May 19, 2026

Achieve Life Sciences Presents Safety Data from 52 Weeks of Continuous Cytisinicline Treatment

ORCA-OL data complete the clinical evidence package supporting the cytisinicline smoking cessation NDA

No new safety signals identified by the independent Data Safety Monitoring Committee over 52 weeks of continuous exposure

Nausea — a common barrier to treatment adherence with smoking cessation therapies — was reported in only 2.5% of participants over 52 weeks of continuous exposure[1]

SEATTLE and VANCOUVER, British Columbia, May 19, 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 the presentation of comprehensive long-term safety data from the ORCA-OL study at the American Thoracic Society (ATS) 2026 Annual Meeting. Additional cytisinicline data will be presented at ATS on May 20.

The ORCA-OL trial, an open-label, long-term, exposure safety study, enrolled 475 adults who smoke cigarettes, use e-cigarettes, or both. Participants received cytisinicline 3 mg three times daily for up to 52 weeks of continuous exposure, with a median cumulative duration of 361 days.[1] This final clinical dataset completes the comprehensive evidence package supporting Achieve's New Drug Application (NDA), demonstrating that cytisinicline maintains a favorable safety profile across extended treatment duration in a diverse population of adults with nicotine dependence.

ORCA-OL is the first long-term safety study of cytisinicline in adults using combustible cigarettes, e-cigarettes, or both — extending the clinical safety dataset well beyond the 6- and 12-week treatment durations evaluated in the pivotal Phase 3 ORCA-2 and ORCA-3 trials. The 52-week exposure findings support the long-term tolerability of cytisinicline in adults with nicotine dependence.

“The ORCA-OL dataset provides important long-term safety and tolerability information across a broad population of adults with nicotine dependence, including individuals using combustible cigarettes and e-cigarettes,” said Mark Rubinstein, MD, Chief Medical Officer of Achieve. “Additional data from our clinical program, shared over the coming days, further reinforce cytisinicline's potential to address a critical treatment gap. We remain focused on navigating the regulatory process and ultimately bringing this new therapy to patients in need.”

The ORCA-OL trial included smokers (84.6%), e-cigarette users (12.8%), and dual users (2.5%), adding to the growing safety database for multiple types of nicotine dependence. Among the participants, 66.3% experienced one or more treatment-emergent adverse events, the majority of which were considered unrelated or unlikely to be related to cytisinicline by the investigator. Notably, 94.8% of these adverse events were mild or moderate in severity, with serious adverse events reported in only 6.5% of participants. No new safety signals were identified by the independent Data Safety Monitoring Committee. The most commonly reported adverse events were abnormal dreams (8.4%), insomnia (8.4%), and upper respiratory tract infection (6.7%).[1] The incidence of nausea was 2.5%, consistent with the nausea rates observed across the Phase 3 program, and only 5.7% of participants discontinued the trial due to treatment-related adverse events.

“The ORCA-OL data represent an important milestone in our regulatory pathway,” said Andrew D. Goldberg, MD, Chief Executive Officer of Achieve. “With our complete clinical evidence package now in hand, we are positioned to advance cytisinicline toward potential approval and to bring forward a new, much-needed treatment option for patients.”

Featured at ATS 2026
Cytisinicline will be the subject of a dedicated oral symposium presented by Nancy Rigotti, MD, Professor of Medicine at Harvard Medical School and Associate Chief for Academic Advancement in the Division of General Internal Medicine at Massachusetts General Hospital. Dr. Rigotti served as principal investigator of the pivotal Phase 3 ORCA-2 and ORCA-3 trials.

> *Scientific Tobacco Action Committee Scientific Symposium — “For the First Time in Forever”: Cytisinicline, a New Medication for Nicotine Dependence. Wednesday, May 20 — 8:30-8:45 AM ET.*

Additionally, Mark Rubinstein, MD, Chief Medical Officer of Achieve, will present comparative effectiveness data in a poster discussion session at ATS.

> *Poster Discussion Session — Comparative Effectiveness of Cytisinicline and Varenicline for Smoking Cessation: A Matching-Adjusted Indirect Comparison (MAIC). Wednesday, May 20 — 11:00 AM-1:00 PM ET.*

About Cytisinicline
There are approximately 25 million adults in the United States who smoke combustible cigarettes.[3] Tobacco use is currently the leading cause of preventable death, responsible for more than eight million deaths worldwide and nearly half a million deaths in the United States annually.[4,5]

In addition, there are nearly 18 million adults in the United States who use e-cigarettes, also known as vaping.[3] In 2024, approximately 1.6 million middle and high school students in the United States reported using e-cigarettes.[6] There are no FDA-approved treatments indicated

specifically as an aid to nicotine e-cigarette cessation. The 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.

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.

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 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

[1]Rigotti NA, et al. Cytisinicline for cigarette smoking and e-cigarette vaping cessation: Long-term safety data from the ORCA-OL clinical trial. Poster #325 presented at the American Thoracic Society 2026 Annual Meeting; May 15–20, 2026; Orlando, FL, USA.

[2]Achieve Life Sciences. Achieve Life Sciences Meets Key Milestones Advancing Cytisinicline NDA for Smoking Cessation. News release. November 3, 2025.

[3]Agaku I. Tobacco Product Use among U.S. Adults, 2023–2024, NEJM, doi: 10.1056/EVIDpha2500339.

[4]World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization; 2017.

[5]U.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 Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2014.

[6]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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Source: Achieve Life Sciences