

October 23, 2024



## **Achieve Life Sciences President and CMO, Dr. Cindy Jacobs, Speaks at FDA and NIH Smoking Cessation Public Meeting**

SEATTLE and VANCOUVER, British Columbia, Oct. 23, 2024 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a late-stage pharmaceutical company dedicated to the global development and commercialization of cytisinicline for the treatment of nicotine dependence, announced that Dr. Cindy Jacobs, Achieve's President and Chief Medical Officer, presented at the U.S. Food and Drug Administration (FDA) and the National Institutes of Health (NIH) Joint Public Meeting on "Advancing Smoking Cessation: FDA and NIH Priorities" held on October 21, 2024.

The public meeting was initiated by Robert Califf, M.D., who currently serves as the 25th Commissioner of the FDA. The meeting included other representatives from the FDA, the NIH, the National Institute on Drug Abuse, and key academic and industry organizations with the stated focus of the meeting on accelerating innovation to advance treatments for smoking cessation.

"We are appreciative that the FDA and NIH are making an effort to bring together experts who share a common goal of reducing the number of lives lost every year due to smoking-related diseases," stated Dr. Jacobs. "It has been nearly two decades since a new prescription smoking cessation treatment has been approved by the FDA. Cytisinicline is currently the only nicotine dependence treatment in late-stage development. We have completed two randomized Phase 3 clinical trials in over 1,600 subjects demonstrating robust evidence supporting safety and efficacy, based on the gold-standard clinical endpoint of continuous smoking cessation. We are currently working to complete a longer-term safety exposure study in subjects and look forward to our continued engagement with the FDA as we move towards our NDA filing and potential approval."

Dr. Jacobs was one of 10 participants at the meeting selected to deliver a 4-minute presentation. In her presentation Dr. Jacobs reminded the attendees that cytisine has been a smoking cessation treatment for decades in Eastern and Central Europe. She also pointed out that although the efficacy and safety profile has been well-established for this older marketed product, the treatment involves a complex 25-day titration regimen. Dr. Jacobs highlighted Achieve's redevelopment of this drug into a novel treatment for nicotine

addiction, now known as cytisinicline. This new cytisinicline product features a revised formulation and tablet strength, easier streamlined dosing schedule, and extended treatment durations, demonstrating strong efficacy and excellent safety in the completed Phase 3 trials. In closing, Dr. Jacobs urged the FDA to re-assess how new drugs are being approved for smoking cessation treatment, especially given that no new prescription medications have been approved in nearly two decades, versus how other new nicotine or tobacco products are being approved in the US.

Full comments from the public meeting have been submitted to the public docket and are available at [www.regulations.gov/document/FDA-2024-N-4085-0001](https://www.regulations.gov/document/FDA-2024-N-4085-0001).

### **About Achieve and Cytisinicline**

Achieve's focus is to address the global smoking health and nicotine addiction epidemic through the development and commercialization of cytisinicline. There are approximately 29 million adults and 2.25 million middle and high school students in the United States alone who smoke combustible cigarettes.<sup>1,2</sup> 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.<sup>3,4</sup> 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.<sup>3</sup>

In addition, there are over 11 million adults in the United States who use e-cigarettes, also known as vaping.<sup>5</sup> In 2024, approximately 1.6 million middle and high school students in the United States reported using e-cigarettes.<sup>6</sup> Currently, there are no FDA-approved treatments indicated specifically as an aid to nicotine e-cigarette cessation.

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, data results and commercialization activities, the potential market size for cytisinicline, the potential benefits, efficacy, safety and tolerability of cytisinicline, the ability to discover and develop new uses for cytisinicline, including but not limited to as an e-cigarette cessation product, 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, 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.

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### **References**

<sup>1</sup>VanFrank 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.

<sup>2</sup>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

<sup>3</sup>World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization, 2017.

<sup>4</sup>U.S. Department of Health and Human Services. The Health Consequences of Smoking – 50 Years of Progress. A Report of the Surgeon General, 2014.

<sup>5</sup>Cornelius ME, Loretan CG, Jamal A, et al. Tobacco Product Use Among Adults – United States, 2021. MMWR Morb Mortal Wkly Rep 2023;72:475–483.

<sup>6</sup>Park-Lee E, Jamal A, Cowan H, et al. *Notes from the Field*: E-Cigarette and Nicotine Pouch Use Among Middle and High School Students — United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:774–778.



Source: Achieve Life Sciences