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Emerald Bioscience's NB1111 Demonstrates Superiority in Lowering Intraocular Pressure Compared to Global Standard of Care Glaucoma Treatment in Preclinical Model

LONG BEACH, Calif., 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 demonstrating the superiority of its advanced formulation of NB1111, the prodrug of tetrahydrocannabinol (THC-valine-hemisuccinate; THCVHS) in lowering intraocular pressure (IOP) in the eye in a validated animal model. Increased IOP is a cause of glaucoma, and in this study NB1111 was compared to the current IOP-lowering standards-of-care for treating glaucoma: latanoprost, a prostaglandin-based therapy, and timolol, a beta-blocker. The data was presented at the 2019 American Academy of Ophthalmology Annual Meeting (AAO).

In this study, intraocular pressure (IOP) was measured in normotensive (normal ocular pressure) rabbits following a single topical dose of Bioscience's proprietary nanoemulsion formulation of NB1111 compared to commercially available formulations of latanoprost and timolol. NB1111 demonstrated a statistically superior intensity as well as duration of IOP decline. The data were reported in a poster, "IOP Profiles Following Single-Dose Δ9-Tetrahydrocannabinol-Valine-Hemisuccinate (NB1111) Nanoemulsion and Latanoprost," presented by the University of Mississippi and Eli Labs of Oxford, MS.

Statistical comparisons of the IOP profiles of tested formulations	
Formulation	**P-value** Statistical significance is recognized as $p < 0.05$
NEC-THC-VHS vs Timolol	<0.0001
NEC-THC-VHS vs Latanoprost	0.0018
NEC-THC-VHS vs NEC-THC	<0.0001

"The newer formulation of NB1111 encapsulates the prodrug in a nanoemulsion and is supplemented by an additive, carbopol, which increases the residence time of the drug on the eye after being administered (NEC-THC-VHS). This formulation is being developed for human use and it exhibited highly significant lowering of intraocular pressure not only against latanoprost and timolol, but also against natural THC, highlighting the importance of having a prodrug formulation to enhance entry of the drug into the eye," noted Soumyajit Majumdar, PhD, Professor of Pharmaceutics and Drug Delivery and Associate Dean for

Research and Graduate Programs in the School of Pharmacy. “Time of therapeutic impact was also enhanced and the data suggest potential for once-daily dosing of this drug. This is the most advanced and successful formulation of a cannabinoid-based ocular therapy that we have tested.”

“We anticipate the presentation of data examining multi-day dosing of NEC-THCVHS at the upcoming American Academy of Pharmaceutical Scientists (AAPS) 2019 meeting in November. Data will compare the IOP impact and time of pharmacologic activity of NB1111 versus the commercially available formulation of latanoprost, the most-prescribed medication for glaucoma in the world,” stated Brian Murphy, MD, CEO of Emerald Bioscience. “These are important experiments prior to initiating multiple human studies, which we project will be conducted throughout 2020.”

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 the University of Mississippi

The University of Mississippi, the state's flagship institution, 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.

About Eli Labs

Eli Labs is a privately held corporation located in Oxford, MS that performs analytical validation testing as well as research involving drug discovery. The company President is Mahmoud Elsohly, PhD, who is a Research Professor in the National Center for Natural Products Research at the University of Mississippi

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.

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