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ProMIS Neurosciences Offers its Perspective on the Likelihood of Regulatory Approval of Aducanumab

Regulatory progress is spurring the development of safe and effective therapies for Alzheimer's disease

TORONTO and CAMBRIDGE, Mass., Oct. 21, 2020 (GLOBE NEWSWIRE) -- ProMIS Neurosciences, Inc. (TSX: PMN) (OTCQB: ARFXF), a biotechnology company focused on the discovery and development of antibody therapeutics targeting toxic oligomers implicated in the development of neurodegenerative diseases, released a white paper today that offers its perspective on aducanumab's likelihood of regulatory approval in advance of its U.S. Food and Drug Administration Advisory Committee (AC) review on November 6. The white paper, available at www.promisneurosciences.com, chronicles aducanumab's history, regulatory support, positive data outcomes and potential impetus for development of improved second-generation therapies. If approved, aducanumab would be the first disease-modifying treatment for Alzheimer's disease, offering a therapeutic option for the millions of Americans living with the disease.

Aducanumab was originally designed to target amyloid-beta plaque, now believed to be an ineffective drug target for AD. An accumulating body of data has shifted the drug development focus to a different species of amyloid-beta called the toxic oligomer which has since been shown to be the real culprit in driving disease progression. Aducanumab's ability to cross-react and partially neutralize toxic oligomers results in its modest treatment benefit. By contrast, published data show that PMN310, ProMIS' antibody candidate for Alzheimer's disease, is highly selective for the toxic oligomer of amyloid-beta, positioning it as a second-generation drug candidate with more precise targeting capabilities and a potentially improved safety and efficacy profile.

Despite aducanumab's modest treatment benefit, the white paper argues that FDA approval is likely based on the following:

1. FDA has encouraged Biogen to submit its application, granting it Priority Review; has endorsed continued clinical use of aducanumab in an open-label study, and; has demonstrated a willingness in the past to approve drugs despite limited data in instances where the unmet medical need is significant.

2. Aducanumab's phase 3 EMERGE trial was unequivocally positive and additional evidence for effectiveness is confirmed by results from the Phase 1b PRIME trial and subset data from the phase 3 ENGAGE trial.

3. We anticipate the Advisory Committee members will most likely conclude that aducanumab's data demonstrate the requisite "substantial evidence of effectiveness" and acceptable safety.

"Aducanumab represents a milestone treatment, and we applaud Biogen's unrelenting commitment to its advancement," said Dr. Elliot Goldstein, ProMIS Neurosciences' President and CEO. "We and many others in the Alzheimer's community look forward to the upcoming FDA Advisory Committee meeting and subsequent regulatory actions in support of addressing the unmet need for disease modifying therapies for Alzheimer's disease."

The FDA's Advisory Committee will be virtually convened and streamed via internet on November 6, 2020.

About ProMIS Neurosciences
ProMIS Neurosciences, Inc. is a development stage biotechnology company whose unique core technology is the ability to rationally predict the site and shape (conformation) of novel targets known as Disease Specific Epitopes (DSEs) on the molecular surface of proteins. In neurodegenerative diseases, such as Alzheimer's, ALS and Parkinson's disease, the DSEs are misfolded regions on toxic forms of otherwise normal proteins. In the infectious disease setting, these DSEs represent peptide antigens that can be used as an essential component to create accurate and sensitive serological assays to detect the presence of antibodies that arise in response to a specific infection, such as COVID-19. ProMIS proprietary peptide antigens can also be used to create potential therapeutic antibodies, as well as serve as the basis for development of vaccines. ProMIS is headquartered in Toronto, Ontario, with offices in Cambridge, Massachusetts. ProMIS is listed on the Toronto Stock Exchange under the symbol PMN, and on the OTCQB Venture Market under the symbol ARFXF.

Visit us at www.promisneurosciences.com, follow us on Twitter and LinkedIn. To learn more about protein misfolding diseases, listen to Episodes 11, 24, of Saving Minds, a podcast available at iTunes or Spotify.

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Source: ProMIS Neurosciences Inc.