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Achieve Life Sciences Announces Initiation of the Phase 3 ORCA-3 Clinical Trial Evaluating Cytisinicline for Smoking Cessation

SEATTLE and VANCOUVER, British Columbia, Jan. 25, 2022 (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 it has initiated screening of ORCA-3, the confirmatory Phase 3 trial required for registrational approval of cytisinicline in the United States. ORCA-3 will evaluate the efficacy and safety of 3 mg cytisinicline dosed 3 times daily compared to placebo in 750 adult smokers at 15 clinical sites.

Similar to the first registrational Phase 3 ORCA-2 trial, ORCA-3 participants will be randomized to one of three study arms to evaluate cytisinicline administered for either 6 or 12 weeks, compared to placebo. All subjects will receive standard behavioral support and will be assigned to one of the following groups:

- Arm A: 12 weeks of placebo
- Arm B: 6 weeks of cytisinicline, followed by 6 weeks of placebo
- Arm C: 12 weeks of cytisinicline

The primary outcome measure of success in the ORCA-3 trial is biochemically verified continuous abstinence during the last four weeks of treatment in the 6 and 12-week cytisinicline treatment arms compared with placebo. Each treatment arm will be compared independently to the placebo arm, and the trial will be determined to be successful if either or both of the cytisinicline treatment arms show a statistical benefit compared to placebo. Secondary outcome measures will be conducted to assess continued abstinence rates through 6 months from the start of study treatment.

“With the kickoff of the ORCA-3 trial, upcoming topline data results from ORCA-2, and the anticipated initiation of the ORCA-V1 e-cigarette cessation trial, we believe 2022 will be a pivotal year for Achieve,” stated John Bencich, Chief Executive Officer of Achieve. “We are

grateful for the ORCA-3 investigators and the trial's future participants who are committed to quitting smoking in the New Year."

Achieve recently announced completion of the last subject visit in the ongoing Phase 3 ORCA-2 trial, with topline data results expected in the second quarter of 2022. Additionally, the grant-funded Phase 2 ORCA-V1 study, which is expected to investigate the efficacy of cytisinicline in approximately 150 adult nicotine e-cigarette users, is anticipated to initiate by the end of the second quarter of 2022, subject to grant funding timelines.

For additional information on cytisinicline and the ORCA-3 trial, visit achievelifesciences.com or orcaprogram.com.

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, 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, 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.

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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.



Source: Achieve Life Sciences