

Glauconix Presents Data Validating Impact of Emerald Bioscience's Prodrug on the Ocular Endocannabinoid System in Glaucoma

Study Points to Unique Link Between the Endocannabinoid System and the Inflammatory Cascade in the Eye

LONG BEACH, CA, Oct. 15, 2019 (GLOBE NEWSWIRE) -- via NEWMEDIAWIRE – Emerald Bioscience, Inc. (OTCQB: EMBI), focused on the development of cannabinoid-based therapeutics to address global medical indications, especially those of unmet medical need, today announced data validating mechanisms of action of its drug candidate, NB1111, a prodrug of tetrahydrocannabinol (THC-valine-hemisuccinate; THCVHS) by testing the active component of the prodrug, THC, in human donor tissue. The study was conducted by Glauconix Biosciences, Inc., which presented the data at the 2019 American Academy of Ophthalmology Annual Meeting (AAO) held in San Francisco.

The data demonstrated THC's ability to lower intraocular pressure in the eye by enhancing drainage of ocular fluid over the trabecular meshwork, one of the major tissues for regulating IOP in the eye. The meshwork is known to contain a high density of cannabinoid receptors, a binding target of THC, indicating NB1111's potential as a promising drug candidate to treat glaucoma and possibly other ocular disorders that threaten the optic nerve. In addition, THC also lowered biomarkers associated with inflammation and fibrosis, two processes associated with damaged tissues, indicating a previously unrecognized interaction between the endocannabinoid system and the inflammatory cascade in the eye. Understanding this connection could hold the potential for utilizing cannabinoids in other disease indications. The data was presented via e-poster discussion: "IOP-Lowering Ability of NB-1111 Active Moiety, THC, in a Human Tissue Model".

"Glauconix used its 3D human trabecular meshwork model (3D-HTM™) that consists of human donor cells containing physiologically relevant characteristics of hypertensive (high ocular pressure) glaucoma. Although the mechanism of action of THC in glaucomatous eyes is not well understood, the study performed in our model resulted in statistically significant results supporting the influence of the endocannabinoid system on the inflammatory response, in both normal and diseased tissue. This study also highlights that there appears to be pathways by which THC may lower pressure in the eye, downstream from activating cannabinoid receptors," commented Karen Torrejon, PhD, Chief Science Officer and co-founder of Glauconix. "We believe cannabinoid-based therapies could be a revolutionary new class of drugs for diseases of the eye."

"These data suggest THC's ability to lower IOP is multifactorial, which would be unique among therapies for glaucoma. Emerald anticipates performing two human clinical trials in 2020, both in Australia, examining the effects of NB1111 on normal eyes as well as among

patients with either glaucoma or underlying ocular hypertension,” stated Brian Murphy, MD, CEO of EMBI. “Evidence using this human tissue model as well as our prior data from rabbit models provide substantive data supporting the advancement of this drug into human testing to combat the second-leading cause of blindness in the world.”

About Glaucoma and NB1111

Glaucoma is considered one of the optic neuropathies, indicating that there is damage to the cells that comprise the optic nerve. The damage is irreversible, leading to progressive vision loss and ultimately blindness if left untreated. There are over one million fibers that comprise the optic nerve and these can become damaged when pressure in the eye rises to a level that results in a direct crush injury or deprives these fibers of oxygen or nutrients from neighboring blood vessels.

Currently approved therapies are focused on lowering intraocular pressure (IOP) in order to sustain the nerve fibers and prevent a process of programmed cell death or apoptosis. These therapies are applied by eyedrop, with dosages ranging from once daily to up to three times per day, depending on the class of medicine used. The goal of the particular therapies is either to enhance drainage out of the eye, or lower fluid production inside the eye.

Globally, more than half of those treated for glaucoma require two or more drug classes to manage their disease as this is often referred to as a non-responder market. The elusive goal in managing glaucoma is the ability to provide direct neuroprotection to these optic nerve cells in order to preserve vision beyond just lowering IOP.

