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Achieve Life Sciences Announces Data from Cytisinicline ORCA-V1 Program to be Presented at Society of General Internal Medicine (SGIM) Annual Meeting

SEATTLE and VANCOUVER, British Columbia, May 17, 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 data from the Phase 2 ORCA-V1 vaping cessation trial will be presented today, Friday, May 17, 2024, at the Society of General Internal Medicine (SGIM) Annual Meeting being held in Boston, MA.

Dr. Nancy Rigotti, ORCA-V1 Principal Investigator and Professor of Medicine at Harvard Medical School, and Director of the Tobacco Research and Treatment Center at Massachusetts General Hospital, will present data from the Phase 2 ORCA-V1 trial. This study explored the efficacy and safety of cytisinicline in adult smokers seeking to quit nicotine e-cigarettes. In the study, treatment with cytisinicline more than doubled the likelihood of quitting compared to placebo.

“We are honored to have the ORCA-V1 findings presented at the SGIM Annual Meeting as we believe this audience of healthcare providers plays a vital role in helping people who battle with nicotine dependence in its various forms,” stated Cindy Jacobs, MD, PhD, President and Chief Medical Officer at Achieve Life Sciences. “Cytisinicline has shown promising data in aiding smoking cessation, has been well tolerated, and we believe it will be key in helping people quit vaping as well.”

Dr. Rigotti’s presentation will be included in the “SAN2: Scientific Abstract Oral Presentations in Mental/Behavioral Health and Substance Use” session today, Friday, May 17, at 2:45 PM EDT.

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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. ORCA-V1 participants were randomized to receive 3 mg 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.[1] 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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Source: Achieve Life Sciences