

Emerald Bioscience Reports that Superior Reduction of Intraocular Pressure of its Unique Nanoemulsion Formulation of THCVHS is Published in Peer-Reviewed Journal

***Drug Delivery and Translational Research* article highlights significantly better drug load and duration of activity of prodrug of THC compared to leading commercial drugs for treating glaucoma**

San Diego, Calif., Dec. 16, 2020 (GLOBE NEWSWIRE) -- Emerald Bioscience, Inc. (OTCQB: EMBI) (“Emerald” or the “Company”), a preclinical biopharmaceutical company focused on developing proprietary molecules with strong clinical and commercial differentiation, announced the publication of a peer-reviewed paper reporting that THCVHS, the Company’s novel THC prodrug, was optimized through a nanoemulsion formulation (THCVHS-NE) for drug delivery into the eye and demonstrated significantly better reduction of intraocular pressure (IOP) compared to the commercially approved standard of care in normotensive rabbits.

Response was determined by measuring reduction in IOP from baseline following a single treatment with either THCVHS-NE (1% w/v), latanoprost (0.005% w/v), or timolol (0.25% w/v), which was measured every 30 minutes post-treatment up to 180 minutes, followed by measurements at 240, 360 and 480 minutes post-treatment. Duration of response was determined as the time required for IOP to return to 90% of baseline. THCVHS-NE achieved a maximum drop in IOP of 23% compared to latanoprost (13%) and timolol (14%). In addition, duration of response for THCVHS-NE was ≤480 minutes, compared to latanoprost (≤360 minutes) and timolol (≤90 minutes) ($p < 0.05$) in normotensive rabbits. Therefore, a nanoemulsion formulation of THCVHS appears to not only be more effective at reducing IOP, but also has a longer duration of response when compared to standard of care treatment for glaucoma.

The article, entitled “Effect of surfactant concentration and sterilization process on intraocular pressure–lowering activity of Δ^9 -tetrahydrocannabinol- valine-hemisuccinate (NB1111) nanoemulsions,” authored by Sweeney, C., Dudhipala, N., Thakkar, R. et al, was published in the November 2020 issue of *Drug Delivery and Translational Research*. The experiments were conducted by researchers at the University of Mississippi.

“Our aim is to be able to offer ophthalmologists and their patients a superior new class of treatment for glaucoma, with better intraocular-pressure-lowering activity to prevent vision loss. The intriguing scenario is that THC’s ability to lower intraocular pressure is already validated – we know it works, based on prior human studies! We also know, however, that to successfully employ THC as a good medicine for glaucoma we need to have an effective

method of local delivery into the eye, consistent with the American Academy of Ophthalmology's recommendation against systemic use of cannabis to manage glaucoma. This is precisely what our drug offers," said Punit Dhillon, CEO of Emerald.

"What is additionally and particularly notable is that our unique, synthetic bioengineered THCVHS molecule has potential capabilities that current treatments are unable to provide. A large percentage of glaucoma patients do not experience increased IOP but nevertheless experience vision loss believed to result from other neurodegenerative effects on the cells of the optical nerve. THC is also known to have neuroprotective properties. If our drug can protect against vision loss in patients with normal IOP as well, we would have an extraordinary new solution to offer for the prevention of glaucoma-related vision loss.

"We are working to complete our preclinical work in the near term and then start our planned human study in the third quarter of 2021. The nature of this disease will allow us to simultaneously provide safety and early efficacy outcomes in a first human study that is relatively fast and low-cost compared to the typical realization of such results in the clinical trial process," added Mr. Dhillon.

This study assessed alternative formulations of Emerald's optimized THCVHS-loaded formulation compared to leading glaucoma drugs latanoprost and timolol with respect to their delivery and drug loading into the eye, including into the anterior segments of the eye, along with the extent and duration of lowering intraocular pressure. This research also compared variations of different carrier oils, surfactants, and co-surfactants. Importantly, the study showed the formulation could be sterilized without detrimentally impacting its pharmaceutical activity (a common challenge faced in the design and manufacturing of pharmaceutical drugs), which is an important step in manufacturing a drug for human use. Based on the foundational data reported in this publication, additional formulation work has further extended the drug's residence time in the eye and further enhanced the duration of IOP lowering activity. This is the formulation Emerald is moving forward into additional planned preclinical IND enabling studies and its planned human study.

