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Gilgamesh Pharma Wins $14M Grant to Develop Safer Ibogaine for Opioid Disorder

Grant to support IND-enabling toxicology and Phase 1/1b development of novel cardiac-safe ibogaine analog, GM-3009

Gilgamesh Pharmaceuticals, a clinical-stage neuroscience company committed to developing best-in-class, rapid-acting treatments for mental health disorders, today announced that it has been awarded a multi-year $14 million grant from the National Institute on Drug Abuse (NIDA) to develop GM-3009, its novel, cardiac-safe ibogaine analog for the treatment of substance use disorders. As summarized in a recent New York Times article (Powerful Psychedelic Gains Renewed Attention as a Treatment for Opioid Addiction), ibogaine, a plant-derived psychoactive compound, has accumulated data from trials and case reports that point to its robust efficacy as a treatment for substance use disorders. However, the development of ibogaine as a pharmaceutical has long been hindered by its significant cardiovascular toxicity.

This grant provides non-dilutive funding to support IND-enabling toxicology studies, GMP manufacturing, and Phase 1/1b clinical trials in healthy volunteers and opioid use disorder (OUD) patients for GM-3009. The planned clinical work will seek to confirm that GM-3009 eliminates the cardiovascular risks associated with ibogaine and demonstrate proof-of-concept efficacy in attenuating symptoms associated with OUD. Following completion of the funded development, GM-3009 will be ready to enter larger Phase 2 efficacy studies.

GM-3009 represents a potential pivotal advance in the fight against the opioid epidemic, which claimed the lives of more than 100,000 Americans in 2023, as a rapid-acting, effective, durable, and safe treatment. Gilgamesh's novel approach mitigates the known cardiovascular risks of ibogaine, while potentially increasing its efficacy. GM-3009 may revolutionize the treatment of OUD.

Jonathan Sporn, CEO of Gilgamesh, commented on the significance of this grant, "Receiving this grant from NIDA is an important endorsement of Gilgamesh's scientific rigor and commitment to addressing one of the most pressing public health crises of our time. By funding these critical early-stage studies, NIDA is facilitating the translation of innovative scientific research into tangible treatments that can significantly impact public health."

GM-3009 is part of a library of more than 200 ibogaine analogs from multiple scaffolds developed by Gilgamesh founders Andrew Kruegel and Dalibor Sames, Professor of Chemistry at Columbia University, and licensed from Columbia.

"Dr. Sames has deep expertise in the therapeutic effects of ibogaine, having researched compounds in this class for over 15 years," said Beth Kauderer, Senior Technology Licensing Officer at Columbia Technology Ventures. "We are pleased this grant from NIDA will advance GM-3009 to the clinic, allowing the discoveries made by Dr. Sames to be one step closer to benefitting patients suffering from addiction."

This funding not only accelerates Gilgamesh's research but also shines a spotlight on the importance of cutting-edge science in identifying and advancing therapeutic solutions that can overcome the limitations of current treatments. As Gilgamesh moves forward with its clinical trials, the company is poised to lead a new era in addiction treatment, marked by safer, more effective, and scientifically validated therapies.

Source & Image Credit: Gilgamesh Pharmaceuticals

Published on : Thu, 14 Mar 2024