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Achieve Life Sciences Announces Data from Cytisinicline ORCA Program to be Presented at the 2024 Society for Research on Nicotine and Tobacco (SRNT) Annual Meeting

SEATTLE and VANCOUVER, British Columbia, March 20, 2024 (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 three oral presentations featuring data from both of the Phase 3 ORCA-2 and ORCA-3 clinical trials of cytisinicline for smoking cessation and from the Phase 2 ORCA-V1 trial for e-cigarette cessation will be presented at the Society for Research on Nicotine and Tobacco (SRNT) Annual Meeting, being held in Edinburgh, Scotland, March 20–23, 2024.

Presentation Schedule and Highlights

- March 21, 2024, 11:30 AM GMT: Achieve's Director of Clinical Operations, Roxann Becco, will present patient-reported outcomes from the Phase 3 ORCA-2 and ORCA-3 clinical trials. Data collected include trial participants' experiences, such as cravings and withdrawal symptoms, personal impact on overall health, and opinions on future use.

- March 22, 2024, 8:30 AM GMT: Achieve's Chief Medical Officer and President, Dr. Cindy Jacobs, will present data from the second, completed Phase 3 ORCA-3 trial that evaluated the efficacy and safety of cytisinicline in 792 adult smokers in the United States. Findings confirmed results from the previous Phase 3 ORCA-2 trial demonstrating that cytisinicline, when dosed at the 3mg, three times daily schedule for either 6 or 12 weeks, increased smoking abstinence when compared with placebo and was very well-tolerated with no treatment-related serious adverse events reported.

- March 23, 2024, 9:45 AM GMT: Dr. Nancy Rigotti, ORCA-V1 Principal Investigator and Professor of Medicine at Harvard Medical School and Director of Tobacco Research and Treatment Center, Massachusetts General Hospital, will present data from the Phase 2 ORCA-V1 trial. ORCA-V1 evaluated the effectiveness and safety of cytisinicline in users of nicotine e-cigarettes who wanted to quit vaping. Similar to the efficacy and tolerability findings observed in the combustible cigarette cessation Phase 3 trials, ORCA-V1 participants who received cytisinicline had increased successful vaping cessation rates, compared with placebo, and reported minimal rates of adverse events.

“We are appreciative of this opportunity at the SRNT Annual Meeting to share multiple data presentations that reflect the promising results we have seen in the cytisinicline ORCA program for both smoking and vaping cessation,” stated Dr. Cindy Jacobs, Achieve Chief Medical Officer. “New solutions to help the millions of people who struggle with nicotine dependence are long overdue, and we believe cytisinicline will be an important new option for those who want to quit nicotine whether they are smoking or vaping.”

For additional information on the cytisinicline presentations and the Society for Research on Nicotine and Tobacco (SRNT) Annual Meeting please visit Achieve or SRNT Annual Meeting.

ORCA-V1 is supported by the National Institute on Drug Abuse of the National Institutes of Health (NIH) under Award Number 4R44DA054784-02. The content is the sole responsibility of the authors and does not necessarily represent the official views of the NIH.

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.[3] 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 conditions, including inflation, rising interest rates, instability in the global banking sector, and public health crises, such as the COVID-19 pandemic, 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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[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]Birdsey J, Cornelius M, Jamal A, et al. Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023. MMWR Morb Mortal Wkly Rep 2023;72:1173–1182.

Source: Achieve Life Sciences