Cannabinoid molecules, particularly THC, have been shown to stimulate two types of cannabinoid receptors in the body. These receptors were previously believed to be located only in the brain and bone marrow, however it is now recognized that these receptors are located throughout the body, with one of the highest densities located in the eye. These ocular receptors are particularly located on organs in the eye that regulate IOP. Stimulation of the receptors by THC, results in opening of channels in organs associated with fluid drainage such as the trabecular meshwork, the uveoscleral vein, and the iris and ciliary body.

NB1111 is a prodrug of THC which has no physiological activity itself, but is designed to help transport the active part of the molecule, THC, into the eye. Once inside the eye, NB1111 is cleaved by enzymes in the eye, and THC is then released to bind to cannabinoid receptors. THC has been shown in both human and animal experiments since the 1970's to lower IOP however the cannabinoid chemistry was not conducive to direct ocular delivery. NB1111 is unique because this is the first time a direct topical application of THC, bioengineered for optimal absorption into the eye, has been shown in animal experiments to have a sustained lowering of IOP, supporting development as a drug.

Cannabinoids are also known to possess neuroprotective qualities and this is why many types are being studied for conditions associated with neurodegeneration, like epilepsy, Parkinson's disease, and multiple sclerosis. Data from multiple species have shown the utility of cannabinoids like THC in preventing programmed cell death of the cells comprising the optic nerve. Experiments performed at the University of Mississippi have shown that topical administration of NB1111 into the eyes of rabbits have resulted in THC reaching the retina and binding to receptors there, strengthening the evidence for use as a

neuroprotectant as well as lowering IOP. This duality in activity would make NB1111 valuable not only in hypertensive glaucoma, but could also meet the needs of Asian patients with normotensive glaucoma; direct neuroprotection of the optic nerve without the presence of elevated IOP.

About the Glaucoma Market

Glaucoma is the second leading cause of blindness globally. It accounts for roughly 35 million prescriptions in the \$3 billion US market (source: Market Watch, 2018), and projections estimate the worldwide market could exceed \$8 billion by 2023 as the prevalence of this eye disease increases, especially in Asia. Current therapies focus on lowering intraocular pressure to help preserve retinal ganglion cells that comprise the optic nerve. The two major goals in developing a cannabinoid-based therapy for glaucoma are to not only lower intraocular pressure but exert a direct neuroprotective effect on the cells comprising the optic nerve to preserve vision for affected patients, a capability that current drugs are unable to provide. It is estimated that roughly 10% - 15% of patients in North America and the European Union that have glaucoma remain undiagnosed and untreated.

About Glauconix Biosciences

Glauconix Biosciences is a leading developer of ophthalmic ex-vivo dynamic 3D human tissue models for accelerating therapeutic innovation and drug discovery. Their 3D tissue models can de-risk ophthalmic assets and expedite drug development. Glauconix adds value to their clients and partners by expediting early identification and validation of effective compounds or biologics in the preclinical phase and those entering clinical trials. To learn more about Glauconix Biosciences, visit www.glauconix-biosciences.com.

About Emerald Bioscience, Inc.

Emerald Bioscience is a biopharmaceutical company headquartered in Long Beach, California, focused on the discovery, development, and commercialization of bioengineered cannabinoid-based therapeutics for significant unmet medical needs in global markets. With proprietary technology licensed from the University of Mississippi, Emerald is developing novel ways to deliver cannabinoid-based drugs for specific indications with the aim of optimizing the clinical effects of such drugs while limiting potential adverse events. Emerald's strategy is to clinically develop a number of proprietary biosynthetic compounds, alone or in combination with corporate partners.

Emerald Bioscience is part of the [Emerald Group](#), which comprises multiple companies focused on developing pharmaceutical, botanical, and nutraceutical products providing wellness and medical benefits by interacting with the human body's endocannabinoid system.

For more information, visit www.emeraldbio.life

FORWARD LOOKING STATEMENTS

This press release contains forward-looking statements, including statements regarding our product development, business strategy, product branding, 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.

CONTACT

Emerald Bioscience Investor Relations
Emerald Health Sciences

Karam Takhar
Email: ir@emeraldbio.life
Phone: 949-336-3437

Douglas Cesario
Chief Financial Officer
Email: doug@emeraldbio.life
Phone: 949-336-3437



Source: Emerald Bioscience, Inc.