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Achieve Life Sciences Announces Presentation of Cytisinicline E-Cigarette Cessation (ORCA-V1) Results at Society for Research on Nicotine and Tobacco Europe (SRNT-E) Annual Meeting

SEATTLE and VANCOUVER, British Columbia, Sept. 11, 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 Phase 2 ORCA-V1 trial results will be presented at the Society for Research on Nicotine and Tobacco Europe (SRNT-E) Annual Meeting, being held in London September 11–13, 2023.

Data from the ORCA-V1 trial, which evaluated cytisinicline as a treatment for e-cigarette cessation, will be presented today, September 11, 2023, by ORCA-V1 Principal Investigator, Dr. Nancy Rigotti, Professor of Medicine at Harvard Medical School and Director, Tobacco Research and Treatment Center, Massachusetts General Hospital.

The positive topline results from the ORCA-V1 trial, announced earlier this year, will be presented, as well as additional findings. The primary endpoint analysis demonstrated 2.6 times higher odds, or likelihood, of vaping cessation with 3mg cytisinicline dosed three times daily for a period of 12 weeks compared to placebo in 160 adults in the U.S. who use nicotine vapes daily ($p = 0.035$). The study population had a mean age of 34 years, 72% had been previous smokers, and a majority vaped e-cigarettes with fruit flavoring.

Additional analyses showed that vaping abstinence with cytisinicline treatment started by the second week of treatment, with the odds of vaping cessation improving throughout the 12-week treatment period. The odds of vaping cessation for cytisinicline were 1.8 times, 2.2 times, and 2.6 times higher than placebo at Week 3-6, Week 6-9, and Week 9-12, respectively. During the Week 12-16 follow-up period, subjects treated with cytisinicline continued to demonstrate 2.0 times higher odds of vaping cessation compared to placebo.

Similar to previous trials conducted in smoking cessation, cytisinicline treatment was well tolerated with only insomnia and abnormal dreams trending higher when compared to placebo, while rates of nausea and headache were lower for the 12-week cytisinicline treatment arm than observed in the placebo arm.

“Vaping continues to be a rapidly growing public health epidemic with more than 11 million adults in the U.S. alone who have reported use of e-cigarettes,” commented John Bencich, CEO of Achieve. “The results from ORCA-V1 provide strong evidence of the potential role of cytisinicline to address nicotine dependence more broadly and, if approved by the FDA, may provide a new treatment option to the millions of people who want to quit smoking and e-cigarette use.”

For additional information on the SRNT Annual Meeting, please visit www.srnt-e.org.

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About ORCA-V1

The Phase 2 ORCA-V1 trial evaluated 160 adults who used e-cigarettes on a daily basis at 5 clinical trial locations in the United States. The trial was initiated in June 2022 and completed enrollment in approximately 4 months, with topline results reported in April 2023. ORCA-V1 participants were randomized to receive 3mg cytisinicline three times daily or placebo for 12 weeks in combination with standard cessation behavioral support. The dose and administration of cytisinicline in the ORCA-V1 study is identical to that used in the Phase 3 registrational trials for smoking cessation. ORCA-V1 was supported by the National Institute on Drug Abuse (NIDA) of the National Institutes of Health (NIH) through grant funding which was awarded in two phases totaling $2.8 million.

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 2022, approximately 2.5 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, 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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Source: Achieve Life Sciences