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

SEATTLE, Wash and VANCOUVER, British Columbia, Jan. 09, 2023 (GLOBE NEWSWIRE)

-- Achieve Life Sciences, Inc. (NASDAQ: ACHV), a late-stage clinical pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine dependence, today announced that the final subject of the Company's Phase 3 ORCA-3 trial has completed treatment in the study. Similar to the previously reported [ORCA-2 trial](#), ORCA-3 is evaluating the smoking cessation efficacy, safety, and tolerability of 3 mg cytisinicline dosed three times daily for either 6 or 12 weeks compared with placebo.

"With the milestone achieved of last ORCA-3 subject completing study treatment, we are pleased to remain on schedule for announcing data results as expected in the second quarter," stated John Bencich, Chief Executive Officer of Achieve. "It will be a busy and exciting year ahead with the completion of both ORCA-3 and ORCA-V1, evaluating cytisinicline for e-cigarette cessation, and the preparation for FDA filing in the U.S., which is already underway."

The ORCA-3 trial randomized 792 subjects in total across 20 clinical trial locations in the United States. Participants are being monitored through 24 weeks post randomization and will receive standard behavioral support for the duration of the trial. The ORCA-3 primary endpoint is biochemically verified continuous abstinence during the last four weeks of treatment. Each treatment arm will be compared independently to the placebo arm and the trial will be determined to be successful if either or both of the cytisinicline treatment arms show a statistical benefit compared to placebo.

ORCA-3 is designed to enable U.S. Food and Drug Administration, or FDA, registration of cytisinicline, and if approved, would be the first non-nicotine smoking cessation prescription treatment made available to American smokers 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 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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References

¹World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization, 2017.

²U.S. Department of Health and Human Services. The Health Consequences of Smoking – 50 Years of Progress. A Report of the Surgeon General, 2014.

³Cornelius ME, Wang TW, Jamal A, Loretan CG, Neff LJ. Tobacco Product Use Among Adults — United States, 2019. MMWR Morb Mortal Wkly Rep 2020;69:1736–1742. DOI: 10.15585/mmwr.mm6946a4

⁴Ogunwale, Mumiye A et al. (2017) Aldehyde Detection in Electronic Cigarette Aerosols. ACS omega 2(3): 1207-1214. DOI: 10.1021/acsomega.6b00489].

⁵Gentzke AS, Wang TW, Cornelius M, et al. Tobacco Product Use and Associated Factors Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021. MMWR Surveill Summ 2022;71(no. SS-5):1-29. DOI: 10.15585/mmwr.ss7105a1.

⁶Elizabeth C. Hair, Alexis A. Barton, Siobhan N. Perks, Jennifer Kreslake, Haijun Xiao, Lindsay Pitzer, Adam M. Leventhal, Donna M. Vallone, Association between e-cigarette use and future combustible cigarette use: Evidence from a prospective cohort of youth and young adults, 2017–2019, Addictive Behaviors, Volume 112, 2021, 106593, ISSN 0306-4603. DOI: 10.1016/j.addbeh.2020.106593.



Source: Achieve Life Sciences