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Achieve Announces Clinical Trial Supply and Cooperation Agreement with the University of Auckland for the Evaluation of Cytisine Compared to Varenicline for Smoking Cessation

BOTHELL, Wash. and VANCOUVER, British Columbia, Nov. 28, 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 an agreement with Auckland UniServices Limited, as the commercial arm of the University of Auckland, to provide cytisine for use in the Phase 3 "RAUORA" clinical trial.

"RAUORA" is an investigator-sponsored and led, single-blind, randomized, non-inferiority trial that will evaluate the efficacy, safety and cost-effectiveness of cytisine compared to varenicline for smoking cessation in 2,140 Māori (indigenous New Zealanders) and whānau (family) of Māori. Comparing quit rates at six months, the trial hypothesizes that 12 weeks of cytisine plus behavioral support will be at least as effective as 12 weeks of varenicline plus behavioral support.

"In an effort to achieve New Zealand's Smokefree 2025 goal, smoking rates need to decrease substantially, particularly for Māori and their whānau, who have the highest prevalence of smoking and the slowest decline in prevalence over the last 20 years," commented Dr. Natalie Walker, Associate Professor at the University of Auckland and Principal investigator for the RAUORA trial. "The use of tobacco products and exposure to tobacco smoke is recognized as the leading preventable cause of death worldwide and additional smoking cessation aids need to be made available."

Rick Stewart, Chairman and CEO of Achieve, added, "We are pleased to contribute cytisine to this important initiative to help improve the health and well-being of Māori and their whānau. This trial is well-aligned with our mission at Achieve, which is to bring cytisine forward as a new treatment option around the globe 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 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. Achieve expects to initiate a Phase 3 trial of cytisine in the United States in mid-2018.

About RAUORA

RAUORA is a collaboration between the University of Auckland and the Lakes District Health Board (both in New Zealand), and Brunel University London. RAUORA is an investigator-initiated and led study funded by the Health Research Council of New Zealand. RAUORA study results will be published to maximize the impact on health outcomes. Additional trial information can be found by visiting https://rauora.nihi.auckland.ac.nz/

About Achieve & 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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