June 26, 2025



Achieve Life Sciences Announces Partnership with Omnicom to Execute Integrated, Data-Driven Launch of the First Potential New Treatment for Nicotine Dependence in Nearly Two Decades

Omnicom cross-agency collaboration to drive technology-led, innovative launch strategy

Partnership brings together promising science, top-tier talent, and advanced technologies to enable a faster, smarter, and more effective path to address a critical public health need

SEATTLE and VANCOUVER, British Columbia, June 26, 2025 (GLOBE NEWSWIRE) --Achieve Life Sciences, Inc. (Nasdaq: ACHV), a late-stage specialty pharmaceutical company focused on the global development and commercialization of cytisinicline as a treatment of nicotine dependence for smoking cessation, today announced it has named Omnicom (NYSE: OMC) as its strategic innovation partner and agency of record to lead initiatives in support of Achieve's planning for U.S. commercial launch.

"We're excited to expand our partnership with Omnicom, building on the strong foundation we've established over the past several years," said Jaime Xinos, Chief Commercial Officer of Achieve Life Sciences. "This fully integrated extension of our commercial team shares the belief that the first treatment innovation for nicotine dependence in decades should be matched by an equally modern and strategic launch approach."

Led by Omnicom's technology powerhouse, Credera, Achieve's U.S. launch platform is being developed based on world-class, AI-enabled marketing technology proven across healthcare and other industries to enhance precision targeting, optimize channel performance, and accelerate meaningful engagement with both healthcare professionals and patients.

"To be selected by Achieve to help address a major public health crisis is truly an honor," said Michael Collins, President, Health & Wellness for Omnicom Advertising Collective. "Over the past several years, Achieve Life Sciences has been singularly focused on preparing to transform the nicotine dependence market and we are deeply committed to building a best-in-class approach with top talent and tools from across the network to help Achieve realize the full potential of cytisinicline."

Along with Credera, to deliver a comprehensive and connected commercialization strategy, Omnicom has assembled a unified agency team drawing on specialized talent from Goodby, Silverstein & Partners, DDB Health, and Ketchum Health. This cross-functional team will provide expertise in consumer brand development, medical education, and strategic public relations and communications, applying proven insights from across industries to support a launch strategy designed to set a new standard for biopharma commercialization.

Xinos continued, "As an emerging biopharma company, we recognize we can't follow the traditional playbook historically used to launch new medicines. We're designing a launch platform that's purpose-built for a company bringing its first product to market in today's environment. It leverages data-driven insights to guide decisions and deploy resources with precision, agility, and efficiency. These aren't untested ideas—they're established best practices in marketing excellence, and we're applying them with focus and intent to drive value across our stakeholders."

Smoking remains the leading cause of preventable death and disease in the U.S., with over 29 million adults still smoking. Achieve has successfully completed two Phase 3 studies with cytisinicline for smoking cessation and has fully enrolled its ongoing open-label safety study. Achieve announced it submitted its new drug application (NDA) for cytisinicline as a treatment of nicotine dependence for smoking cessation on June 25, 2025. If approved, Achieve aims to help address this ongoing public health crisis by making cytisinicline available to those ready to quit and providing them with a new, evidence-based path to cessation.

Achieve's collaboration with Omnicom enables the integration of innovative technologies like generative AI, predictive analytics and social listening to enhance targeting and personalization and will also include partnerships with healthcare apps, pharmacies, and data providers to expand the reach and depth of insights, making Achieve's approach uniquely comprehensive.

"We're so proud to have been chosen by Achieve Life Sciences and to be part of history by addressing one of the biggest public health issues of our time and applying our latest technologies and offerings to ensure a highly successful launch," said Michele Markus, Head of Global Health Accounts for Omnicom. "This issue is personal for many of us and the commitment and dedication of our integrated team reflects our belief in their mission – one we know has the ability to significantly save and change lives."

About Achieve

Achieve Life Sciences is a late-stage specialty pharmaceutical company committed to addressing the global smoking health and nicotine dependence epidemic through the development and commercialization of cytisinicline. In June 2025, the company submitted its New Drug Application to the FDA for cytisinicline as a treatment of nicotine dependence for smoking cessation in adults, based on two successfully completed Phase 3 studies and its fully enrolled open-label safety study. Additionally, the company has completed a Phase 2 study with cytisinicline in vaping cessation and conducted a successful end-of-Phase 2 meeting with the FDA for a future vaping indication.

