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# Achieve Life Sciences Announces Last Subject Last Visit Completed in Phase 3 ORCA-3 Trial of Cytisinicline for Smoking Cessation

## Topline Data Expected in 2Q 2023

SEATTLE, Wash. and VANCOUVER, British Columbia, March 29, 2023 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a late-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine dependence, today announced that the last study follow-up visit for the last subject enrolled in the Phase 3 ORCA-3 trial has occurred.

“We are pleased to have reached this final milestone in the Phase 3 ORCA-3 trial and continue to expect topline data results from this trial, as well as results from the ORCA-V1 trial of cytisinicline as a treatment for e-cigarette cessation, to be reported in the second quarter of this year,” commented John Bencich, Chief Executive Officer of Achieve.

The ORCA-3 trial randomized 792 subjects across 20 clinical locations in the United States. Similar to the Phase 3 ORCA-2 trial, participants received 3mg cytisinicline dosed 3 times daily for either 6 or 12 weeks and were monitored through 24 weeks post randomization. The trial is blinded, placebo-controlled, and all subjects received behavioral support for the duration of the trial. Biochemically verified continuous abstinence during the last four weeks of treatment is the trial’s primary endpoint. The trial will be determined to be successful if either or both of the cytisinicline treatment arms show a statistical benefit when compared independently to the placebo arm.

ORCA-3 is designed to enable U.S. Food and Drug Administration, or FDA, registration of cytisinicline for the treatment of smoking cessation. If approved, it would be the first, non-nicotine smoking cessation prescription treatment made available to smokers in the U.S. in nearly two decades.

For more information on cytisinicline or the ORCA-3 trial, please visit

www.achievelifesciences.com.

**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 over 9 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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