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Achieve Life Sciences Announces Initiation of ORCA-OL Clinical Trial Evaluating Long-Term Exposure of Cytisinicline in People who Smoke or Use Nicotine E-Cigarettes

The open-label trial is being conducted at 29 sites in the United States and will provide required longer-term safety data for the cytisinicline NDA submission, which is expected to occur in the first-half of 2025.

SEATTLE and VANCOUVER, British Columbia, May 29, 2024 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), or Achieve, a late-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine dependence, today announced it has initiated screening of subjects for the open-label ORCA-OL clinical trial. The trial is expected to provide long-term cytisinicline safety exposure data from subjects who currently smoke or use nicotine e-cigarettes and is required for submission of the cytisinicline New Drug Application, or NDA, and ultimately potential approval and marketing authorization in the United States.

ORCA-OL is designed to evaluate the long-term exposure of 3 mg cytisinicline treatment dosed three times daily in U.S. adults who want to quit smoking or vaping. Recruitment to the study is focused on engaging prior ORCA Phase 2 or Phase 3 trial participants, who have relapsed or continued to smoke or vape. Results of the trial are expected to meet the U.S. Food and Drug Administration, or FDA, requirement to provide safety data on a minimum of 300 subjects treated with cytisinicline for a cumulative period of six months as part of the anticipated NDA submission. Subsequently, data on at least 100 subjects treated for a total cumulative period of one year will be provided prior to potential product approval. ORCA-OL is being conducted at 29 clinical trial sites across the United States, all of which participated in previous ORCA-program clinical trials.

“We are excited to have initiated our final clinical requirement for the cytisinicline NDA and based on feedback to date, we expect the trial to enroll swiftly this year,” stated Cindy

Jacobs, PhD, MD, President and Chief Medical Officer of Achieve. “Our outreach to the more than 1,100 previous study participants has yielded great interest, with roughly two-thirds expressing eagerness to participate in the upcoming trial. There are about a quarter of prior participants who are not eligible because of their continued abstinence since trial completion, which is very encouraging.”

To date, Achieve has conducted two, highly successful randomized Phase 3 clinical trials evaluating cytisinicline for smoking cessation and a placebo-controlled randomized Phase 2 trial for adults who wish to quit nicotine e-cigarettes. All trials have demonstrated an excellent safety profile and statistically significant increases in likelihood to quit nicotine compared to placebo with behavioral support. There have been no new treatments approved by the FDA for smoking cessation in nearly two decades, and currently no treatments are specifically approved to meet the unique needs of people who vape and want to quit. Achieve is targeting the first half of 2025 for NDA submission in the United States. If approved, cytisinicline has the potential to help millions of people who are battling nicotine dependence.

For additional information on cytisinicline and the ORCA-OL study, 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. There are an estimated 28 million adults in the United States alone 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 over 11 million adults in the United States who use e-cigarettes, also known as vaping.[1] In 2023, approximately 2.1 million middle and high school students in the United States reported using e-cigarettes.[4] 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 the 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 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, 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 macroeconomic and geopolitical conditions, including inflation, rising interest rates, increased 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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Source: Achieve Life Sciences