

October 21, 2026



Achieve Life Sciences Presents 52-Week Cytisinicline Results for Smoking and Vaping Cessation at CHEST 2026

Nearly one in three adults who were still smoking or vaping after a prior ORCA trial had quit at the end of a year of cytisinicline treatment, with quit rates rising through the year

Among the participants new to cytisinicline (prior attempt on placebo), 39% had quit at the end of the year

Participants were in their mid-fifties on average, ranging up to age 79, and many had a history of chronic conditions; the typical participant who smoked had made five quit attempts before ORCA-OL, and every participant chose to try again

SEATTLE and VANCOUVER, British Columbia, Oct. 21, 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 for nicotine dependence, today announced positive 52-week efficacy results from its long-term, open-label ORCA-OL clinical trial evaluating cytisinicline for cigarette smoking and e-cigarette cessation. The findings were presented at the CHEST 2026 Annual Meeting in Phoenix, Arizona.

The ORCA-OL trial enrolled 479 adults, of whom 475 received at least one dose of cytisinicline 3 mg three times daily for up to 52 weeks and form the analysis population. Of these, 84.6% smoked cigarettes, 12.8% vaped exclusively, and 2.5% did both. This was a hard-to-treat population by design: every participant had already made a counseling-supported quit attempt in a prior ORCA trial (71% with cytisinicline), was still smoking or vaping, and chose to try again, and more than a third of those who smoked had also tried varenicline, bupropion, or both and were still smoking. People who smoked averaged 56 years of age and had smoked for an average of 37 years; many participants had a history of hypertension, depression, anxiety, cancer, or COPD, and 86% were taking other medications. Four-week sustained abstinence rates, the measure of quitting used in the trial, increased from 25.5% at Weeks 9–12 to 30.3% at Weeks 21–24 to 31.2% during the final four weeks of treatment (Weeks 49–52) in the total study population.

All of these are repeat-attempt results: the participants who smoked had made a median of five quit attempts before ORCA-OL, including their prior ORCA trial. Among participants who had received placebo in their prior trial and were still smoking or vaping, 26.3% had quit at Weeks 9–12 and 39.4% at Weeks 49–52. Among those who had already received cytisinicline in their prior trial and were still smoking or vaping, 27.8% had quit at Weeks 49–52. To the Company's knowledge, ORCA-OL is the first year-long cessation study to include people who vape (73 participants), every one of them still vaping after a medically supported quit attempt. At the end of the year, in this repeat attempt, 32.8% of people who exclusively smoked and 24.6% of those who exclusively vaped had quit (31.2% overall).

“Most people need more than one attempt to quit, yet treatment beyond 12 weeks and retreatment had not previously been studied with cytisinicline,” said Mark Rubinstein, MD, Chief Medical Officer, Achieve. “These results provide the first data on extended treatment and retreatment with cytisinicline, and suggest that longer treatment of up to 52 weeks may help some people who smoke or vape sustain abstinence.”

“This is the first year-long treatment trial we know of in people who were still smoking or vaping after a medically supported quit attempt, and the people in it look like the patients clinicians see every day: older, on other medications, and living with chronic conditions, many having also tried other treatments and still smoking,” said Andrew D. Goldberg, MD, Chief Executive Officer, Achieve. “Every one of them chose to try again, and nearly a third were not smoking or vaping at the end of a year.”

The median duration of cytisinicline exposure was 361 days, with 69.7% (334/479 enrolled) of participants completing the 52-week study. The most common treatment-related adverse events were abnormal dreams (7.8%), insomnia (6.5%), and headache (3.8%); 3.6% of participants discontinued due to a treatment-related adverse event. Treatment-related nausea occurred in 1.5%. The independent Data Safety Monitoring Committee (DSMC) identified no new safety signals.

ORCA-OL was an open-label study designed to evaluate the long-term safety, tolerability, and efficacy of cytisinicline in adults who smoke cigarettes, use nicotine-containing e-cigarettes, or use both products. Participants received cytisinicline 3 mg three times daily alongside behavioral support for up to 52 weeks. Efficacy assessments included four-week sustained abstinence and seven-day point prevalence abstinence, providing insights into cessation outcomes during extended treatment.

Achieve has completed two Phase 3 clinical trials, ORCA-2 and ORCA-3, evaluating cytisinicline for smoking cessation, as well as the Phase 2 ORCA-V1 trial evaluating cytisinicline for vaping cessation. The ORCA-OL findings provide additional long-term clinical evidence supporting the potential role of cytisinicline in treating nicotine dependence.

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, responsible for more than seven 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 2025, approximately 1.4 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 Achieve the

Commissioner's National Priority Voucher for e-cigarette or vaping cessation and granted Breakthrough Therapy designation to address this critical need.

Cytisinicline is an investigational compound that binds to nicotinic receptors. It is being developed as an aid to smoking cessation treatment in adults and as an aid to nicotine e-cigarette cessation.

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 for 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. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including, without limitation, statements regarding the ORCA-OL results and their interpretation, the potential of cytisinicline for extended treatment, retreatment, and smoking and vaping cessation, the timing and outcome of Achieve's planned NDA resubmission for cytisinicline, the timing of any FDA decision, the potential benefits of cytisinicline, the potential market for cytisinicline, the Company's commercialization plans and readiness. Achieve may not achieve its plans, projections, or other expectations and may not be able to successfully complete its NDA resubmission or obtain regulatory approval for cytisinicline on the anticipated timeline or at all. ORCA-OL was an open-label, uncontrolled study, and its results, including results in subgroups of participants, may not be predictive of results in controlled clinical trials or in clinical practice. These statements are based on management's current expectations and beliefs and are subject to risks, uncertainties, and assumptions that could cause actual results to differ materially from those described in the forward-looking statements, including those detailed in Achieve's most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission. Achieve undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by applicable law.

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²World Health Organization. WHO Report on the Global Tobacco Epidemic, 2025. Geneva: World Health Organization; 2025.

³U.S. Department of Health and Human Services. The Health Consequences of Smoking, 50 Years of Progress. A Report of the Surgeon General. Centers for Disease Control and

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⁴Eunice Park-Lee, Lauren M Dutra, Hannah Cowan, et al. Tobacco Product Use Among Middle and High School Students in the United States: National Youth Tobacco Survey, 2025, *Nicotine & Tobacco Research*, 2026; ntag116, doi.org/10.1093/ntr/ntag116.



Source: Achieve Life Sciences