



Jaguar Launches Mental Health Entheogen Therapeutics Initiative to Develop Novel, Natural Prescription Medicines Derived from Psychoactive Plants

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Initiative includes leading ethnobotanists and will leverage Jaguar's plant-based medicines expertise and proprietary library of 2,300 medicinal plants

Jaguar and its subsidiary Napo Pharmaceuticals uniquely suited to lead this effort based on successful development and commercialization of Napo's Mytesi® (crofelemer), the first-and-only oral plant-based prescription medicine to receive FDA approval under FDA Botanical Guidance

SAN FRANCISCO, CA / ACCESSWIRE / September 3, 2020 / Jaguar Health, Inc. (NASDAQ:JAGX) announced today the launch of its mental health Entheogen Therapeutics Initiative (ETI) that aims to discover and develop groundbreaking, novel, natural medicines derived from psychoactive plants for treatment of mood disorders, neuro-degenerative diseases, addiction, and other mental health disorders. The initiative will initially focus on plants from the company's proprietary library of 2,300 plants, with the objective of identifying plants that may have the potential to treat mood disorders, including depression, which affects more than 264 million people of all ages around the globe, according to the World Health Organization. Though the market for antidepressants is expected to reach \$19 billion by 2023 and is dominated by selective serotonin reuptake inhibitor (SSRI) drugs, an estimated 30 percent of patients are not effectively treated with SSRIs.

Jaguar is in the process of engaging medicinal tropical scientific strategy team advisors, including ethnobotanists, physicians, pharmacologists, chemists, and experts in neuropharmacology, from around the world and intends to seek corporate partnerships with companies devoted to bringing novel, plant-based psychoactive therapies to patients with mental health conditions in a safe and effective manner, and in a manner that benefits Indigenous peoples and local communities.

"Jaguar is excited to be leading this effort to potentially uncover a pipeline of novel psychoactive plant-based compounds from our library and engaging with our advisors and potential corporate partners to develop these compounds into possible medical breakthroughs," said Lisa Conte, Jaguar's president and CEO. "Clinical research has shown that psychoactive plant-based compounds provide novel mechanisms to potentially provide meaningful healing benefit - not just disease modification, as is the case with SSRIs - to patients suffering from a variety of mental health conditions."

"While we remain steadfastly focused on the commercial success of Mytesi and on the development of crofelemer follow-on indications in the area of GI health, we believe the same competencies and multi-disciplinary scientific strategy that led to the development of crofelemer will support collaborative efforts with potential partners to discover and develop novel first-in-class prescription medicines derived from psychoactive plants," Conte said.

Dr. Elaine Elisabetsky, a professor in the pharmacology and biochemistry departments of the Universidade Federal do Rio Grande do Sul in Brazil who was a member of the original scientific strategy team that contributed to the development of Jaguar's plant library, has joined the Entheogen Therapeutics Initiative as a scientific strategy advisor. Dr. Elisabetsky is a highly regarded ethnopharmacologist and the co-author of the book *Medicinal Resources of the Tropical Forest*.

"I am very delighted to continue this dynamic interdisciplinary research process to discover novel therapies for managing mental health conditions from psychoactive plants that have been utilized by traditional healers for centuries. My field research collaborations in the past have yielded exciting new applications for compounds from a plant used by traditional healers in Nigeria, such as alstonine, which has already demonstrated a potential novel mechanism of action for the treatment of difficult to manage conditions such as schizophrenia. The ability to collaborate with colleagues to analyze the rich collection of data from Jaguar's library of 2,300 plants - which may include other promising leads for new treatments for a variety of neurological conditions - is an exciting fit to my ongoing scientific focus as an ethnopharmacologist," said Dr. Elisabetsky.

The Growing Market for Medicines Derived from Psychoactive Plants

According to the [World Health Organization](#), one in four people in the world will be affected by mental or neurological disorders at some point in their lives. Around 450 million people currently suffer from such conditions, placing mental disorders among the leading causes of ill-health and disability worldwide. Common mental health conditions include depression, PTSD, anxiety, addiction, bipolar disorder (formerly called manic-depressive illness or manic depression), and anorexia nervosa, and expand to include neuro-degenerative diseases such as Parkinson's, Alzheimer's disease, and ALS (amyotrophic lateral sclerosis), among others. Substance use disorders occur when the recurring use of alcohol and/or drugs causes clinically significant impairment, including health problems, disability, and failure to meet major responsibilities at work, home, or school. The Lancet Commission, a group of experts in neuroscience, psychiatry, public health, and related fields, estimates that the cost of mental disorders, currently on the rise in every country, will reach \$16 trillion by 2030, including costs associated with lost productivity.

Clinical research using psychoactive plants is beginning to show positive results. Psilocybin, the psychoactive ingredient found in more than 200 species of mushrooms, received [Breakthrough Therapy designation](#) from the U.S. Food and Drug Administration (FDA) in 2018 for treatment resistant depression and in 2019 for major depressive disorder, and MDMA (midomafetamine) received Breakthrough Therapy designation from FDA for posttraumatic stress disorder in 2017. MC-18, a chemical modification of the active chemical component in certain hallucinogenic plants and the recently approved chemical component in Johnson & Johnson subsidiary Janssen Pharmaceuticals' nasal spray Spravato® (esketamine), is a synthetic analog to the "club drug" ketamine. Spravato received [Fast Track](#) and Breakthrough Therapy designations from FDA and is the first novel non-SSRI antidepressant approved by the FDA in more than 20 years.

