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Achieve Life Sciences Announces Presentation of the Phase 3 ORCA-2 Trial of Cytisinicline at Society for Research on Nicotine and Tobacco (SRNT) Annual Meeting

SEATTLE, Wash. and VANCOUVER, British Columbia, March 03, 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, announced data from the Phase 3 ORCA-2 trial will be presented at the Society for Research on Nicotine and Tobacco (SRNT) Annual Meeting, being held in San Antonio, TX, March 1-4, 2023.

Additional findings from the ORCA-2 trial, that evaluated cytisinicline as a treatment for smoking cessation, will be included in the “Novel Treatments for Smoking Cessation” session held today, March 3, 2023, at 3:15 p.m. CST. The presentation will be given by ORCA-2 Principal Investigator, Dr. Nancy Rigotti, Professor of Medicine at Harvard Medical School and Director, Tobacco Research and Treatment Center, Massachusetts General Hospital.

Positive topline results from the [ORCA-2](#) trial were reported in April 2022, demonstrating 6-8 times increased likelihood of smoking abstinence with 3mg cytisinicline dosed 3 times daily for a period of 6-weeks or 12-weeks compared to placebo in 810 adult U.S. smokers. The study population was approximately 52 years in age, smoked a pack of cigarettes a day, and had made 5 to 6 prior quit attempts.

Additional analyses being reported today confirm that successful abstinence was observed in subgroups of smokers who received cytisinicline, regardless of age, gender, smoking history, or previous quit attempts. Subjects who received either 6 or 12-weeks of cytisinicline treatment experienced consistently higher rates of abstinence. The improvement was observed by the second week of treatment, maintained weekly throughout study treatment and during the 24- week follow-up period, compared to those who received placebo. Study

compliance was high with 82% of subjects completing the 12 weeks of treatment. No treatment-related serious adverse events were reported and the majority of adverse events were mild in all subjects.

Dr. Cindy Jacobs, Achieve Chief Medical Officer and President commented, “The ORCA-2 population represents a vast majority of smokers in the real world who remain heavy smokers, want to quit smoking, and have made multiple, unsuccessful quit attempts utilizing various methods. The ability of cytisinicline to improve the likelihood of quitting, regardless of prior treatments and level of nicotine dependence, will be critical for increased adoption and future prescribing, if ultimately approved by the FDA.”

Achieve is currently conducting the final FDA-registration enabling Phase 3 ORCA-3 trial for smoking cessation and the Phase 2 ORCA-V1 trial evaluating cytisinicline for e-cigarette cessation. The Company continues to expect topline data results for both trials to be announced in the second quarter of 2023. For more information on cytisinicline and Achieve visit www.achievelifesciences.com. To learn more about SRNT or the SRNT Annual Meeting, please visit www.srnt.org.

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.

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, Loretan CG, Wang TW, Jamal A, Homa DM. Tobacco Product Use Among Adults — United States, 2020. *MMWR Morb Mortal Wkly Rep* 2022;71:397–405.

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