

March 4, 2026



Achieve Life Sciences Presents Data at SRNT Demonstrating Successful Cessation in Smokers with Extensive Prior Treatment Exposure; and on Participant Experience in the ORCA-OL Study

A pooled Phase 3 analysis of more than 1,600 people who smoke showed high quit rates; including among those who had previously not succeeded with other smoking cessation medications and regardless of the number of prior quit attempts

Late-breaking survey data from year-long ORCA-OL safety study highlight participant experience with extended cytisinicline use

SEATTLE and VANCOUVER, British Columbia, March 04, 2026 (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 new data showing that 6 and 12 weeks of cytisinicline delivers meaningful quitting success, regardless of participants' prior use of smoking cessation medications or number of previous quit attempts.

Achieve also announces late-breaking survey data from ORCA-OL, demonstrating participant experience with extended cytisinicline use. These findings will be presented during the Society for Research on Nicotine & Tobacco (SRNT) 2026 Annual Meeting, March 4-7 in Baltimore, Maryland.

An oral presentation will examine cytisinicline's efficacy and safety profile according to participants' prior treatment history and number of quit attempts. The analysis pools data from the ORCA-2 and ORCA-3 Phase 3 trials and examines outcomes in 1,602 participants with varying histories of prior quit medications, including varenicline, bupropion, and nicotine replacement therapy (NRT), as well as participants according to whether they had made four or fewer previous quit attempts versus more than four attempts. These analyses demonstrate cytisinicline benefit across a broad range of patients, regardless of their prior quit history.

“In this analysis, cytisinicline helped people to quit smoking, even those individuals who had failed previous quit attempts or had used FDA-approved smoking cessation medications without success,” said Dr. Nancy Rigotti, Professor of Medicine at Harvard Medical School, Director of Tobacco Research and Treatment Center, Massachusetts General Hospital, and ORCA Program Investigator. “Many people have to try to quit several times before they become smoke-free. This finding should offer hope to patients whose prior setbacks might have discouraged them from trying to quit smoking again.”

Additionally, Achieve will present late-breaking survey data from ORCA-OL, the open-label, long-term, exposure safety study of cytisinicline, which followed participants for up to one year of treatment. The voluntary post-trial survey will offer insights into patient-reported experiences with the extended use of cytisinicline beyond the 6- and 12-week courses previously studied, contributing to a more complete understanding of the treatment's impact on the lives of people who smoke as they strive to quit nicotine.

“Patient experience is hugely important for those trying to quit smoking,” said Dr. Mark Rubinstein, Chief Medical Officer of Achieve Life Sciences. “It is encouraging to see trial participants describing meaningful benefits, including successful quitting and improvements in physical health. We're committed to supporting people who want to quit smoking at every stage, whether they're trying to quit for the first time or making another attempt.”

Presentation Details:

- Title: *Cytisinicline in Adult Smokers: Post-Trial Survey From ORCA-OL*
 - Session: Poster Session 1
 - Format: Poster
 - Date & Time: Thursday, March 5, 2026; 11:30 AM – 1:00 PM EST
 - Location: Key Ballroom 7-12

- Title: *Efficacy of Cytisinicline for Smoking Cessation in Adults with and without Multiple Prior Quit Attempts or Prior Pharmacotherapy Use: Pooled Analysis of Two Phase 3 Trials*
 - Session: Podium 3; Session 1
 - Format: Oral Presentation
 - Date & Time: Friday, March 6, 2026; 8:45 – 9:00 AM EST
 - Location: Holiday 6

For additional information on the cytisinicline presentations and the Society for Research on Nicotine and Tobacco (SRNT) Annual Meeting please visit [SRNT Annual Meeting](#).

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. 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. 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. Cytisinicline is an investigational product candidate being developed as a treatment of nicotine dependence for smoking cessation and has not been approved by the FDA 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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References

- ¹VanFrank B, Malarcher A, Cornelius ME, Schecter A, Jamal A, Tynan M. Adult Smoking Cessation — United States, 2022. MMWR Morb Mortal Wkly Rep 2024;73:633–641.
- ²World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization, 2017.
- ³U.S. Department of Health and Human Services. The Health Consequences of Smoking – 50 Years of Progress. A Report of the Surgeon General, 2014.
- ⁴Vahratian A, Briones EM, Jamal A, Marynak KL. Electronic cigarette use among adults in the United States, 2019–2023. NCHS Data Brief, no 524. Hyattsville, MD: National Center for Health Statistics. 2025. DOI: <https://dx.doi.org/10.15620/cdc/174583>.
- ⁵Jamal 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.



Source: Achieve Life Sciences