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Achieve Life Sciences Receives FDA Commissioner's National Priority Voucher for Cytisinicline for Treatment of Nicotine Dependence for E-cigarette or Vaping Cessation

Potential First-in-Class Treatment for Nicotine E-cigarette or Vaping Cessation Receives Unprecedented Expedited Review Pathway

One of Only Nine Therapies Chosen for the FDA's Inaugural National Priority Voucher Program

SEATTLE and VANCOUVER, British Columbia, Oct. 17, 2025 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a late-stage specialty pharmaceutical company focused on the global development and commercialization of cytisinicline as a treatment of nicotine dependence, today announced that the U.S. Food and Drug Administration (FDA) has awarded the company a Commissioner's National Priority Voucher (CNPV) for cytisinicline as a treatment of nicotine dependence for e-cigarette or vaping cessation. This first-of-its-kind designation, available to only nine therapies in the program's inaugural year, is designed to provide enhanced FDA communications and expedited review that reduces FDA-assessment time to one to two months from the standard 10-12 months, once complete materials are submitted for FDA review.

Cytisinicline is a potential first-in-class pharmacotherapy specifically indicated for nicotine e-cigarette or vaping cessation. This market represents a significant and growing unmet medical need, with approximately 60% of the 17 million adult e-cigarette users in the United States expressing a desire to quit.

"Achieve is redefining the future of nicotine dependence," said Rick Stewart, Chief Executive Officer of Achieve. "This voucher accelerates our path to potentially pioneering the first and only FDA-approved treatment of nicotine dependence for e-cigarette or vaping cessation, which would establish an entirely new category to serve the millions of people who want to quit vaping. It's been nearly two decades since a new treatment option for smoking

cessation was approved, and there are currently no treatment options for vaping cessation. Our message to all Americans struggling with nicotine dependence is, 'We are not quitting on you.'"

Cytisinicline demonstrated clinical efficacy in the Phase 2 ORCA-V1 trial, published in JAMA Internal Medicine, where participants treated with cytisinicline were 2.6 times more likely to quit using nicotine e-cigarettes or vapes compared to placebo. The FDA has granted cytisinicline Breakthrough Therapy designation for nicotine e-cigarette or vaping cessation and has agreed on the Phase 3 trial design (ORCA-V2) that, combined with the completed Phase 2 ORCA-V1 study, would support a supplemental New Drug Application (NDA) for vaping cessation indication.

In the October 16th press release issued by FDA, Commissioner Marty Makary, M.D., M.P.H. said, “One of our core goals is to deliver more cures and meaningful treatments—especially ones that have an outsized impact on our most pressing national priorities.”

"The FDA's recognition of vaping cessation as a national priority through this voucher program underscores that nicotine dependence is a medical issue in need of medical intervention," said Dr. Mark Rubinstein, Interim Chief Medical Officer at Achieve.

Separately, Achieve Life Sciences recently announced that the FDA accepted its NDA for cytisinicline for the treatment of nicotine dependence for smoking cessation, with a PDUFA target action date of June 20, 2026.

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 company announced that its New Drug Application, submitted to the U.S. Food and Drug Administration (FDA) in June 2025, had been accepted for review. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) date of June 20, 2026. The NDA is for cytisinicline to be used as a treatment of nicotine dependence for smoking cessation in adults, based on two successfully completed Phase 3 studies and its open-label safety study. 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 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 addiction for smoking 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 an investigational product candidate being developed as a 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 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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