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Achieve Announces Results of Clinical Study Demonstrating Similar Bioavailability of Cytisine in Fed and Fasted Subjects

BOTHELL, Wash. and VANCOUVER, British Columbia, Nov. 14, 2017 /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 results of a clinical study evaluating the effect of food on the bioavailability of 3mg cytisine.

The study evaluated the bioavailability of 3 mg cytisine under fed and fasted conditions in 24 healthy volunteer subjects. Study results demonstrated bioequivalence when cytisine was administered with or without food. Cytisine was extensively absorbed after oral administration with maximum cytisine concentration levels observed in the blood within less than an hour. Total excretion levels of cytisine also remained equivalent in both the fed and fasted states. Further data from this study will be submitted for presentation at an upcoming scientific congress.

Additionally, in preparation to initiate a pivotal Phase 3 program in the United States, Achieve recently began enrollment in a multi-dose, pharmacokinetic and pharmacodynamics (PK/PD) clinical study. An assessment of PK parameters and PD effects is planned to be conducted on both the 1.5mg standard and 3.0mg higher-dose of cytisine administered over the currently indicated 25-day scheduled duration of cytisine treatment. The multi-dose PK/PD study is expected to have results within the first-quarter of 2018.

"We are pleased with the rapid completion of this study in fed versus fasted subjects and the findings that a higher dose of 3 mg cytisine can be administered safely with or without food," said Rick Stewart, Chairman and CEO of Achieve. "The results help to inform our future development plans, including our Phase 3 program which we expect to initiate in mid-2018."

Cytisine is an established smoking cessation treatment that has been approved and marketed in Central and Eastern Europe for more than 20 years. It is estimated that over 20 million people have used cytisine to help combat nicotine addiction, including over 2,000 patients in investigator-conducted, Phase 3 clinical trials in Europe and New Zealand.

About 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].

Cytisine is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. Two prior, large-scale Phase 3 clinical studies of cytisine, with favorable outcomes, have been successfully completed in over 2,000 patients. The TASC trial was a 740 patient, double-blind, placebo controlled trial conceived by Professor Robert West at University College London and funded by the U.K. National Prevention Research Initiative. The CASCAID trial was a 1,310 patient, single-blind, non-inferiority trial comparing cytisine to nicotine replacement therapy (NRT). The CASCAID trial was conceived by Dr. Natalie Walker, National Institute for Health Innovation, University of Auckland and funded by the Health Research Council of New Zealand. Both trials were published in the New England Journal of Medicine.

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 timing of clinical development of cytisine, the 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 the final Proxy Statement/Prospectus/Information Statement filed pursuant to Rule 424(b)(3) in connection with Achieve's recent merger, and 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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