About Glaucoma and THCVHS

Glaucoma leads to progressive damage to the optic nerve through various mechanisms, such as increased pressure within the eye, decreased blood flow, or poor drainage of fluids, which can lead to vision loss and is the leading cause of irreversible blindness. Prolonged elevated IOP within the eye that is higher than the tolerance pressure of the retinal ganglion cell (RGC) results in the degeneration of the RGCs. Once RGCs are damaged they are not regenerated, which is why glaucoma is known as a silent disease - there are no major warning signs until vision loss begins. A meta-analysis estimated that 76 million people worldwide have glaucoma in 2020, and this number will increase to 111.8 million by 2040 (Global prevalence of glaucoma and projections of glaucoma burden through 2040. *Ophthalmology*. 2014;121:2081–90).

Current commercialized IOP-lowering drugs are unable to provide complete and long-term solutions to lower IOP. Patients eventually switch or combine drugs in an attempt to extend their utility.

THC has been validated as a potentially effective IOP-lowering new class of anti-glaucoma medication. Unfortunately, systemic administration of THC through inhaled or ingested

methods of cannabis consumption is challenged by poor and variable absorption into the eye, requires large doses, and results in undesirable physiological effects. Alternatively, local topical delivery of a native THC molecule in oil directly on the eye is challenged by poor aqueous solubility which limits its delivery and utility.

Emerald's THCVHS was bioengineered and formulated to enhance its aqueous solubility, enabling significantly enhanced local topical delivery and absorption into the eye. In preclinical studies it has demonstrated IOP lowering activity superior to leading drugs currently on the market.

About the University of Mississippi

The University of Mississippi, the state's flagship university, is among the elite group of R-1: Doctoral Universities - Highest Research Activity in the Carnegie Classification. The university has a long history of producing leaders in public service, academics, research and business. Its 15 academic divisions include a major medical school, nationally recognized schools of accountancy, law and pharmacy, and an Honors College acclaimed for a blend of academic rigor, experiential learning and opportunities for community action. Over 50 years ago, the university was awarded the first federal government contract to cultivate cannabis for research.

About Emerald Bioscience, Inc.

Emerald Bioscience Inc. is a biopharmaceutical company focused on the discovery and development of proprietary molecules with strong clinical and commercial differentiation for conditions with significant global, unmet medical needs. With synthetic cannabinoid-derived molecules licensed from the University of Mississippi, the Company is developing novel approaches to pharmaceutically target the endocannabinoid system for specific indications to provide therapeutic benefit. The Company's lead program aims to protect and preserve vision loss in patients with glaucoma, the world's number one cause of irreversible blindness. For more information, visit www.emeraldbio.life

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FORWARD LOOKING STATEMENTS

This press release contains forward-looking statements, including statements regarding our product development, business strategy, relocation of corporate headquarters, timing of clinical trials and commercialization of cannabinoid-based therapeutics. Such statements and other statements in this press release that are not descriptions of historical facts are forward-looking statements that are based on management's current expectations and assumptions and are subject to risks and uncertainties. If such risks or uncertainties materialize or such assumptions prove incorrect, our business, operating results, financial condition and stock price could be materially negatively affected. In some cases, forward-looking statements can be identified by terminology including "anticipated," "contemplates," "goal," "focus," "aims," "intends," "believes," "can," "could," "challenge," "predictable," "will,"

“would,” “may” or the negative of these terms or other comparable terminology. We operate in a rapidly changing environment and new risks emerge from time to time. As a result, it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements the Emerald may make. Risks and uncertainties that may cause actual results to differ materially include, among others, our capital resources, uncertainty regarding the results of future testing and development efforts and other risks that are described in the Risk Factors section of Emerald’ most recent annual or quarterly report filed with the Securities and Exchange Commission. Except as expressly required by law, Emerald disclaims any intent or obligation to update these forward-looking statements.



Source: Emerald Bioscience, Inc.