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Achieve Life Sciences Announces Completion of Enrollment in ORCA-OL Clinical Trial & Successful Outcome of the First Data Safety Monitoring Committee Meeting

SEATTLE and VANCOUVER, British Columbia, Oct. 10, 2024 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a late-stage pharmaceutical company dedicated to the global development and commercialization of cytisinicline for the treatment of nicotine dependence, announced today an update on the ORCA-OL clinical trial, evaluating long-term exposure of the novel 3 mg cytisinicline treatment dosing regimen in individuals who smoke cigarettes or vape nicotine.

Enrollment for the ORCA-OL trial has been completed with an enrollment of 479 participants at 29 clinical trial sites across the United States. All clinical sites and participants were previously involved in Achieve's ORCA “Ongoing Research of Cytisinicline for Addiction” program for smoking and e-cigarette cessation studies, which is thought to have facilitated the rapid enrollment of this trial in just over four months. Achieve believes that the 479 participants enrolled will be sufficient to meet the safety information required by U.S. Food and Drug Administration (FDA).

Additionally, Achieve announced that the first Data Safety Monitoring Committee (DSMC) review for the ORCA-OL trial has been recently conducted. The DSMC concluded that there are no safety concerns, the overall safety profile appears to be excellent, and the study may proceed as planned with no modifications.

“We believe the rapid enrollment of this trial strongly reflects the urgent medical need for a new smoking cessation treatment and we are thrilled to have completed this critical milestone, bringing us one step closer to our planned filing of the cytisinicline NDA in the first half of 2025,” stated Cindy Jacobs, PhD, MD, President and Chief Medical Officer of Achieve. “We are also grateful to the DSMC members for their diligence and guidance as we continue to closely monitor the long-term use of cytisinicline with their oversight.”

The ORCA-OL clinical trial is designed to meet the 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 New Drug Application (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.

To date, Achieve has successfully completed two Phase 3 clinical trials of cytisinicline in more than 1,600 subjects who smoke combustible cigarettes and one Phase 2 clinical trial for adults who vape nicotine e-cigarettes and desire to quit. In July 2024, the FDA granted Breakthrough Therapy Designation to cytisinicline for the treatment of e-cigarette dependence. The Company expects to meet with the FDA in the coming weeks to finalize plans for further evaluation of the vaping cessation indication.

For more information on Achieve and cytisinicline, visit the Achieve website.

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 approximately 29 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.[4] In 2024, approximately 1.6 million middle and high school students in the United States reported using e-cigarettes.[5] 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 nicotine craving 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.

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, volatile interest 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.

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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]Cornelius ME, Loretan CG, Jamal A, et al. Tobacco Product Use Among Adults – United States, 2021. MMWR Morb Mortal Wkly Rep 2023;72:475–483.

[5] Park-Lee E, Jamal A, Cowan H, et al. *Notes from the Field:* E-Cigarette and Nicotine Pouch Use Among Middle and High School Students — United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:774–778

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