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Achieve Announces Early Completion of Target Enrollment in Cytisinicline e-Cigarette Cessation Trial

Phase 2 ORCA-V1 Data Expected in 1H2023

SEATTLE, Wash and VANCOUVER, British Columbia, Nov. 08, 2022 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a late-stage clinical pharmaceutical company committed to the global development and commercialization of cytisinicline for nicotine dependence, today announced that target enrollment has been reached in the Phase 2 ORCA-V1 clinical trial.

ORCA-V1 is evaluating the efficacy and safety of cytisinicline in adult users of nicotine e-cigarettes or vapes. The study enrolled subjects who only used nicotine e-cigarettes, were not currently smoking combustible cigarettes, and who wanted to quit their vaping nicotine dependance. The randomized, placebo-controlled trial will treat 150 subjects in a 2:1 ratio to receive either cytisinicline, dosed at 3 mg three times daily (TID), or placebo, for a period of 12 weeks. Subjects were stratified by prior smoking history. All subjects are receiving standardized behavioral support throughout the trial. The primary outcome will be continuous vaping abstinence during the final 4 weeks of treatment. ORCA-V1 is being supported by the National Institute on Drug Abuse (NIDA) of the National Institutes of Health (NIH) through grant funding.

“The earlier-than-expected completion of enrollment in the ORCA-V1 trial further elucidates the critical need for treatment options specific for nicotine vape users who are interested in quitting,” stated John Bencich, Chief Executive Officer of Achieve. “In our previous trials, cytisinicline demonstrated a clear smoking cessation benefit compared to placebo and a very well tolerated safety profile, which we anticipate will apply to vaping cessation and treating nicotine dependence more broadly. We look forward to reporting topline results from ORCA-V1 in the first half of next year.”

Earlier this year Achieve announced positive, statistically significant results in its Phase 3 ORCA-2 clinical trial of cytisinicline in 810 adult smokers across 17 clinical trial locations in the United States. ORCA-2 evaluated the efficacy and safety of 3 mg of cytisinicline dosed

three times daily for either 6 or 12 weeks compared to placebo in adult smokers. Both the primary and secondary endpoints demonstrated increased quit rates, showing 6-8 times increased odds of smoking abstinence when compared to placebo. Cytisinicline was well tolerated with single-digit rates of adverse events observed and no treatment-related serious adverse events reported. Additionally, Achieve recently announced completion of enrollment for its confirmatory Phase 3 ORCA-3 smoking cessation trial. Topline data are expected in the first half of 2023.

For more information on cytisinicline or the ORCA-V1 trial, please visit www.achievelifesciences.com.

The planned research and clinical study discussed in this press release is supported by the National Institute on Drug Abuse (NIDA) of the National Institutes of Health (NIH) under Award Number 4R44DA054784-02. The content is the sole responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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. 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.[1,2] 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.[2]

In addition, there are nearly 11 million adults in the United States who use e-cigarettes, also known as vaping.[3] While nicotine e-cigarettes are thought to be less harmful than combustible cigarettes, they remain addictive and can deliver harmful chemicals which can cause lung injury or cardiovascular disease.[4] In 2021, e-cigarettes were the most commonly used tobacco product reported by 1.72 million high school students.[5] Research shows adolescents who have used e-cigarettes are seven times more likely to become smokers one year later compared to those who have never vaped.[6] 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 withdrawal symptoms, and reducing the reward and satisfaction associated with nicotine products. Cytisinicline is an investigational product candidate being developed for treatment of nicotine addiction and has not been approved by the Food and Drug Administration for any indication in the United States. For more information on cytisinicline and Achieve visit www.achievelifesciences.com.

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, data results and commercialization activities, the potential market size for cytisinicline, the potential benefits, 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, and the development and effectiveness of new treatments. 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 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 the COVID-19 pandemic or similar public health crises 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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