August 11, 2021

Achieve Announces Two Patents Granted by USPTO for Novel Cytisinicline Dosing and Administration Regimen

SEATTLE, WA and VANCOUVER, BC / ACCESSWIRE / August 11, 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, today announced that the United States Patent and Trademark Office (USPTO) has issued U.S. Patent No. 11,083,715 and U.S. Patent No. 11,083,716 covering the novel 3.0 mg three times daily (TID) cytisinicline dosing regimen.

"We are pleased the USPTO has officially granted these patents as the 3.0 mg TID dosing regimen demonstrated improved efficacy and safety compared to the traditional cytisinicline dosing in our ORCA-1 Phase 2 trial," commented John Bencich, Chief Executive Officer of Achieve. "Upon approval of cytisinicline in the United States, we expect these patents would be eligible for inclusion in the FDA's Orange Book and could provide us marketing exclusivity for the TID cytisinicline dosing regimen until at least the third quarter of 2040."

The patents include claims covering the expected 3.0 mg commercial dose of cytisinicline administered TID and stem from results obtained in the ORCA-1 clinical study that evaluated various doses and administrations of cytisinicline. The allowed claims cover this novel dose and administration method for the treatment of nicotine addiction and for promoting a reduction and/or cessation in smoking and vaping in treatment naïve and refractory patients who have failed previous smoking cessation treatments. Not including any patent term extensions to which Achieve may be entitled, the patents will expire in the third quarter of 2040.

Achieve recently announced completion of enrollment in the Phase 3 ORCA-2 clinical trial, evaluating 3.0 mg cytisinicline TID 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 United States 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.

Cytisinicline is an investigational product candidate being developed for treatment of nicotine addiction and has not been approved by the FDA for any indication in the United States. Achieve recently announced completion of enrollment in the Phase 3 ORCA-2 trial, evaluating cytisinicline 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.

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 ability to provide patent protection for Achieve's cytisinicline program, the potential listing of the patents in the FDA's Orange Book, descriptions of the anticipated commercial dosing of cytisinicline, 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.

Media Contact

Glenn Silver
Glenn.Silver@Finnpartners.com
(646) 871-8485

Investor Relations Contact
Jason Wong
jwong@bplifescience.com
(415) 375-3340 ext. 4

References

[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.

SOURCE: Achieve Life Sciences, Inc.

View source version on accesswire.com:
https://www.accesswire.com/659144/Achieve-Announces-Two-Patents-Granted-by-USPTO-for-Novel-Cytisinicline-Dosing-and-Administration-Regimen