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Achieve Life Sciences Announces Presentation of Additional Cytisinicline Analyses at the Society for Research on Nicotine & Tobacco (SRNT) Annual Meeting

SEATTLE and VANCOUVER, British Columbia, March 12, 2020 /CNW/ -- 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, announced that additional analyses from the ORCA-1 Phase 2b trial will be presented today, Thursday, March 12th, at the SRNT Annual Meeting in New Orleans.

Previously reported data from the ORCA-1 trial of 254 smokers demonstrated significant quit rates in all cytisinicline-treated subjects compared to placebo, particularly in the 3.0 mg cytisinicline-treated three times daily (TID) arm. Smokers who received 3.0 mg cytisinicline dosed TID over 25 days demonstrated a 54% abstinence rate at week 4 compared to 16% for placebo ($p < 0.0001$). A 4-week continuous abstinence rate, weeks 5 through 8, of 30% for cytisinicline was also observed compared to 8% for placebo ($p= 0.005$).

New analyses from the ORCA-1 trial indicate that the cytisinicline benefit, abstinence and reduction in number of cigarettes smoked, was consistently observed across all demographics, smoking history, and clinical trial locations. Additionally, clinical benefit was observed with cytisinicline regardless of prior smoking cessation treatments utilized, including Chantix® (varenicline), Zyban® (bupropion), or Nicotine Replacement Therapy (NRT). Smokers in the ORCA-1 trial had an average smoking history of 32.1 years, smoked 18 cigarettes per day, and had 4.5 previous quit attempts, indicating a highly nicotine-addicted population.

New analyses also demonstrate cytisinicline biochemical efficacy via measurement of serum cotinine as well as the previously reported carbon monoxide (CO) efficacy. Similar to CO analyses, all subjects in the cytisinicline-treated arms had a statistically significant reduction in serum cotinine levels by the end of study treatment. Both expired CO and serum cotinine levels are biochemical products from cigarette smoking or metabolizing nicotine and were objective biochemical markers used in the study to assess cigarette smoking or nicotine intake.

"The additional analyses further validate our belief that cytisinicline could be an effective aid to smoking cessation regardless of demographics, prior smoking history, or numerous quit attempts," stated Dr. Cindy Jacobs PhD, MD, Chief Medical Officer of Achieve. "With over 34 million smokers in the United States alone and the growing, global vaping epidemic, new

potential treatment options like cytisinicline are desperately needed to treat nicotine addiction."

Achieve plans to initiate the Phase 3 development program in mid-2020, subject to the availability of capital. Additional information on cytisinicline and the ORCA program can be found at www.achievelifesciences.com or www.orcaprogram.com.

About Achieve & Cytisinicline
Tobacco use is currently the leading cause of preventable death and is responsible for more than eight million deaths annually worldwide[1]. It is estimated that 28.7% of cancer deaths in the U.S. are attributable to cigarette smoking[2]. Achieve's focus is to address the global smoking and nicotine addiction health epidemic and 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.

About ORCA-1
ORCA-1 is the first in Achieve's ORCA (Ongoing Research of Cytisinicline for Addiction) Program, which aims to evaluate the safety and effectiveness of cytisinicline for smoking cessation and potentially other addiction 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. Positive ORCA-1 topline results were announced in June 2019 and enrolled 254 smokers at eight centers across the United States.

Overall adherence to study treatment was greater than 94% across all treatment arms and 98% in the 3.0 mg TID arm, specifically. Cytisinicline was generally well-tolerated with no serious or severe adverse events (AEs) reported.

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 for cytisinicline, the potential benefits 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; 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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[1] World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization, 2017
[2] Annals of Epidemiology, Volume 25, Issue 3, 179 - 182.e1