October 7, 2020

Achieve Life Sciences Announces Start of Phase 3 ORCA-2 Clinical Trial Evaluating Cytisinicline for Smoking Cessation

Designed to Assess the Efficacy and Safety of 3 mg Cytisinicline Three Times Daily Dosing Compared to Placebo

Phase 3 ORCA-2 Trial to Enroll 750 Smokers Across 15 Clinical Trial Sites in the United States

SEATTLE and VANCOUVER, B.C., Oct. 7, 2020 /PRNewswire/ -- 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 initiation of the Phase 3 ORCA-2 clinical trial. ORCA-2 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 in the United States.

"We are very excited to be participating in this important trial that will hopefully lead to a widely available new treatment option for smokers in the U.S. and around the globe," commented Nancy Rigotti, MD, Massachusetts General Hospital, Professor of Medicine at Harvard Medical School, and Primary Investigator of the ORCA-2 trial. "Smoking remains the number one cause of preventable death and we clearly need new options to help people who smoke avoid the enormous toll of illness and death attributable to cigarette smoking."

ORCA-2 participants will be randomized to one of three study arms to determine the smoking cessation efficacy and safety profile of 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-2 trial is biochemically verified continuous abstinence during the last four weeks of treatment in the 6 and 12-week cytisinicline treatment arms compared to 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.

"We are optimistic that the ORCA-2 trial will add to the growing body of evidence demonstrating that cytisinicline, if approved, can be an effective and well-tolerated treatment for smokers who want to quit," stated John Bencich, Chief Executive Officer of Achieve. "Importantly, based on the findings of ORCA-1 and modifications to the cytisinicline treatment regimen, including a longer duration of treatment and a higher dose, we believe

ORCA-2 results may yield an improvement in quit rates compared to previously reported data."

For additional information on cytisinicline and the ORCA-2 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 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.

As an approved, branded product in Central and Eastern Europe for more than two decades, it is estimated that over 20 million people have used cytisinicline to help combat nicotine addiction.

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, the timing and nature of cytisinicline clinical development activities, the potential market size for cytisinicline and the effectiveness and potential uses and benefits of cytisinicline. 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 cytisinicline may not be effective in treating a larger breadth of diseases and addictions; 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; impacts from the COVID-19 pandemic; 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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[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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