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Achieve Announces Successful Results from the Investigator-Initiated RAUORA Head-to-Head Non-Inferiority Clinical Trial Comparing Cytisinicline and Chantix® (varenicline) as a Treatment to Quit Smoking

Cytisinicline demonstrated quit rates at least as effective as varenicline

Participants on cytisinicline experienced significantly fewer side effects than those on varenicline

SEATTLE and VANCOUVER, BC, June 29, 2020 /CNW/ -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine addiction, today announced the successful topline results from the New Zealand RAUORA Phase 3 non-inferiority clinical trial comparing cytisinicline to varenicline (Chantix®) in Māori (indigenous New Zealanders) and whānau (family) of Māori. The study was led by Dr. Natalie Walker, Associate Professor at the University of Auckland, and was funded by the Health Research Council of New Zealand.

The RAUORA trial was designed to evaluate the effectiveness, safety, and cost-effectiveness of cytisinicline compared to varenicline as a smoking cessation aid. In total, the study randomized 679 subjects to receive 12 weeks of either cytisinicline or varenicline. The primary endpoint was a comparison of biochemically confirmed continuous abstinence rates at 6 months, and the trial was designed to assess if the two agents were non-inferior to each other. The trial achieved statistical significance in showing that cytisinicline plus behavioral support was at least as effective as varenicline plus behavioral support at six months. In addition, the trial showed that cytisinicline resulted in significantly fewer reported adverse events when compared to varenicline. The final RAUORA trial results have been submitted for presentation at The Society for Research on Nicotine and Tobacco Europe (SRNT-E) Annual Meeting in September 2020.

"The positive topline results of the RAUORA Phase 3 trial, which is the first, direct head-to-head comparative study between cytisinicline and varenicline, provide additional evidence that cytisinicline is at least as effective as varenicline while offering improved tolerability," said Rick Stewart, Chairman and Chief Executive Officer of Achieve. "Importantly, these benefits were achieved using a lower dose of cytisinicline. Future cytisinicline clinical trials, sponsored by Achieve, will use a higher dose and optimized dosing schedule, and we believe that this change will allow us to demonstrate even better efficacy than what was seen in the RAUORA trial."

"In an effort to achieve New Zealand's Smokefree 2025 goal, smoking rates need to decrease substantially, particularly for Māori and their family, who have the highest prevalence of smoking and the slowest decline in prevalence over the last 20 years," said Dr. Natalie Walker, Associate Professor at the University of Auckland and Principal investigator for the RAUORA trial. "We found that cytisinicline was just as good as Chantix in helping people to quit smoking and stay quit. In addition, we found that fewer people in the

cytisinicline group reported any side effects from the medicine compared to those in the Chantix group. These results demonstrated that the study was successful."

"We look forward to seeing the publication of full results from this important study which will add to the growing body of clinical evidence supporting cystisinicline's potential as a new tool in the fight against smoking and nicotine addiction. We expect that 2020 will continue to be a pivotal year for our company as we continue to publish new data and expect to initiate our Phase 3 U.S. trial of cytisinicline later this year," added Stewart.

About the RAUORA Study
The RAUORA study was conducted by the researchers at the University of Auckland, in conjunction with the Health Economics Research Group (HERG) at Brunel University London, and Lakes District Health Board. Currently, 3 in 10 Māori smoke, three times more than non-Māori, and supporting this population to quit smoking is a priority of the New Zealand government. The study compared cytisinicline administered on a schedule of 25 days of downward dosing titration followed by twice-daily dosing for a total of 12 weeks with varenicline administered on a schedule of 7 days of upward titration followed by twice-daily dosing for a total of 12 weeks. The primary endpoint was continuous abstinence from smoking for 6 months post-quit date.

In total, 1,105 Māori or whānau (Māori extended family members) expressed interest in participating in the study and a total of 679 were randomized to receive either cytisinicline or varenicline. The average age of participants in the trial was 43 years and approximately 70% of the participants were women. Contact was sought over a period of six to 12 months to collect data and support their quit journey.

About Achieve and Cytisinicline
Tobacco use is currently the leading cause of preventable death and is responsible for more than eight million deaths annually worldwide[1]. It is estimated that 28.7% of cancer deaths in the U.S. are attributable to cigarette smoking[2]. Achieve's focus is to address the global smoking health and nicotine addiction epidemic through the development and commercialization of cytisinicline.

Cytisinicline is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is believed to aid in smoking cessation by interacting with nicotine receptors in the brain by reducing the severity of nicotine withdrawal symptoms and by reducing the reward and satisfaction associated with smoking.

As an approved, branded product in Central and Eastern Europe for more than two decades, it is estimated that over 20 million people have used cytisinicline to help combat nicotine addiction.

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, the timing, and nature of cytisinicline clinical development activities, the potential market size for cytisinicline and the potential benefits of cytisinicline. 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 cytisinicline 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 cytisinicline; the risk that cytisinicline 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; impacts from the COVID-19 pandemic; 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 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.

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[1] World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization, 2017

[2] Annals of Epidemiology, Volume 25, Issue 3, 179 - 182.e1

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