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Achieve Announces Initiation of Cytisine Clinical Development Program

BOTHELL, Wash. and VANCOUVER, British Columbia, Aug. 16, 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 initiation of the Cytisine Clinical Development Program.

Cytisine 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 over 2,000 patients in investigator-conducted, Phase 3 clinical trials in Europe and New Zealand.

In preparation to initiate a pivotal Phase 3 trial in the United States, Achieve expects to conduct the following clinical studies in 2017:

- Evaluation of the effect of food on the bioavailability of cytisine - enrollment has started, the first subjects have been dosed and data analysis expected to be completed in Q4 2017.
- Assessment of repeat-dose pharmacokinetic (PK) parameters and pharmacodynamics (PD) - expected to commence in Q4 2017.

"In the last month Achieve has announced the closing of our merger with OncoGenex and subsequent listing on NASDAQ, the FDA acceptance of Achieve's cytisine IND, and now the initiation of the cytisine clinical development program," said Rick Stewart, Chairman and CEO of Achieve. "We are focused on achieving our milestones with our primary goal of initiating a U.S. pivotal Phase 3 trial next year."

About Cytisine
Achieve's focus is to address the global smoking health epidemic through the development and commercialization of cytisine. Smoking is currently the leading cause of preventable death and is responsible for nearly six million people losing their lives annually worldwide.

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. 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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