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Achieve Life Sciences Announces Results from Evaluation of Cytisinicline (cytisine) versus Chantix® (varenicline) in 5-HT3 Receptor Binding Assay Study

Provides Mechanistic Rationale for the Clinical Findings that Cytisinicline (Cytisine) Treatment is Associated with Lower Rates of Nausea and Vomiting compared to Chantix

SEATTLE, and VANCOUVER, British Columbia, Sept. 18, 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, today announced data presented at the Society for Research on Nicotine and Tobacco European (SRNT-E) Annual Meeting.

The presentation, *"Cytisine's Lower Potency at 5-HT_3 Receptors May Explain its Lower Incidence of Nausea and Vomiting than Varenicline",* provides a rationale based on detailed receptor pharmacology to explain why the incidence of nausea and vomiting associated with cytisinicline appears to be consistently lower than that seen with varenicline.

The study, conducted at the University of Cambridge Department of Biochemistry by Professor Sarah Lummis and Dr. Kerry Price, was designed to examine the in vitro binding characteristics of cytisinicline compared to varenicline at the human 5-HT_3 receptor. Using a radioligand antagonist displacement design, the study reported an IC_{50} of 0.50 mM for cytisinicline and 0.25 µM for varenicline, representing a 2000-greater fold agonist binding affinity to the 5-HT_3 receptor for varenicline compared to cytisinicline.

"It is well-established that agonist activation of 5-HT_3 receptors in the brain stem directly leads to nausea and vomiting. These data provide further rationale to explain what has been consistently observed in clinical studies reporting the adverse event profiles of cytisinicline and varenicline," commented Achieve's Chief Scientific Officer, Dr. Anthony Clarke. "Nausea and vomiting can greatly impact smoker's compliance with medication, their willingness to complete the course of treatment, and ultimately, their ability to successfully quit smoking."

Additional safety and efficacy data from the RAUORA head-to-head non-inferiority trial of cytisinicline vs. varenicline will be presented later today by Dr. Natalie Walker at 4:15PM CET. For additional information please visit http://ir.achievelifesciences.com/events-and-webcasts.

About Achieve and 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 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] Annals of Epidemiology, Volume 25, Issue 3, 179 - 182.e1

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