About Cytisinicline

There are approximately 29 million adults in the United States 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 approximately 17 million adults in the United States who use ecigarettes, also known as vaping.⁴ In 2024, approximately 1.6 million middle and high school students in the United States reported using e-cigarettes.⁵ There are no FDA-approved treatments indicated specifically as an aid to nicotine e-cigarette cessation. Cytisinicline has been granted Breakthrough Therapy designation by the FDA to address this critical need.

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 nicotine craving symptoms, and reducing the reward and satisfaction associated with nicotine products. Cytisinicline is an investigational product candidate being developed as a treatment of nicotine dependence for smoking cessation and has not been approved by the Food and Drug Administration for any indication in the United States.

About Omnicom Group Inc.

Omnicom Group Inc. (NYSE: OMC) (<u>www.omnicomgroup.com</u>) is a leading global marketing and corporate communications company. Omnicom's branded networks and numerous specialty firms provide advertising, strategic media planning and buying, digital and interactive marketing, direct and promotional marketing, public relations and other specialty communications services to over 5,000 clients in more than 70 countries. Follow us on <u>X</u> for the latest news.

About Goodby, Silverstein & Partners

At Goodby Silverstein & Partners, we believe in mass intimacy—creating campaigns that speak to millions but feel like they're made just for you. We combine brilliant strategy, breakthrough creativity and the innovative use of technology to build enduring ideas that drive results for some of the world's most iconic brands. While maintaining our independent spirit, our network affiliation provides global scale and access to proprietary tools and discipline-specific specialists including PR, multicultural, experiential and media. Visit us at <u>goodbysilverstein.com</u>.

About DDB Health

DDB Health is a global network of healthcare communications companies. At DDB Health we are 100% dedicated to healthcare, particularly in the specialty science space. DDB Health specializes in HCP promotions, including brand and campaign development, insight/data generation, portfolio management, scientific branding, and market-shaping activities, ensuring customers are educated in the latest advancements to help them engage effectively with patients and caregivers. We are uniquely supported by a range of specialized services, including multichannel engagement, innovation experts, strategic planning, medical execution, and data and analytics. As a part of Omnicom Health, DDB Health has access to in-network resources with expertise in payer, media, and medical education. Visit us at <u>ddbhealth.com</u>.

About Credera

Credera is a global, boutique consulting firm that creates measurable results at the intersection of strategy, data, innovation, and technology. Credera works with leading companies across the globe from strategy through execution at offices in 16 countries. Credera's deep business acumen and technical expertise, combined with a true dedication to building trusted relationships, unlocks remarkable performance for our clients. Our mission is to make an extraordinary impact on our clients, our people, and our communities. Visit us at <u>Credera</u>.

About Ketchum

Established in 1923, Ketchum's century of continuous evolution is a testament to our progress. Our storied journey is fueled by our guiding principles of empathy and intelligence. Progress allows us to create a thriving environment where we embrace innovation and deliver excellence with our people and partners, producing work that matters. Driven by data, we develop culture-first work at the intersection of industry and capability. With 150+ Cannes Lions, our global communications consultancy is one of the most creatively awarded firms in our industry. We are Ketchum: Progress at Work. For more information on Ketchum, a part of Omnicom PR Group, visit <u>www.ketchum.com</u>.

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, data results and commercialization activities, the potential market size for cytisinicline, the potential benefits, efficacy, safety and tolerability of cytisinicline, the development and effectiveness of new treatments, and the successful commercialization 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 forwardlooking 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 and commercialization of cytisinicline; the risk that cytisinicline will not receive regulatory approval in a timely manner or at all, or be successfully commercialized; the risk that new developments in the smoking and vaping cessation landscapes 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 and geopolitical conditions, including fluctuating inflation, interest and tariff rates, volatility in the debt and equity markets, actual or perceived instability in the global banking system, global health crises and pandemics and geopolitical conflict 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.

Achieve Contact

Nicole Jones

ir@achievelifesciences.com 425-686-1510

References

¹VanFrank B, Malarcher A, Cornelius ME, Schecter A, Jamal A, Tynan M. Adult Smoking Cessation — United States, 2022. MMWR Morb Mortal Wkly Rep 2024;73:633–641.

²World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization, 2017.

³U.S. Department of Health and Human Services. The Health Consequences of Smoking – 50 Years of Progress. A Report of the Surgeon General, 2014.

⁴Vahratian A, Briones EM, Jamal A, Marynak KL. Electronic cigarette use among adults in the United States, 2019–2023. NCHS Data Brief, no 524. Hyattsville, MD: National Center for Health Statistics. 2025. DOI: <u>https://dx.doi.org/ 10.15620/cdc/174583</u>.

⁵Jamal A, Park-Lee E, Birdsey J, et al. Tobacco Product Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:917–924.



Source: Achieve Life Sciences