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Achieve Life Sciences Awarded Grant from the National Institutes of Health to Conduct Phase 2 Trial of Cytisinicline in Nicotine e-cigarette Users

Company awarded $2.5 million to enable initiation of the Phase 2 ORCA-V1 clinical trial

SEATTLE and VANCOUVER, British Columbia, June 01, 2022 (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 addiction, today announced that it has been awarded $2.5 million in grant funding from the National Institute on Drug Abuse (NIDA) of the National Institutes of Health (NIH) to evaluate the use of cytisinicline as a treatment for cessation of nicotine e-cigarette use.

This grant award will provide funding that enables Achieve to initiate the Phase 2 ORCA-V1 clinical trial, which aims to evaluate the efficacy and safety of cytisinicline in approximately 150 adult nicotine e-cigarette users at 5 clinical trial locations in the United States. Dr. Nancy Rigotti, Professor of Medicine at Harvard Medical School and Director of the Tobacco Research and Treatment Center at Massachusetts General Hospital, will be the Principal Investigator of the trial.

“We are grateful for the continued partnership with the NIH that has provided Achieve with non-dilutive funding that allows us to proceed with ORCA-V1 trial initiation in the coming weeks,” commented John Bencich, Chief Executive Officer of Achieve. “Cytisinicline’s efficacy and tolerability observed in clinical trials to date demonstrates its potential to help nicotine-dependent people overcome their addiction. With more than 10 million users of nicotine e-cigarettes in the United States alone, and no FDA-approved treatments available specifically for this indication, we believe cytisinicline has the ability to help meet the needs of this growing and underserved population.”

In July 2021, an initial grant award of $320,000 was provided to Achieve to complete critical regulatory and clinical operational activities, including submission of a new IND to FDA for investigating cytisinicline in nicotine e-cigarette users. In total, $2.8 million has now been awarded under both the initial and current grant awards from the NIH and is expected to cover approximately half of the ORCA-V1 trial costs.

The use of e-cigarettes continues to be widespread, with the 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. In a survey conducted by Achieve of 508 users of nicotine vaping devices or e-cigarettes, 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.

In addition to the upcoming ORCA-V1 trial evaluating cytisinicline in nicotine e-cigarette users, Achieve is evaluating smoking cessation of combustible cigarettes in its Phase 3 clinical development program. The ORCA-2 clinical trial, comprised of 810 adult smokers, recently reported positive topline results. Smokers who received cytisinicline in ORCA-2 were up to 8 times more likely to have quit smoking compared to those who received placebo. The ORCA-3 trial, the intended confirmatory Phase 3 trial required for regulatory submission of cytisinicline, is currently enrolling smokers at 15 clinical trial locations in the United States. For additional information on Achieve or the cytisinicline development program, visit achievelifesciences.com or orcaprogram.com.

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 4R44DA054784-02. 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

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 nearly 11 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]

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. 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, 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, the development and effectiveness of new treatments, and the intention to submit cytisinicline to the FDA for approval. 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 Russian military action in Ukraine; 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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