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Achieve Life Sciences Announces FDA Acceptance of IND Application for Cytisinicline's Second Planned Indication for Nicotine E-cigarette Cessation

SEATTLE, Wash and VANCOUVER, British Columbia, Nov. 02, 2021 (GLOBE NEWSWIRE) -- -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine addiction, today announced that the U.S. Food and Drug Administration (FDA) has completed its review and accepted an Investigational New Drug (IND) application to investigate cytisinicline as a cessation treatment for nicotine e-cigarette users. There are currently no FDA-approved treatment options indicated to assist in e-cigarette cessation. In addition to the ongoing Phase 3 program for cytisinicline treatment in combustible cigarette cessation, the company expects to initiate the ORCA-V1 e-cigarette and vape cessation trial in the second quarter of 2022.

The Phase 2 ORCA-V1 study will enroll approximately 150 adult nicotine e-cigarette users in the U.S. and will be led by Dr. Nancy Rigotti, Professor of Medicine at Harvard Medical School and Director, Tobacco Research and Treatment Center, Massachusetts General Hospital and Dr. Cindy Jacobs, President and Chief Medical Officer of Achieve. Grant funding to support the trial has been awarded in two phases from the National Institute on Drug Abuse (NIDA) of the National Institutes of Health (NIH). Completion of required milestones for the first phase of grant funding included the submission of the IND and clearance to proceed with the clinical trial by FDA.

"We are pleased to have reached this critical milestone allowing us to proceed with our clinical development efforts to evaluate the role of cytisinicline across a broader patient population," stated Cindy Jacobs, President and Chief Medical Officer of Achieve. "There is a significant unmet need for cessation options in a growing number of e-cigarette users who seek to quit and we believe cytisinicline has the potential to play a key role in their success."

The use of e-cigarettes continues to be widespread, with most recent reports from the Centers for Disease Control and Prevention indicating that there were nearly 11 million adult users in the United States alone in 2019. While e-cigarettes have been historically viewed as

less harmful than combustible cigarettes, their long-term safety remains controversial. In a recent study conducted by Achieve, where approximately 500 users of nicotine vaping devices or e-cigarettes were surveyed, approximately 73% of participants responded that they intend to quit vaping within the next 3 to 12 months. Of those who intended to quit even sooner, within the next 3 months, more than half stated they would be extremely likely to try a new prescription product to help them do so.

Achieve recently announced completion of enrollment in the Phase 3 ORCA-2 clinical trial, evaluating cytisinicline as a treatment for combustible cigarette cessation. Topline results from the ORCA-2 trial are expected in the first half of 2022.

The planned research and clinical study discussed in this press release is supported by the National Institute on Drug Abuse (NIDA) of the National Institutes of Health (NIH) under Award Number R42DA054784. The content is the sole responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

About Achieve and 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] Achieve's focus is to address the global smoking health and nicotine addiction epidemic through the development and commercialization of cytisinicline.

Cytisinicline is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is believed to aid in smoking cessation by interacting with nicotine receptors in the brain by reducing the severity of nicotine withdrawal symptoms and by reducing the reward and satisfaction associated with smoking.

Cytisinicline is an investigational product candidate being developed for treatment of nicotine addiction and has not been approved by the FDA for any indication in the United States. Achieve recently announced completion of enrollment in the Phase 3 ORCA-2 trial, evaluating cytisinicline for combustible cigarette cessation. Topline results from the ORCA-2 trial are expected in the first half of 2022. For more information on Achieve Life Sciences and cytisinicline please 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 activities, the timing and proposed use of grant awards, the potential market size and market acceptance for cytisinicline, the potential benefits of cytisinicline 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; 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 law.

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

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

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Source: Achieve Life Sciences