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Achieve Announces Update on Cytisinicline Clinical Development Program

SEATTLE and VANCOUVER, British Columbia, Dec. 18, 2018 /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 provided a clinical development update.



The U.S. Food and Drug Administration (FDA) has confirmed that they are in agreement with Achieve's Initial Pediatric Study Plan, specifically, providing a full waiver for evaluating

cytisinicline in a pediatric population. The reasons for the full waiver were based on the low numbers of children smoking under the age of 12 and the logistical difficulties of recruiting treatment-seeking smokers in the adolescent age group. The agreed Pediatric Study Plan will be included as part of Achieve's future application for marketing approval of cytisinicline.

The Company recently announced initiation of the first clinical study in the ORCA (*Ongoing Research of Cytisinicline for Addiction*) Program. ORCA-1 is a Phase 2b optimization trial that is currently enrolling 250 smokers at eight trial locations throughout the United States. The trial is evaluating various dosing schedules of cytisinicline and will determine efficacy based on the overall reduction in the number of cigarettes smoked during the various study treatment doses and schedules. It will also compare smoking cessation rates, compliance, and safety profiles, compared to the respective placebo groups. ORCA-1 data results are expected in mid-2019.

Dr. Cindy Jacobs, Chief Medical Officer at Achieve commented, "We are pleased with our recent progress, specifically, initiating the ORCA-1 trial and reaching agreement with FDA on our Pediatric Study Plan for a future market application."

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 six million deaths annually worldwide¹. It is estimated that 28.6% of all cancer deaths in the U.S. are attributable to cigarette smoking². Achieve's focus is to address the global smoking health epidemic through the development and commercialization of cytisinicline, also known as cytisine.

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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"ORCA is a trademark of Achieve Life Sciences, Inc."

¹ World Health Organization. WHO Report on the Global Tobacco Epidemic, 2011, Geneva: World Health Organization, 2011.

² Annals of Epidemiology, Volume 25 , Issue 3 , 179 - 182.e1

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