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Achieve Announces Final Data from Cytisinicline Phase I/II Multi-Dose, Pharmacokinetic and Pharmacodynamics (PK/PD) Clinical Study to be Presented at Society for Research on Nicotine & Tobacco Annual Meeting

SEATTLE and VANCOUVER, British Columbia, Feb. 22, 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 final data from their Phase I/II multi-dose, pharmacokinetic and pharmacodynamics (PK/PD) clinical study of cytisinicline in smokers. Study results will be presented today, Friday, February 22nd, at the Society for Research on Nicotine & Tobacco (SRNT) Annual Meeting in San Francisco.

The study evaluated the repeat-dose PK and PD effects of 1.5 mg and 3.0 mg cytisinicline in 26 healthy volunteer smokers when administered over the standard 25-day course of treatment. Smokers in the study had a mean age of 39 years, smoked on average 17.2 cigarettes a day, and were not required to quit smoking or have a predetermined quit date while on study. All subjects had a significant and immediate reduction in cigarettes smoked within 2 days of initiating cytisinicline treatment. By Day 26, subjects had an average 80% reduction in cigarettes smoked, 82% reduction in expired carbon monoxide, and 46% had stopped smoking. The biochemically verified smoking cessation rates were 39% and 54% in the 1.5 mg and 3.0 mg cytisinicline treated groups, respectively.

The PK results indicated expected increases in plasma concentration between the standard 1.5 mg and higher 3.0 mg doses of cytisinicline with no evidence of drug accumulation.

Cytisinicline at either dose was well tolerated with only transient, mild-to-moderate headache as the most common adverse event, which was not treatment limiting. No adverse events were severe, serious, or led to withdrawal from the study.

Dr. Cindy Jacobs, Chief Medical Officer at Achieve commented, "Given the short 25-day treatment period, the abstinence rates observed are impressive, particularly since subjects were not required to commit to quitting and received minimal behavioral support during the study. These results continue to support our belief that cytisinicline could be a well-tolerated and effective potential treatment option for the millions of people who are battling nicotine addiction."

Earlier this week, Achieve announced completion of enrollment in the 254-subject Phase 2b ORCA-1 trial evaluating various doses and schedules of cytisinicline. 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 topline efficacy and safety data are expected to be announced in mid-2019.

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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