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Achieve Life Sciences Announces Publication in Thorax of Data Demonstrating Cytisinicline's Potential Efficacy and Tolerability for Smoking Cessation in Individuals with COPD

New data address critical treatment gap for millions of Americans with COPD who face unique smoking cessation challenges

SEATTLE and VANCOUVER, British Columbia, Sept. 22, 2025 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a late-stage specialty pharmaceutical company focused on the global development and commercialization of cytisinicline as treatment of nicotine dependence, today announced the publication of new data in *Thorax* demonstrating that cytisinicline significantly improved smoking quit rates compared to placebo in adults with and without chronic obstructive pulmonary disease (COPD).

The *Thorax* publication, entitled "Cytisinicline for smoking cessation in individuals with self-reported COPD: a post hoc analysis of the ORCA-2 and ORCA-3 trials," builds on data from over 1,600 participants in two large, randomized, placebo-controlled Phase 3 trials (ORCA-2 and ORCA-3). In this newly published post hoc analysis, researchers evaluated the efficacy and safety of cytisinicline in the subgroup of participants with self-reported COPD, a population at high risk from continued smoking and for whom effective, well-tolerated cessation therapies are urgently needed.

Dr. Judith Prochaska, lead author and Professor of Medicine at Stanford University, said, "COPD patients in our study smoked for many years and had high levels of nicotine addiction. Importantly, we found that cytisinicline significantly increased the odds of quitting for this high-risk group, with an excellent tolerability profile. If approved, cytisinicline would be a new treatment tool for providers in improving health outcomes for millions living with COPD."

Cytisinicline was associated with robust and statistically significant increases in continuous smoking abstinence compared to placebo for both COPD and non-COPD subgroups. Despite having more severe tobacco use histories and greater prior prescription treatment exposure, participants with COPD achieved quit rates with cytisinicline comparable to those without COPD, supporting cytisinicline as a potential new pharmacologic option for people with COPD who smoke. Importantly, cytisinicline demonstrated a favorable safety profile in both COPD and non-COPD subgroups, with no serious treatment-related adverse events and low rates of common side effects.

“These data highlight the meaningful addition cytisinicline could make for COPD patients who are seeking a safe and effective way to quit smoking,” added Dr. Mark Rubinstein, study co-author and Head of Medical Affairs at Achieve. “For physicians, these results provide much-needed evidence supporting a well-tolerated potential new treatment option for a specific sub-population that traditionally faces significant barriers to successful smoking cessation. This publication reinforces Achieve’s commitment to improving outcomes for patients and empowering healthcare providers with new tools in the fight against nicotine dependence.”

According to U.S. Centers for Disease Control and Prevention (CDC), nearly 16 million U.S. adults reported that they have been diagnosed with COPD. Among those diagnosed with COPD, 6 million reported they currently smoke cigarettes. Given that almost 80% of COPD deaths are attributed to smoking, quitting is the most effective way to prevent and improve outcomes in smokers with COPD. This underscores the need for new smoking cessation tools like cytisinicline.

Achieve recently announced that the FDA accepted its cytisinicline New Drug Application for treatment of nicotine dependence for smoking cessation, with a PDUFA target action date of June 20, 2026. Additionally, the company has completed a Phase 2 trial with cytisinicline in vaping cessation.

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 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. Cytisinicline has been granted Breakthrough Therapy designation by the FDA to address this critical need.

Cytisinicline is a plant-derived 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 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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Source: Achieve Life Sciences