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Achieve Life Sciences Announces Presentation of Cytisinicline Data at the 21st Annual Society for Research on Nicotine & Tobacco (SRNT-E) Virtual Conference

SEATTLE, WA & VANCOUVER, BC / ACCESSWIRE / September 14, 2021 / 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, announced that cytisinicline data will be presented at two sessions during the upcoming Society for Research on Nicotine & Tobacco (SRNT-E) Conference to be held virtually September 15-17, 2021.

Presentation Details

- ***"Cytisinicline may benefit smokers who previously failed to quit smoking with varenicline: A subgroup analysis of the ORCA-1 trial"***
 - A subgroup analysis from the ORCA-1 Phase 2 study of smokers who had previously failed Chantix® (varenicline) demonstrated a Week 4 abstinence rate of 51.3% upon treatment with cytisinicline using the three times daily (TID) regimen, compared with 15.8% with placebo ($p=0.009$). The estimated Odds Ratios for smoking cessation through Weeks 5-8 were 1.8 for the titration and 4.3 for the TID regimen. The cytisinicline TID regimen appeared to be more effective for smokers who had previously failed to quit on varenicline than the titration regimen.
 - The data will be presented on Thursday, September 16th, Oral Session 5: "Smoking cessation interventions in special populations".
- ***"Time to Sustained Abstinence with Cytisinicline in the ORCA-1 trial"***
 - A new analysis of the ORCA-1 Phase 2 study determined that smokers treated in the study with cytisinicline showed an earlier onset of sustained abstinence compared with placebo. Smokers who received the cytisinicline 3 mg TID had the

shortest time to sustained smoking abstinence with a median of only 7 days of treatment compared to 18 days for placebo.

- The data will be presented on Friday, September 17th, Poster Session 5: "Clinical".

"This additional analysis continues to reinforce our belief that the 3 mg dose of cytisinicline taken three times daily provides the greatest potential for smokers, regardless of prior treatments, to successfully quit," commented John Bencich, CEO of Achieve. "We are also pleased to have new insights on the short time to response seen with cytisinicline. We believe this early abstinence could inspire smokers to continue their treatment and stay quit."

Achieve recently announced completion of enrollment in the Phase 3 ORCA-2 clinical trial, evaluating cytisinicline as a treatment for combustible cigarette cessation. Topline results from the ORCA-2 trial are expected in the first half of 2022. For more information on Achieve Life Sciences and cytisinicline please visit www.achievelifesciences.com.

About Achieve and Cytisinicline

Tobacco use is currently the leading cause of preventable death that is responsible for more than eight million deaths worldwide, and nearly half a million deaths in the U.S. annually.^{1 2} More than 87% of lung cancer deaths, 61% of all pulmonary disease deaths, and 32% of all deaths from coronary heart disease are attributable to smoking and exposure to secondhand smoke.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.

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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 and nature of cytisinicline clinical development activities, the potential market size and market acceptance for cytisinicline, the potential benefits of cytisinicline and the development and effectiveness of new treatments. 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; 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 law.

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

² U.S. Department of Health and Human Services. The Health Consequences of Smoking - 50 Years of Progress. A Report of the Surgeon General, 2014.

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