

January 6, 2025



Achieve Life Sciences to Host Meetings During the J.P. Morgan Healthcare Conference Week

SEATTLE and VANCOUVER, British Columbia, Jan. 06, 2025 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a late-stage pharmaceutical company focused on the development and commercialization of cytisinicline for nicotine dependence, announced today that the company will be hosting in-person one-on-one meetings coinciding with the 43rd Annual J.P. Morgan Healthcare Conference in San Francisco, January 13-16, 2025.

Rick Stewart, Chief Executive Officer of Achieve, along with other members of senior management, will provide an overview of Achieve's late-stage cytisinicline program for smoking and vaping cessation, highlight key milestones, and discuss plans for the upcoming year.

To date, Achieve has successfully completed two Phase 3 clinical trials of cytisinicline in more than 1,600 subjects who smoke combustible cigarettes and one Phase 2 clinical trial for adults who vape nicotine e-cigarettes and desire to quit. Achieve expects to submit a New Drug Application (NDA) for cytisinicline as an aid to smoking cessation in the second quarter of 2025. Additionally, it expects to commence a single Phase 3 clinical trial of cytisinicline for nicotine e-cigarette or vaping cessation in the third quarter of 2025.

To schedule a one-on-one meeting with Achieve, please contact Investor Relations at ir@achievelifesciences.com.

About Achieve Life Sciences, Inc.

Achieve Life Sciences is a specialty pharmaceutical company committed to addressing the global smoking health and nicotine addiction epidemic through the development and commercialization of cytisinicline. The company has successfully completed two Phase 3 studies with cytisinicline for smoking cessation and one Phase 2 study with cytisinicline in vaping cessation. The company has fully enrolled its ongoing open-label safety study with cytisinicline and plans to submit its new drug application for smoking cessation in Q2 2025.

Achieve has conducted a successful end-of-Phase 2 meeting with the FDA for the vaping indication and expects to initiate its single Phase 3 clinical study in vaping later in 2025.

About Cytisinicline

There are approximately 29 million adults 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 over 11 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 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 for the treatment of nicotine addiction 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 regarding the timing and nature of cytisinicline clinical development and regulatory review and approval, the potential market size for cytisinicline, the potential benefits, efficacy, safety and tolerability of cytisinicline, 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, among others, the risk that cytisinicline may not demonstrate the hypothesized or expected benefits; the risk that Achieve may not be able to obtain additional financing to fund the development and commercialization of cytisinicline; the risk that cytisinicline will not receive regulatory approval or be successfully commercialized; the risk that new developments in the smoking cessation landscape require changes in business strategy or clinical development plans; the risk that Achieve’s intellectual property may not be adequately protected; general business and economic conditions; risks related to the impact on our business of macroeconomic and geopolitical conditions, including inflation, volatile interest rates, volatility in the debt and equity markets, actual or perceived instability in the global banking system, global health crises and pandemics and geopolitical conflict and the other factors described in the risk factors set forth in Achieve’s filings with the Securities and Exchange Commission from time to time, 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.

Achieve Contact

Nicole Jones

ir@achievelifesciences.com

425-686-1510

References

¹VanFrank B, Malarcher A, Cornelius ME, Schechter 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.

⁴Cornelius ME, Loretan CG, Jamal A, et al. Tobacco Product Use Among Adults – United States, 2021. MMWR Morb Mortal Wkly Rep 2023;72:475–483.

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