

Press Release

# Enveric Biosciences and University of Calgary Collaborate on a Groundbreaking Clinical Trial for EVM-101 in Cancer Related Distress

February 17, 2022

*Clinical trial aim is to include the identification and characterization of the Cancer Related Distress symptoms most responsive to psychedelic-associated therapy*

NAPLES, Fla., Feb. 17, 2022 /CNW/ – [Enveric Biosciences](#) (NASDAQ: ENVB) (“Enveric” or the “Company”), a cutting-edge neuroscience company developing next-generation, psychedelic-inspired mental health medicines, is working with the University of Calgary’s [Hotchkiss Brain Institute](#) (“HBI”), a leading neurosciences center of excellence, at the Cumming School of Medicine in Calgary, Canada that is dedicated to advancing brain and mental health research and education, to establish a groundbreaking clinical trial of EVM-101 for the treatment of Cancer Related Distress (“CRD”).

Approximately 50% of cancer patients report clinical levels of psychological distress having depressed mood, anxiety, demoralization, stress-induced clinical manifestations, and reduced quality of life<sup>1</sup>. Up to 40% of cancer patients meet the criteria for a mood disorder requiring treatment<sup>2</sup>. CRD is a significant unmet medical need with no current regulatory approval of pharmacotherapies and an urgent need to optimize the current standard of care for patients with cancer.<sup>3</sup>

A clinical trial, expected to launch later this year, of EVM-101, a first-generation psychedelic treatment, for CRD will be led by HBI researcher, Dr. Valerie Taylor, Head of the Department of Psychiatry, in Calgary, Canada.

“We are excited to collaborate with Enveric to study next-generation medicines that we hope will help people cope with the mental health challenges of a cancer diagnosis. This work will allow us to mobilize our combined resources to research options for cancer patients living with CRD,” says Dr. Valerie Taylor.

The EVM-101 study will directly assess the core features of CRD that are most affected and amenable to improvement following a psilocybin-based treatment.

“With the rising rates of cancer and its associated psychological ailments that have been underestimated and underdiagnosed until recently, we are working hard to develop new treatments that help cancer patients suffering from CRD” said Dr. Bob Dagher, Enveric’s Chief Medical Officer. “Our collaboration with the research team at the University of Calgary’s Hotchkiss Brain Institute and IMPACT Clinical Trial Accelerator will help us to demonstrate the potential benefits of these novel treatments and get them to market as quickly as possible.”

A regulatory submission to Health Canada is expected to soon be finalized. Patient enrollment in the clinical trial is expected to begin late in 2022 or early in 2023. The study design will employ proprietary psychiatry and psychotherapy-focused treatments for cancer patients with CRD. Patients will receive a single oral dose of EVM-101 in a supportive environment with psychotherapy to improve outcomes.

Enveric is committed to discovering and developing more effective treatments for cancer patients living with psychological distress and is currently working on three classes of new medicines: EVM-101, a first-generation oral psilocybin; EVM-201, a second-generation pro-drug; and EVM-301, a third-generation psychedelic-inspired and optimized new molecule.

#### References:

1. Mehnert, A., Hartung, T. J., Friedrich, M., Vehling, S., Brahler, E., Harter, M., et al. (2018). One in two cancer patients is significantly distressed: prevalence and indicators of distress. *Psychooncology* 27, 75-82. Doi: 10.1002/pon.4464
2. Holland et al. (2013). Distress Management. *J Natl Compr Cancer Network* 2013 Feb 1;11(2):190-209. doi: 10.6004/jnccn.2013.0027
3. Peters, L., Brederecke, J., Franzke, A., Zwaan, M., Zimmermann, T. (2020). Psychological Distress in a Sample of Inpatients with Mixed Cancer-A Cross-Sectional Study of Routine Clinical Data. *Front Psychol.* 2020 Nov 30; 11:591771. doi: 10.3389/fpsyg.2020.591771

#### About Enveric Biosciences

Enveric Biosciences (NASDAQ: ENVB) is a cutting-edge neuroscience company developing next-generation psychedelic-inspired mental health medicines. Enveric's robust pipeline supports drug development from the clinic to commercialization for millions of patients in need around the world suffering from conditions that include cancer-related distress, PTSD, and more. For more information, please visit [www.enveric.com](http://www.enveric.com).

#### About Hotchkiss Brain Institute

The Hotchkiss Brain Institute is an internationally recognized center of excellence in brain and mental health research and education, based at the University of Calgary's Cumming School of Medicine. The Hotchkiss Brain Institute was launched in October 2004 by a foundational gift from Calgary's own Hotchkiss family, the late Harley Hotchkiss, well-known entrepreneur, supporter of neuroscience research, and key founder of the Calgary Flames. The Institute is devoted to understanding the mechanisms and impact of brain injury, disease, disorders and mental health. Today the HBI is composed of nearly 1400 people, including over 220 members spanning 12 academic departments and nine faculties at the University of Calgary, all working towards a shared vision: Healthy Brains for Better Lives. [www.hbi.ucalgary.ca](http://www.hbi.ucalgary.ca)

#### About IMPACT Clinical Trials Accelerator

IMPACT is a program for new ventures in the life sciences or biomedical industries who are seeking guidance in conducting clinical trials to secure regulatory approval for their new health-related inventions. IMPACT disrupts traditional healthcare innovation by accelerating marketing approval via a tailored evidence collection and regulatory framework. [research.ucalgary.ca/innovation/ecosystem/impact-clinical-trials-accelerator](http://research.ucalgary.ca/innovation/ecosystem/impact-clinical-trials-accelerator)

#### Forward-Looking Statements

This press release contains forward-looking statements and forward-looking information within the meaning of applicable securities laws. These statements relate to future events or future performance. All statements other than statements of historical fact may be forward-looking statements or information. Generally, forward-looking statements and information may be identified by the use of forward-looking terminology such as "plans", "expects" or "does not expect", "proposed", "is expected", "budgets", "scheduled", "estimates", "forecasts", "intends", "anticipates" or "does not anticipate", or "believes", or variations of such words and phrases, or by the use of words or phrases which state that certain actions, events or results may, could, would, or might occur or be achieved. Forward-looking statements consist of statements that are not purely historical, including any statements regarding

beliefs, plans, expectations, or intentions regarding the future. Such forward-looking statements are based on the beliefs of management as well as assumptions made by and information currently available to management. Actual results could differ materially from those contemplated by the forward-looking statements as a result of certain factors, including, but not limited to, the ability to achieve the value creation contemplated by technical developments; the impact of the novel coronavirus (COVID-19) on Enveric's ongoing and planned clinical trials; the geographic, social and economic impact of COVID-19 on Enveric's ability to conduct its business and raise capital in the future when needed; delays in planned clinical trials; the ability to establish that potential products are efficacious or safe in preclinical or clinical trials; the ability to establish or maintain collaborations on the development of therapeutic candidates; the ability to obtain appropriate or necessary governmental approvals to market potential products; the ability to obtain future funding for developmental products and working capital and to obtain such funding on commercially reasonable terms; Enveric's ability to manufacture product candidates on a commercial scale or in collaborations with third parties; changes in the size and nature of competitors; the ability to retain key executives and scientists; and the ability to secure and enforce legal rights related to Enveric's products, including patent protection. A discussion of these and other factors, including risks and uncertainties with respect to Enveric, is set forth in Enveric's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Enveric disclaims any intention or obligation to revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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