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Achieve Announces Publication of the ORCA-1 Phase 2b Clinical Trial of Cytisinicline in Adult Smokers in Nicotine and Tobacco Research

Cytisinicline Up to Five Times More Likely to Result in Smoking Abstinence Compared to Placebo

Phase 3 ORCA-2 Trial Currently Enrolling at 16 sites in United States

SEATTLE, WA and VANCOUVER, BC / ACCESSWIRE / April 14, 2021 / 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 publication of the results from the Phase 2b ORCA-1 trial in the scientific journal *Nicotine and Tobacco Research*.

ORCA-1 evaluated the efficacy and safety of cytisinicline across various dosing and administration schedules in 254 smokers in the United States. The published results indicate that subjects treated with cytisinicline, regardless of dose or schedule, had statistically significantly higher ($p < 0.001$) end of treatment abstinence rates compared to those treated with placebo. Participants in the 3.0 mg cytisinicline 3 times daily (TID) arm, were 5-times more likely to quit smoking than those in the placebo arm (OR of 5.04, 95% CI: 1.42, 22.32, $p < 0.001$).

Cytisinicline was well-tolerated with no serious or severe adverse events (AEs) reported. Overall, in subjects treated with cytisinicline, all individual AE's reported were below a rate of 10%. In the 3.0 mg TID treatment arm versus placebo, the most common AEs were abnormal dreams, insomnia, and constipation (each 6% vs 2%), upper respiratory tract infections (6% vs 14%), and nausea (6% vs 10%). Adherence to study treatment was greater than 94% across all treatment arms and 98% in the 3.0 mg TID arm, specifically.

"As demonstrated in ORCA-1, cytisinicline is an efficacious and tolerable smoking cessation treatment that, when available, will be well-received by physicians and smokers who desperately need new cessation options," stated Dr. Mitch Nides, ORCA-1 Primary

Investigator. "The ongoing Phase 3 ORCA-2 trial is enrolling rapidly, and I would encourage those who are interested in quitting and who are near a trial location to consider participating."

Healthcare providers, smokers, and their loved ones can learn more about how smokers can participate in the Phase 3 ORCA-2 trial by visiting www.orca-2.com.

About ORCA-1

ORCA-1 was the first study in Achieve's ORCA (Ongoing Research of Cytisinicline for Addiction) Program, which aims to evaluate the safety and effectiveness of cytisinicline for smoking cessation, nicotine addiction, and potentially other indications. The study was designed to evaluate the declining titration schedule, currently utilized in Central and Eastern Europe, compared to a simplified TID schedule at both the 1.5 mg and 3.0 mg cytisinicline doses compared to placebo. ORCA-1 topline results were announced in June 2019 and enrolled 254 smokers at eight centers across the United States.

To access the ORCA-1 publication, visit <https://academic.oup.com/ntr/advance-article/doi/10.1093/ntr/ntab073/6224724?searchresult=1>.

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 U.S. 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 U.S. Achieve is currently enrolling smokers in the 750-subject, Phase 3 ORCA-2 study of cytisinicline at 16 sites in the U.S. For more information on cytisinicline and the ORCA-2 study, visit www.achievelifesciences.com or www.orca-2.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 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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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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