

PRESS RELEASE

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Entity: MitoPower, LLC

Contact: David Murphy

Phone:+1-858-774-9052

Email: dm@nventmarketing.com

Entity: Institute of Human Virology

Contact: Nora Samaranayake

Phone:+1-443-823-0613

Email: nsam@ihv.umaryland.edu

6.5M SBIR Grant Awarded to IHV and MitoPower

Novel Treatment for Alcoholic Liver Disease-Associated Kidney Dysfunction to be Developed

Baltimore, MD and Palo Alto, CA — November 5, 2021 — [The Institute of Human Virology \(IHV\)](#) at the University of Maryland School of Medicine and [MitoPower LLC](#) (“MitoPower”) were awarded an SBIR (Small Business Innovation Research) grant of up to \$6.5 million over five years from the National Institutes of Health’s National Institute on Alcohol Abuse and Alcoholism. The funds will support the development of MitoPower’s lead compound, MP-04, for the treatment of kidney dysfunction due to alcoholic liver disease, a condition known as alcoholic liver disease associated hepatorenal syndrome (HRS). The IHV, a Center of Excellence of the Global Virus Network (GVN), will conduct first-in-human single and multiple ascending dose studies to test the safety of the compound, followed by a Phase 1b study in patients.

“There are no current therapeutic options that specifically address the cellular dysfunction and systemic inflammatory response that contribute to the severe impairment of liver and kidney function and progressive organ failure in patients with severe alcoholic hepatitis,” said Mani Subramanian, MD, PhD and CEO of MitoPower LLC. “We are working to complete IND-enabling studies for MP-04 and are excited to collaborate with IHV to characterize this promising compound in human studies.”

More than 250,000 hospitalizations each year in the U.S. are due to complications of alcoholic liver disease. HRS is an acute complication of cirrhosis (liver scarring) or a severe alcoholic hepatitis (liver inflammation) progressive condition leading to kidney failure. HRS is associated with mortality rates reaching 50%, with many patients requiring invasive treatments such as dialysis and/or liver transplant. MitoPower's MP-04 is a small molecular therapeutic that has shown promising results in pre-clinical studies modulating inflammatory response associated with HRS.

"There is an urgent, unmet need for an effective therapy to treat HRS caused by severe alcoholic hepatitis and cirrhosis. Globally, the incidence and prevalence of alcoholic liver disease continues to increase and remains a significant cause of liver failure and liver transplantation," said Prof. Shyam Kottlilil, MBBS, PhD, Professor of Medicine and Director of the Division of Clinical Care and Research, Institute of Human Virology at the University of Maryland School of Medicine and senior advisor to the Global Virus Network (GVN). "MP-04 is a novel therapeutic that has shown promise in preclinical studies to reverse organ dysfunction and systemic inflammatory response syndrome (SIRS) holds promise in potentially reversing HRS."

"The Institute is pleased to see our Clinical Trials Unit's portfolio continue to grow under the terrific leadership of Prof. Kottlilil," said Prof. Robert Gallo, MD, The Homer & Martha Gudelsky Distinguished Professor in Medicine, Co-Founder & Director of the Institute of Human Virology at the University of Maryland School of Medicine, and Co-Founder and International Scientific Director of the Global Virus Network (GVN). "While we continue to focus on therapeutics for viruses such as HIV and SARS-CoV-2, it is also important that we research innovations that can combat devastating chronic illnesses, such as liver disease and kidney dysfunction."

Dean [E. Albert Reece, MD, PhD, MBA](#), Executive Vice President for Medical Affairs, UM Baltimore, and the John Z. and Akiko K. Bowers Distinguished Professor of UMSOM said: "HRS affects many Native American and Alaskan Natives disproportionately, and Black and Mexican Americans are more likely to suffer worse outcomes. Developing an effective treatment will be the first step in finding a way to address these disparities."

This award was granted by the National Institutes of Health under Award Number U44 AA029833. The content of this press release is solely the responsibility of the author and does not necessarily represent the official views of the NIH.

About MitoPower: Palo Alto, California-based MitoPower, LLC is a biopharmaceutical company established in 2017 to develop novel therapies to treat disorders associated with mitochondrial dysfunction. MitoPower maintains numerous academic collaborations in the context of energy metabolism, liver biology and immune function. It has working relationships with world-class CROs in pharmaceutical development, pre-clinical pharmacology, and toxicology. The company's leadership team has deep experience in drug discovery, along with the development, commercialization, and financing of pharmaceutical ventures. Its advisors bring expertise in medicinal chemistry, pharmacology, toxicology, and regulatory matters. For more information about MitoPower, visit www.mitopower.com.

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David Murphy

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dm@nventmarketing.com

About the Institute of Human Virology: Formed in 1996 as a partnership between the State of Maryland, the City of Baltimore, the University System of Maryland, and the University of Maryland Medical System, the IHV is an institute of the University of Maryland School of Medicine and is home to some of the most globally-recognized and world-renowned experts in all of virology. The IHV combines the disciplines of basic research, epidemiology, and clinical research in a concerted effort to speed the discovery of diagnostics and therapeutics for a wide variety of chronic and deadly viral and immune disorders - most notably, HIV the virus that causes AIDS. For more information, visit www.ihv.org and follow us on Twitter @IHVmaryland.

About the University of Maryland School of Medicine: Now in its third century, the University of Maryland School of Medicine was chartered in 1807 as the first public medical school in the United States. It continues today as one of the fastest growing, top-tier biomedical research enterprises in the world -- with 46 academic departments, centers, institutes, and programs, and a faculty of more than 3,000 physicians, scientists, and allied health professionals, including members of the National Academy of Medicine and the National Academy of Sciences, and a distinguished two-time winner of the Albert E. Lasker Award in Medical Research. With an operating budget of more than \$1.2 billion, the School of Medicine works closely in partnership with the University of Maryland Medical Center and Medical System to provide research-intensive, academic and clinically based care for

nearly 2 million patients each year. The School of Medicine has nearly \$600 million in extramural funding, with most of its academic departments highly ranked among all medical schools in the nation in research funding. As one of the seven professional schools that make up the University of Maryland, Baltimore campus, the School of Medicine has a total population of nearly 9,000 faculty and staff, including 2,500 students, trainees, residents, and fellows. The combined School of Medicine and Medical System ("University of Maryland Medicine") has an annual budget of over \$6 billion and an economic impact of nearly \$20 billion on the state and local community. The School of Medicine, which ranks as the 8th highest among public medical schools in research productivity (according to the Association of American Medical Colleges profile) is an innovator in translational medicine, with 606 active patents and 52 start-up companies. In the latest U.S. News & World Report ranking of the Best Medical Schools, published in 2021, the UM School of Medicine is ranked **#9** among the 92 public medical schools in the U.S., and in the top 15 percent (**#27**) of all 192 public and private U.S. medical schools. The School of Medicine works locally, nationally, and globally, with research and treatment facilities in 36 countries around the world. Visit medschool.umaryland.edu

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Nora Samaranayake

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nsam@ihv.umaryland.edu