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Achieve Announces Preliminary Data from Cytisine Phase I/II Multi-Dose, Pharmacokinetic and Pharmacodynamics (PK/PD) Clinical Study

BOTHELL, Wash. and VANCOUVER, British Columbia, Feb. 20, 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 preliminary data from their Phase I/II multi-dose, pharmacokinetic and pharmacodynamics (PK/PD) clinical study of cytisine.

The study, initiated in October 2017, evaluated the repeat-dose PK and PD effects of 1.5mg and 3mg cytisine in 24 healthy volunteer smokers aged 18-65 years when administered over the standard 25-day course of treatment. The PK results indicated expected increases in plasma concentration between the standard and higher doses of cytisine with no evidence of drug accumulation. Smokers in the study were not required to have a designated or predetermined quit date, however, 58% of the subjects overall in the trial achieved biochemically verified smoking abstinence at day 26. Half (6/12) of the subjects on the 1.5mg arm and 67% (8/12) of the subjects on the 3.0mg arm achieved abstinence on day 26. Subjects who did not achieve abstinence had a significant reduction in number of daily cigarettes smoked by the end of treatment.

Cytisine was well-tolerated and reported adverse events were mostly mild and short-lived. Transient headache was the most commonly reported event, but was not treatment-limiting. No adverse events were severe, serious, or led to withdrawal from the study. Study results will be included in a clinical symposium on cytisine at the Society for Research on Nicotine and Tobacco (SRNT) Annual Meeting in Baltimore on Friday, February 23rd.

"The abstinence rates observed with cytisine are particularly impressive given the short 25-day treatment period. In addition, subjects did not commit to quitting and received only minimal behavioral support. Setting an actual quit date and receiving enhanced behavioral support are key factors to improve smoking cessation outcomes," said Dr. Cindy Jacobs, Executive Vice President and Chief Medical Officer at Achieve. "We are encouraged by these results that further support our Phase 3 program that we expect to initiate mid-2018."

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 available in Central and Eastern Europe for more than 20 years. Achieve is collaborating with leading opinion leaders and researchers to facilitate cytisine availability globally as well as in the United States. Achieve expects to initiate the cytisine Phase 3 development program in mid-2018 required for FDA approval of cytisine in the United States.

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].

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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