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Achieve Life Sciences Announces Advancement of Cytisine Development Program Following Meeting with the FDA

SEATTLE and VANCOUVER, British Columbia, July 11, 2018 /PRNewswire/ -- Achieve Life Sciences, Inc. (NASDAQ: ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisine for smoking cessation, today announced an update on the cytisine development program following a meeting conducted with the United States (U.S.) Food and Drug Administration (FDA). The meeting with the FDA on the non-clinical and clinical development plans has further defined Achieve's Phase 3 clinical program and expected future New Drug Application (NDA) submission.

Based on the FDA's recommendations to further characterize cytisine dosing prior to NDA submission, Achieve plans to conduct a Phase 2b optimization trial in approximately 250 smokers in the U.S., with various cytisine dosing schedules to evaluate overall treatment efficacy, safety, and compliance profiles for cytisine.

The Central and Eastern European commercially-approved cytisine dose is 1.5 mg on a declining titration dose over 25-days. The planned Phase 2b trial will evaluate additional dosing of 3.0 mg cytisine using the same 25-day titration schedule, as well as 1.5 mg and

3.0 mg cytisine dosing using a three times daily dosing schedule. The study will be randomized and blinded to compare the effectiveness of all doses and schedules of cytisine to placebo. The primary endpoint of the trial will be reduction in the number of cigarettes consumed during treatment. Achieve plans to initiate this Phase 2b trial in the fourth quarter of 2018 with top line results expected in the second quarter of 2019. The results will be used to help better define the planned U.S. Phase 3 cytisine clinical development program.

"The successful outcome of our discussions with the FDA has provided us with clarity and direction to better inform our Phase 3 clinical development program and our efforts toward expanding cytisine availability," said Rick Stewart, Chairman and Chief Executive Officer of Achieve Life Sciences. "Smoking is responsible for the deaths of nearly a half a million Americans every year and new treatment options are desperately needed to help those battling nicotine addiction."

Following the results from the Phase 2b optimization trial, the Company plans to initiate the Phase 3 program in 2019.

About Achieve and Cytisine

Achieve's focus is to address the global smoking health epidemic through the development and commercialization of cytisine. Tobacco use is currently the leading cause of preventable death and is responsible for nearly six million deaths annually worldwide[1]. It is estimated that 28.6% of all cancer deaths in the U.S. are attributable to cigarette smoking[2].

Achieve is developing cytisine as a smoking cessation aid. Cytisine is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is an established smoking cessation treatment that has been approved and marketed in Central and Eastern Europe for more than 15 years. It is estimated that over 20 million people have used cytisine to help combat nicotine addiction, including approximately 2,000 patients in Phase 3 clinical trials conducted in Europe and New Zealand. Achieve's focus is to address the global smoking health epidemic, which is currently the leading cause of preventable death and is responsible for nearly six million people losing their lives annually worldwide. Discussions have been held with FDA and a European regulatory agency to determine the clinical and regulatory pathway towards making cytisine widely available.

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 cytisine clinical development activities, including a planned Phase 2b trial and Phase 3 clinical development program, the timing of clinical development activities related to cytisine, including the initiation and results of a Phase 2b trial and initiation of a Phase 3 clinical program, the potential market size for cytisine and the potential benefits of cytisine. 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 cytisine 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 cytisine; the risk that cytisine 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, 2011, Geneva: World Health Organization, 2011.
[2] Annals of Epidemiology , Volume 25 , Issue 3 , 179 - 182.e1

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