to quit a new tool so they can break free from nicotine dependence.”

**About Achieve Life Sciences, Inc.**
Achieve Life Sciences is a late-stage specialty pharmaceutical company committed to addressing the global smoking health and nicotine dependence epidemic through the development and commercialization of cytisinicline. In September 2025, the FDA accepted the cytisinicline New Drug Application (NDA) and defined a PDUFA completion date of June 20, 2026. Additionally, the company has completed a Phase 2 study with cytisinicline in vaping cessation and conducted a successful end-of-Phase 2 meeting with the FDA for a future vaping indication.

**About Cytisinicline**
There are approximately 29 million adults in the United States who smoke combustible cigarettes.[1] Tobacco use is currently the leading cause of preventable death that is responsible for more than eight million deaths worldwide and nearly half a million deaths in the United States annually.[2,3] More than 87% of lung cancer deaths, 61% of all pulmonary disease deaths, and 32% of all deaths from coronary heart disease are attributable to smoking and exposure to secondhand smoke.[3]

In addition, there are approximately 17 million adults in the United States who use e-cigarettes, also known as vaping.[4] In 2024, approximately 1.6 million middle and high school students in the United States reported using e-cigarettes.[5] There are no FDA-approved treatments indicated specifically as an aid to nicotine e-cigarette cessation. Cytisinicline has been granted Breakthrough Therapy designation by the FDA to address this critical unmet need.

Cytisinicline is a plant-derived alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is believed to aid in treating nicotine dependence for smoking cessation and e-cigarette cessation by interacting with nicotine receptors in the brain, reducing the severity of nicotine craving symptoms, and reducing the reward and satisfaction associated with nicotine products. Cytisinicline is a new investigational product candidate being developed for the treatment of nicotine dependence for smoking cessation and has not been approved by the Food and Drug Administration for any indication in the United States.

**Forward Looking Statements**
This press release contains forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, including, but not

limited to, statements Achieve makes regarding its expectation of the timing and nature of cytisinicline clinical development and regulatory review and approval, data results and commercialization activities, the potential market size for cytisinicline, the potential benefits, efficacy, safety and tolerability of cytisinicline, the development and effectiveness of new treatments, and the successful commercialization of cytisinicline. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Achieve may not actually achieve its plans or product development goals in a timely manner, if at all, or otherwise carry out its intentions or meet its expectations or projections disclosed in these forward-looking statements. These statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements, including Achieve's Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q. Achieve undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof, other than as may be required by applicable law.

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