October 4, 2017

Achieve Announces Advancement of Cytisine Clinical Development Program

Rapid Progress on Advancing Clinical Program with Commencement of Pharmacokinetic (PK) & Pharmacodynamic (PD) Cytisine Study and Completion of Enrollment in Food Effect PK Study

BOTHELL, Wash. and VANCOUVER, British Columbia, Oct. 4, 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 the commencement of a multi-dose study to evaluate both PK and PD characteristics of cytisine.

In preparation to initiate a pivotal Phase 3 trial in the United States, Achieve recently began enrollment in a multi-dose, 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. Additional data will be collected to help further inform the Phase 3 trial design. The multi-dose PK/PD study is expected to be completed by the end of the year, with data expected by the first-quarter of 2018.

Additionally, Achieve recently completed enrollment in a clinical study evaluating the effect of food on the bioavailability of 3mg cytisine. Data analysis is ongoing and results are expected to be announced by the end of the year.

"We are making rapid progress on the cytisine clinical development program which is essential in meeting our timelines for further discussions with the FDA prior to initiation of our Phase 3 trial, currently expected in mid-2018," said Rick Stewart, Chairman and CEO of Achieve. "According to the Centers for Disease Control and Prevention, tobacco use remains the leading cause of preventable death and cigarette smoking is responsible for more than 480,000 lives lost each year in the U.S. alone. Our mission at Achieve is to bring cytisine forward as a new treatment option to help the millions of smokers who are battling nicotine and tobacco addiction."

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.

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.

Achieve Contact
Jason Wong
jwong@bplifescience.com
(415) 375-3340 ext. 4

[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

View original content with multimedia:http://www.prnewswire.com/news-releases/achieve-announces-advancement-of-cytisine-clinical-development-program-300530475.html

SOURCE Achieve Life Sciences, Inc.