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Achieve Life Sciences Announces Submission of NDA to FDA for Cytisinicline as a Treatment of Nicotine Dependence for Smoking Cessation

Smoking, the leading cause of preventable death and disease, continues to affect nearly 29 million adults in the U.S. alone

If approved, cytisinicline will be the first new FDA-approved pharmacotherapy option for nicotine dependence in two decades

More than 2,000 clinical trial participants contributed to the body of evidence submitted in the NDA demonstrating cytisinicline's efficacy, safety, and tolerability profile

SEATTLE and VANCOUVER, British Columbia, June 26, 2025 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (NASDAQ: ACHV), a late-stage specialty pharmaceutical company focused on the global development and commercialization of cytisinicline for the treatment of nicotine dependence, today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for cytisinicline as a treatment of nicotine dependence for smoking cessation in adults.

"Submitting the cytisinicline NDA represents a decade of research and is a significant milestone toward delivering a new, evidence-based potential treatment for nicotine dependence, an urgent public health challenge with few effective options," stated Dr. Cindy Jacobs, President and Chief Medical Officer of Achieve Life Sciences. "Smoking-related illnesses claim the lives of nearly half a million people annually in the U.S. alone, and we are committed to making an impact. We look forward to collaborating closely with the FDA during the review process and remain hopeful about the potential of cytisinicline to make a meaningful difference for patients and healthcare providers who are seeking new treatment options."

The cytisinicline NDA is supported by a combination of efficacy and well-tolerated safety results from two large, placebo-controlled Phase 3 trials, ORCA-2 and ORCA-3, which evaluated cytisinicline for smoking cessation. In both studies, cytisinicline administered for

either 6 or 12 weeks, alongside standard behavioral support, demonstrated significantly greater abstinence rates by the end of treatment and in long-term abstinence through week 24 compared to placebo. The company has also included safety data on over 300 participants with at least six months of cumulative cytisinicline exposure from the open-label long-term trial, ORCA-OL, without any new safety concerns identified by the Data Safety Monitoring Committee.

“The Achieve NDA submission is a significant milestone in our mission to improve the health and well-being of adults who smoke, and to provide a new tool for healthcare providers to aid in the fight against nicotine dependence. The public health burden of smoking is substantial, impairing the lives of up to 29 million Americans who have few treatment options. It is a serious medical condition that has been proven to increase the risk of developing numerous comorbidities, including respiratory and cardiovascular diseases and multiple cancer types. Patients deserve a new medical solution to help address this unmet medical need,” said Rick Stewart, Chief Executive Officer of Achieve Life Sciences. “We would like to express our sincere gratitude to the ORCA Program clinical trial participants and healthcare providers, as well as to our dedicated Achieve team and all those who continue to support our mission to help people live better and healthier lives by overcoming the powerful grip of nicotine dependence.”

About Achieve Life Sciences, Inc.
Achieve Life Sciences is a late-stage specialty pharmaceutical company committed to addressing the global smoking health and nicotine dependence epidemic through the development and commercialization of cytisinicline. In June 2025, the company submitted its New Drug Application to the FDA for cytisinicline as a treatment of nicotine dependence for smoking cessation in adults, based on two successfully completed Phase 3 studies and its fully enrolled 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. Cytisinicline has been granted Breakthrough Therapy designation by the FDA 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 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 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 in a timely manner or at all, or be successfully commercialized; the risk that new developments in the smoking and vaping cessation landscapes 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 fluctuating inflation, interest and tariff 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 law.

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References

[1]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.

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

[3]U.S. Department of Health and Human Services. The Health Consequences of Smoking – 50 Years of Progress. A Report of the Surgeon General, 2014.

[4]Vahratian 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.

[5]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.

Source: Achieve Life Sciences