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Achieve Life Sciences Announces Successful Completion of the Second and Final DSMC Review of Phase 2b ORCA-1 Trial of Cytisinicline for Smoking Cessation

Topline data from ORCA-1 trial expected in the Second Quarter of 2019

SEATTLE and VANCOUVER, British Columbia, April 2, 2019 /PRNewswire/ -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation, today announced that the Data Safety Monitoring Committee (DSMC) met on March 28, 2019 to conduct its second and final safety review of the ORCA-1 Trial.

The DSMC is an independent committee that advises on continuation or stopping of clinical trials based upon safety and study conduct considerations. The ORCA-1 DSMC has had the responsibility for safeguarding the interests of trial subjects by assessing the safety of the interventions and monitoring the conduct of the ORCA-1 trial. The committee has reviewed the ORCA-1 data twice during the conduct of the study, and has concluded following each review that there are no safety concerns for subjects or study conduct issues, and the trial should continue for completion as planned. ORCA-1 topline efficacy and safety data are expected to be announced by end of the second quarter of 2019.

"We are very pleased with the speed of enrollment and efficient conduct of the ORCA-1 trial, which is attributed to the commitment of the trial subjects, clinical investigators and their support teams," said Dr. Cindy Jacobs, Chief Medical Officer at Achieve. "We look forward to sharing the data results in the near future."

ORCA-1 is the first in Achieve's ORCA (**O**ngoing **R**esearch of **C**ytisinicline for **A**ddiction) Program, which aims to evaluate the effectiveness of cytisinicline for smoking cessation and potentially other addiction indications. ORCA-1 was initiated in October 2018 and enrolled 254 smokers at eight centers across the United States.

The Phase 2b trial is evaluating a 25-day treatment course of 1.5 mg or 3.0 mg doses of cytisinicline using either a declining titration schedule or three times daily dosing. The trial is randomized and blinded to compare the effectiveness of the cytisinicline doses and schedules to respective placebo groups. The primary efficacy endpoint is the overall reduction in the number of cigarettes smoked during the treatment period, with secondary analyses being conducted on smoking cessation rates, safety, and compliance. Smokers who are participating in the trial receive standardized behavioral support.

Additional information on cytisinicline and the ORCA program can be found at www.achievelifesciences.com and www.orcaprogram.com.

About Cytisinicline
Tobacco use is currently the leading cause of preventable death and is responsible for nearly seven 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 health 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, statements regarding the planned cytisinicline clinical development activities, the timing of clinical development activities related to cytisinicline, the potential market size for cytisinicline and the potential 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 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, 2017. Geneva: World Health Organization, 2017
[2]Annals of Epidemiology , Volume 25 , Issue 3 , 179 - 182.e1

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