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Achieve Life Sciences Extends Collaboration with the National Institutes of Health to Advance the Development of Cytisinicline for Smoking Cessation

SEATTLE and VANCOUVER, British Columbia, July 23, 2019 /PRNewswire/ -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a clinical-stage pharmaceutical company focused on nicotine addiction, today announced it has extended its strategic collaboration with the National Center for Complementary and Integrative Health (NCCIH) at the National Institutes of Health (NIH). Under the extended collaboration, the NIH is funding and providing research efforts to conduct additional non-clinical studies as requested by the U.S. Food and Drug Administration (FDA) to be included in the cytisinicline New Drug Application (NDA).



"Given the research results to date, we are extending our partnership with Achieve to aid in moving the science forward regarding this approach for smoking cessation," said David Shurtleff, Ph.D., NCCIH Deputy Director. "Smoking continues to be the leading cause of preventable death around the world, and new treatment options have the potential to complement existing evidence-based cessation strategies."

In discussions with the FDA in 2018, it was determined that a Good Laboratory Practice (GLP) non-clinical reproductive study would be required to support the NDA submission. NCCIH has agreed to sponsor this study which is expected to complete in 2020.

Previously under the collaboration, the NCCIH sponsored the GLP nonclinical studies that were required for the Investigational New Drug (IND) application in order to initiate clinical studies. These studies included genotoxicity testing, safety pharmacology, cardiac conduction studies, pharmacokinetics, toxicokinetics, and the required toxicology studies in two species. Combined fertility and developmental studies were also conducted and co-sponsored by the NCCIH and the National Cancer Institute (NCI) in preparation for initiating the Phase 3 development program. In total, the NIH has committed approximately \$6 million dollars to the development of cytisinicline.

About Cytisinicline

Tobacco use is currently the leading cause of preventable death and is responsible for nearly seven million deaths annually worldwide¹. It is estimated that 28.7% of 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.

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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