Plant-derived psychoactive compounds appear to have a novel mechanism of action that targets higher regions of the brain than the most widely used SSRI class. These higher regions of the brain are believed to be where the pathology/biology of depression lies.

There appears to be growing enthusiasm among patients and the healthcare community for pure compounds derived from psychoactive plants, likely because of encouraging clinical trial results, and a survey of 2,000 Americans conducted by OnePoll found one in two of those surveyed have eschewed more traditional medicine in favor of natural alternatives.

Leveraging Jaguar's Library of 2,300 Medicinal Plants

Jaguar's library of approximately 2,300 medicinal plants from tropical regions comprises a unique asset to drive drug discovery. The plant collection was assembled over a decade by integrated ethnobotanist physician teams who conducted primary, first-hand field investigations and plant identification work in rainforest regions around the globe in addition to gathering data about traditional medicinal uses of plants from shamans and other Indigenous healers. Jaguar also has FDA-approved commercial GMP manufacturing systems in place, which has allowed the company to take crofelemer from a plant sustainably harvested in the rainforest to a pure compound and finished, FDA-approved prescription product, Mytesi, a non-opioid antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy.

"Our team has always recognized and valued the unique and powerful knowledge Indigenous and traditional peoples have about plants, ecosystems, and healing compounds," said Steven King, Ph.D., Jaguar's chief sustainable supply and ethnobotanical research officer. "We look forward to continuing our mission to advance sustainably derived plant-based medicines while establishing a responsible harvesting program to ensure both quality and ecological integrity."

Jaguar's library contains plant specimens gathered from Central America, South America, Africa, and South East Asia, including a broad diversity of plant extracts from roots, shrubs, bark, leaves, fruits and seeds.

Many members of the scientific strategy team that contributed to the development of Jaguar's plant library were trained by the late Dr. Richard Evans Schultes, who is often referred to as the father of modern ethnobotany. Dr. Schultes was the Jeffrey Professor of Biology and Director of the Botanical Museum of Harvard University. He conducted field studies for 48 years during his career, much of that time in the Colombian Amazon. He focused his research on medicinal, psychoactive plants and new sources of rubber, and investigated a wide diversity of psychoactive plants including but not limited to peyote, psilocybin mushrooms, viola snuffs, as well as Ayahuasca and its many admixtures.

About Jaguar Health, Inc. and Napo Pharmaceuticals, Inc.

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, plant-based, non-opioid, and sustainably derived prescription medicines for people and animals with GI distress, specifically chronic, debilitating diarrhea. Our wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human gastrointestinal pharmaceuticals from plants harvested responsibly from rainforest areas. Our Mytesi® (crofelemer) product is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy and the only oral plant-based prescription medicine approved under FDA Botanical Guidance.

For more information about Jaguar, please visit <https://jaguar.health>. For more information about Napo, visit www.napopharma.com.

About Mytesi®

Mytesi (crofelemer) is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). Mytesi is not indicated for the treatment of infectious diarrhea. Rule out infectious etiologies of diarrhea before starting Mytesi. If infectious etiologies are not considered, there is a risk that patients with infectious etiologies will not receive the appropriate therapy and their disease may worsen. In clinical studies, the most common adverse reactions occurring at a rate greater than placebo were upper respiratory tract infection (5.7%), bronchitis (3.9%), cough (3.5%), flatulence (3.1%), and increased bilirubin (3.1%).

See full Prescribing Information at Mytesi.com. Crofelemer, the active ingredient in Mytesi, is a botanical (plant-based) drug extracted and purified from the red bark sap of the medicinal *Croton lechleri* tree in the Amazon rainforest. Napo has established a sustainable harvesting program for crofelemer to ensure a high degree of quality and ecological integrity.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements related to expectations that the market for antidepressants will reach \$19 billion by 2023, Jaguar's plans to seek corporate partnerships with companies devoted to bringing novel, plant-based psychoactive therapies to patients with mental health conditions, the belief that the same competencies and multi-disciplinary scientific strategy that led to the development of crofelemer will support collaborative efforts with potential partners to discover and develop novel first-in-class prescription medicines derived from psychoactive plants, the belief that Jaguar's library of approximately 2,300 plants may include promising leads for new treatments for a variety of neurological conditions, the projection that the cost of mental disorders will reach \$16 trillion by 2030, including costs associated with lost productivity, and the belief that Jaguar's library of approximately 2,300 medicinal plants comprises a unique asset to drive drug discovery. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "aim," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this release are only predictions. Jaguar has based these forward-looking statements largely on its current expectations and projections about future events. These forward-looking statements speak only as of the date of this release and are subject to several risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond Jaguar's

control. Except as required by applicable law, Jaguar does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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