October 24, 2019

Achieve Life Sciences Announces Presentation of Cytisinicline Data at Society for Research on Nicotine & Tobacco Oceania (SRNT-O) Inaugural Conference

SEATTLE, Wash. and VANCOUVER, British Columbia, Oct. 24, 2019 /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 that data from the Phase 2b ORCA-1 trial will be presented at the SRNT-O Inaugural Conference.

"Successful Smoking Abstinence with Cytisinicline in the ORCA-1 Trial: What Happens Next?" will be presented at the SRNT-O meeting by Achieve's Chief Scientific Officer, Dr. Anthony Clarke, on Friday, October 25th in Sydney. The results of the ORCA-1 trial, to be discussed in the presentation, confirm that future Phase 3 clinical trials are expected to utilize 3.0 mg TID dosing of cytisinicline. The Company plans to extend dosing in the Phase 3 trials from 25 days to 42 days, or six weeks. The slightly longer dosing will allow for the primary endpoint of continuous abstinence over 4 weeks to be measured while subjects are still on treatment and potentially improve quit rates.

ORCA-1 was designed to evaluate cytisinicline efficacy and safety across various dosing and administration schedules in 254 smokers in the United States. Topline results, reported earlier this year, demonstrated a 54% abstinence rate at week 4 in the 3.0 mg three times daily (TID) cytisinicline arm compared to 16% for placebo ($p < 0.0001$). Additionally for the 3.0 mg TID cytisinicline arm, a 4-week continuous abstinence rate, weeks 5 through 8, of 30% for cytisinicline was observed compared to 8% for placebo ($p= 0.005$). Continuous abstinence for 4 weeks is the relevant endpoint for regulatory approval.

Overall adherence to study treatment was greater than 94% across all treatment arms and 98% in the 3.0 mg TID arm, specifically. Cytisinicline was well-tolerated with no serious or severe adverse events (AEs) reported. Overall, in subjects treated with cytisinicline, all individual AE's reported were below a rate of 10%. Minimal rates of abnormal dreams, insomnia, upper respiratory tract infections, and nausea were reported compared with placebo.

The Company plans to initiate the Phase 3 development program in 2020, subject to the availability of capital. Additional information on cytisinicline and the ORCA program can be found at www.achievelifesciences.com.

About Cytisinicline
Tobacco use is currently the leading cause of preventable death and is responsible for nearly seven 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 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.

About ORCA-1
ORCA-1 is the first in Achieve's ORCA (**O**ngoing **R**esearch of **C**ytisinicline for **A**ddiction) Program, which aims to evaluate the safety and effectiveness of cytisinicline for smoking cessation and potentially other addiction indications. The study was designed to evaluate the declining titration schedule, currently utilized in Central and Eastern Europe, compared to a simplified TID schedule at both the 1.5 mg and 3 mg cytisinicline doses compared to placebo. ORCA-1 topline results were announced in June 2019 and enrolled 254 smokers at eight centers across the United States.

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 planned cytisinicline clinical development activities, the timing of clinical development activities related to cytisinicline, 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; 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.

Achieve Contact
Jason Wong

jwong@bplifescience.com
(415) 375-3340 ext. 4

---

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

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

SOURCE Achieve Life Sciences, Inc.