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Achieve Life Sciences Announces Phase 2b ORCA-1 Trial Data Accepted for Oral Presentation at Society for Research on Nicotine & Tobacco Europe (SRNT-E) 19th Annual Conference

SEATTLE, Wash. and VANCOUVER, British Columbia, June 21, 2019 /PRNewswire/ -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a clinical-stage pharmaceutical company focused on nicotine addiction, today announced that an abstract featuring data from the Phase 2b ORCA-1 trial has been accepted for oral presentation at the SRNT-E Annual Conference, to be held in Oslo, September 12-14, 2019.

The abstract "A Multicenter, Double-blind, Randomized, Placebo-controlled Phase 2b Trial of Cytisinicline in Adult Smokers" and oral presentation will include updated cytisinicline data from the recently completed ORCA-1 trial.

As recently reported, the 254-subject ORCA-1 dose-selection trial of cytisinicline demonstrated a statistically significant improvement in quit rates for a simplified 3.0 mg, three times daily dose administered over a 25-day treatment period. In the trial, adherence to study treatment was greater than 98.5% across all arms and cytisinicline was well-tolerated with no serious adverse events reported.

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.

About ORCA-1
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 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 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.

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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