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Achieve Announces Completion of Target Enrollment of 750 Subjects in Phase 3 ORCA-2 Smoking Cessation Trial of Cytisinicline

ORCA-2 Designed to Assess the Efficacy and Safety of 3 mg Cytisinicline Three Times Daily Dosing Compared to Placebo in Adult Smokers in the United States

SEATTLE, WA and VANCOUVER, BC / ACCESSWIRE / June 29, 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 that the Phase 3 ORCA-2 trial of cytisinicline has reached its enrollment target of 750 adult smokers. The ORCA-2 trial sites are no longer enrolling new subjects, however those currently in screening will be allowed to participate provided they meet entry criteria.

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 and will be compared with placebo. Subjects in the trial will be monitored through 24 weeks post randomization and will receive standard behavioral support for the duration of the trial. More than 750 participants have been randomized across the 17 clinical sites in the United States.

"There remain more than 50 million Americans addicted to some form of tobacco, including over 34 million cigarette smokers in the United States alone and completion of ORCA-2 enrollment is a critical milestone in advancing cytisinicline, a potential new treatment that could make a major impact on the global public health smoking epidemic," stated John Bencich, Chief Executive Officer of Achieve. "We extend our gratitude to the participants in the ORCA-2 trial and wish them much success in their quitting journey, as well as to our clinical trial sites for all of their hard work."

Topline ORCA-2 data results are expected to be reported within the first half of 2022. The primary outcome measure of success in the ORCA-2 trial is biochemically verified continuous abstinence during the last four weeks of treatment in either the 6 or 12-week cytisinicline treatment arms as compared with placebo. Each treatment arm will be

compared independently to the placebo arm, and the trial will be declared successful if either or both cytisinicline treatment arms show a statistical benefit as compared with placebo. Secondary outcome measures include continued abstinence rates to 6 months after study randomization. Previously, in the Phase 2b ORCA-1 trial of 254 smokers, subjects treated with the 3 mg TID treatment arm of cytisinicline 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).

For more information on cytisinicline or the ORCA-2 trial, please visit www.achievelifesciences.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 drug product being developed for treatment of nicotine addiction and has not been approved by the FDA for any indication in the United States. For more information on cytisinicline and the ORCA-2 study, 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 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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