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Achieve Life Sciences Announces Phase 3 ORCA-2 Trial of Cytisinicline in Smoking Cessation Clears Final Review by Data Safety Monitoring Committee (DSMC)

Following the fifth and final DSMC review, committee has concluded no concerns with cytisinicline safety or Phase 3 trial conduct

SEATTLE, Wash and VANCOUVER, British Columbia, Nov. 22, 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 the completion of the fifth and final Data Safety Monitoring Committee (DSMC) review for its Phase 3 ORCA-2 smoking cessation trial of cytisinicline.

The DSMC concluded that there are no concerns regarding the Phase 3 study conduct and the safety and adverse event profile remains favorable. Additionally, the DSMC members commented that compliance with study medication was excellent and the study has progressed well despite the challenges of the COVID-19 pandemic.

The ORCA-2 trial is designed to evaluate the smoking cessation effectiveness, safety, and tolerability of 3 mg cytisinicline taken three times daily (TID) for either 6 or 12 weeks, compared with placebo. Subjects in the trial have completed study treatment and continue to receive standard behavioral support while completing follow-up assessments through 24 weeks post randomization. Fully enrolled this July, 810 participants were randomized across the 17 clinical sites in the United States. Preliminary data is expected in the first half of 2022.

“We are grateful to the DSMC members for their diligence and guidance during these reviews and are very pleased with the outcome,” commented Cindy Jacobs, President and Chief Medical Officer of Achieve. “The successful safety reviews during this ORCA-2 study are important for cytisinicline, as we believe the potential safety and tolerability of cytisinicline will be a key differentiator to existing treatments. We look forward to announcing ORCA-2 topline results in the first half of 2022.”

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 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 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, 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 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.

References

[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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