February 29, 2024

Achieve Life Sciences Reaches Agreement with the FDA on Long-Term Cytisinicline Exposure Data Requirements for NDA Submission

Open-label exposure trial expected to initiate in Q2’24 with NDA filing anticipated in 1H 2025

SEATTLE and VANCOUVER, British Columbia, Feb. 29, 2024 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a late-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine dependence, today announced that it has reached agreement with the U.S. Food and Drug Administration (FDA) on the adequacy and timing of long-term cytisinicline exposure data requirements for a New Drug Application (NDA).

During pre-NDA discussions held in the fourth quarter of 2023, the FDA expressed support for an NDA submission based on adequate data to assess for efficacy from the two completed randomized and controlled Phase 3 trials, ORCA-2 and ORCA-3. In addition, the FDA advised that long-term exposure data to assess for safety beyond 12 weeks would be needed to adequately evaluate safety risks given that the FDA views smoking cessation drugs as products for chronic, repeat, or intermittent use as patients may relapse and require subsequent courses of treatment over a lifetime.

Achieve and the FDA have reached agreement that a single, open-label study evaluating for long-term safety exposure of cytisinicline will be sufficient to complete the requirement and enable an NDA submission anticipated in the first half of 2025. Based on FDA agreement, Achieve's NDA submission will include safety data on at least 300 subjects who have received cumulative cytisinicline treatment for six months. Prior to potential approval, Achieve will provide the FDA with safety data from at least 100 subjects treated with cytisinicline for a cumulative duration of one year.

Achieve plans to initiate the “ORCA-OL” open label exposure trial in the second quarter of 2024, which will include investigators and sites who have participated in the ORCA clinical

trial program (ORCA-2, ORCA-3, and ORCA-V1 studies). ORCA-OL will recruit from the more than 1,700 subjects who have participated in these prior trials, including more than 1,100 who have already received cytisinicline treatment for either 6 or 12-weeks. The required total cumulative exposure data for NDA submission and potential final approval will combine the previous subjects' treatment received during their respective ORCA-2, ORCA-3, or ORCA-V1 study participation plus their exposure during the ORCA-OL study. This allows for faster collection of cumulative long-term exposure safety data for the NDA submission. Subjects in ORCA-OL will receive cytisinicline treatment for up to one year and will be monitored for safety.

"We anticipate that data from this long-term exposure study will support the expected use of cytisinicline by patients multiple times throughout their journey to nicotine abstinence," commented Cindy Jacobs, Achieve's President & Chief Medical Officer. "Additionally, we expect this safety data will be supportive of a future cytisinicline label expansion for vaping cessation."

Achieve also announced an approximately $124.2 million financing, which includes $60 million upfront from the sale of common stock and up to an additional $64.2 million upon the exercise of milestone-driven warrants. The milestone-driven warrants will expire on the earlier of (i) three and one-half years following the date of issuance and (ii) 30 days following Achieve's public disclosure of the acceptance of an NDA for cytisinicline by the FDA in a Day 74 Letter or equivalent correspondence. Achieve has also reached non-binding agreement with Silicon Valley Bank on an extension of the maturity date into December 2025 on its outstanding loan.

"We are pleased to now have clarity from the FDA and we are excited about the vote of confidence from leading life science investors who share our enthusiasm for cytisinicline's potential," said John Bencich, Achieve's Chief Executive Officer. "As we continue our discussions with potential commercial partners, we are funded to conduct the ORCA-OL trial and complete the planned NDA submission, bringing us closer to our goal of helping the millions of people who struggle with nicotine dependence."

Achieve expects that existing cash, cash equivalents and restricted cash, together with the net proceeds from the financing, will provide adequate funding through the anticipated NDA filing in the first half of 2025. If all of the milestone-driven warrants are exercised in full, Achieve expects to have runway into 2026 and through potential FDA approval.

About Achieve and Cytisinicline

Achieve's focus is to address the global smoking health and nicotine addiction epidemic through the development and commercialization of cytisinicline. There are an estimated 28 million adults in the United States alone who smoke combustible cigarettes.[1] 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 United States annually.[2,3] 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.[3]

In addition, there are over 11 million adults in the United States who use e-cigarettes, also known as vaping.[3] In 2023, approximately 2.1 million middle and high school students in the United States reported using e-cigarettes.[4] Currently, there are no FDA-approved treatments indicated specifically as an aid to nicotine e-cigarette cessation.

Cytisinicline is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is believed to aid in treating nicotine addiction for smoking and e-cigarette cessation by interacting with nicotine receptors in the brain, reducing the severity of withdrawal symptoms, and reducing the reward and satisfaction associated with nicotine products. Cytisinicline is an investigational product candidate being developed for the treatment of nicotine addiction and has not been approved by the Food and Drug Administration for any indication in the United States. For more information on cytisinicline and Achieve visit www.achievelifesciences.com.

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 and regulatory review and approval, statements regarding the completion of the offering, the expected net proceeds of the offering, the intended use of the proceeds of the offering and the expected sufficiency of such proceeds to fund the development of cytisinicline through potential FDA approval, data results and commercialization activities, the potential market size for cytisinicline, the potential benefits, efficacy, safety and tolerability of cytisinicline, the ability to discover and develop new uses for cytisinicline, including but not limited to as an e-cigarette cessation product, 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; risks related to the impact on our business of macroeconomic conditions, including inflation, rising interest rates, instability in the global banking sector, and public health crises, such as 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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Source: Achieve Life Sciences