June 22, 2026

Achieve Life Sciences Receives Complete Response Letter from FDA for Cytisinicline NDA

CRL Cites Deficiencies at Third-Party Manufacturing Facility

No Efficacy or Clinical Safety Deficiencies Identified

SEATTLE and VANCOUVER, British Columbia, June 22, 2026 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Achieve or the Company) (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 it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for cytisinicline. The CRL relates to outstanding manufacturing-related observations from a current Good Manufacturing Practice (cGMP) inspection of a third-party manufacturing facility and to final product labeling that was not completed by the FDA's action date. The FDA identified no deficiencies regarding the clinical efficacy or safety of cytisinicline.

The deficiencies cited in the CRL concern Achieve's prior third-party manufacturing facility, which received an Official Action Indicated (OAI) classification from the FDA for general cGMP matters at the facility that are not specific to cytisinicline. As the Company disclosed on April 15, 2026, it expected to receive this CRL on or before its June 20, 2026 PDUFA date and had previously partnered with U.S.-based Adare Pharma Solutions (Adare) as its new primary commercial manufacturing partner.

Achieve has completed the analytical method technology transfer to Adare's facility, successfully manufactured its first cytisinicline engineering batch, and fully qualified all testing procedures at the site. Achieve intends to resubmit its NDA in the fourth quarter of 2026, naming Adare as its primary manufacturing partner, with potential FDA approval in the first half of 2027, followed by U.S. commercial launch.

"The FDA's feedback provides a clear and actionable path forward," stated Andrew D. Goldberg, MD, Chief Executive Officer of Achieve. "Our clinical data stands on its own: two successful Phase 3 trials and a robust open-label safety study. As we work with the FDA to

resolve these remaining requirements, we are simultaneously advancing our commercial readiness for launch. We remain fully committed to bringing this treatment to the patients who need it."

The cytisinicline NDA is supported by a comprehensive clinical development program with more than 1,500 clinical trial participants exposed to cytisinicline. In the pivotal Phase 3 ORCA-2 and ORCA-3 trials, 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 compared to placebo. Safety data includes over 400 participants who received at least six months of cumulative cytisinicline exposure and over 200 participants who received at least one year of cumulative exposure. This long-term safety data was previously reported and presented at the American Thoracic Society (ATS) International Conference in May 2026.

About Cytisinicline
There are approximately 25 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]

In addition, there are nearly 18 million adults in the United States who use e-cigarettes, also known as vaping.[1] In 2024, approximately 1.6 million middle and high school students in the United States reported using e-cigarettes.[4] There are no FDA-approved treatments indicated specifically as an aid to nicotine e-cigarette cessation. FDA has awarded the Commissioner's National Priority Voucher for e-cigarette or vaping cessation and granted Breakthrough Therapy designation to address this critical need.

Cytisinicline is a plant-based 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.

About Achieve Life Sciences, Inc.
Achieve Life Sciences, Inc. is a late-stage specialty pharmaceutical company focused on the global development and commercialization of cytisinicline as a treatment of nicotine dependence. Achieve's New Drug Application (NDA) for cytisinicline for smoking cessation in adults is supported by two successfully completed Phase 3 studies and an open-label long-term safety study. Achieve has also completed a Phase 2 study of cytisinicline in nicotine e-cigarette cessation, conducted an end-of-Phase 2 meeting with the FDA, and has received Breakthrough Therapy designation for the vaping cessation indication.

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, nature and outcome of cytisinicline clinical development and regulatory review and approval, data results, the timing, nature and success of Achieve's commercialization activities, the potential market size for cytisinicline, the potential benefits, efficacy, safety and tolerability of cytisinicline, the development and effectiveness of new treatments, the performance of Achieve's third-party manufacturing partners, the successful launch and commercialization of cytisinicline, and statements concerning Achieve Life Sciences' future plans and prospects. 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 those described in 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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[2]World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization, 2017.
[3]U.S. Department of Health and Human Services. The Health Consequences of Smoking — 50 Years of Progress. A Report of the Surgeon General, 2014.
[4]Jamal A, Park-Lee E, Birdsey J, et al. Tobacco Product Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:917–924.

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