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ProMIS Neurosciences Offers Perspectives on Recent Progress in the Alzheimer's/Amyloid Field

Two positive events in January support PMN310 "best in class" positioning

TORONTO and CAMBRIDGE, Mass., Feb. 02, 2021 (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, announced today its perspectives on recent progress in the Alzheimer's field.

Two important events occurred in January 2021, both of which we consider very positive for the Alzheimer's field, for the updated amyloid hypothesis, and for ProMIS Neurosciences. The FDA extended the PDUFA date (Prescription Drug User Fee Act) for review of Biogen's aducanumab from March 7 to June 7, 2021, as announced on January 29. Lilly announced positive clinical results for their antibody, donanemab, on January 11, making it the third antibody with positive clinical results in Alzheimer's disease (AD) due to its targeting of aggregated amyloid-beta (not amyloid monomer). Both these events have positive implications for ProMIS and PMN310, ProMIS' lead antibody therapeutic candidate for AD.

"Several analysts predicted that the FDA might manage its dilemma of believing that aducanumab should be approved despite a negative advisory committee vote by waiting for data to come in from the ongoing high dose extension study, extending the PDUFA date, and then approving the product later. It appears that prediction was correct," stated Eugene Williams, Executive Chairman of ProMIS Neurosciences. "In line with this assessment, we believe the FDA will issue an approval of aducanumab in the summer of 2021."

Biogen's announcement on January 29 was the first update on aducanumab since the events of early November 2020. The FDA came out Nov. 4, 2020 with unequivocally positive support for the approval of aducanumab, but that was followed by a negative advisory committee vote on Nov. 6. As several analysts pointed out at the time, and as we noted in our communications, the FDA has frequently approved a drug in spite of a negative advisory committee vote, which is non-binding. Historically, the FDA has almost always done so after receiving additional information from the drug sponsor. In this case, it is clear that the FDA review division strongly believes, and we agree, that aducanumab at the high dose of 10mg/kg is clinically beneficial and merits approval. We believe that if the FDA were planning to deny approval, it is highly likely they would have already announced that decision, to allow Biogen to get on with the next step. We believe that the FDA will issue an approval of aducanumab in the summer of 2021.

Lilly announced positive data from the 272 subject TRAILBLAZER study of donanemab, an

antibody therapeutic that targets pyroglutamated amyloid-beta, a modified form of amyloid found in plaque, but also known to be involved in toxic oligomer formation. A clinical program of a small molecule which reduced the formation of pyroglutamate amyloid oligomers (Vivoryon's PQ 912) showed benefit after just three months of treatment. Patients were treated for 76 weeks in the Lilly trial. It is possible that the efficacy of donanemab may be due in part to the impact of donanemab on toxic oligomer formation. Like aducanumab and Eisai's BAN2401, donanemab is associated with the side effect of brain swelling or ARIA-E (amyloid related imaging abnormality with edema) associated with plaque binding. With these new results, there are now three programs showing clinical benefit due to the targeting of aggregated amyloid, all three of which likely have an impact on toxic oligomers. The "updated" amyloid hypothesis continues to gain clinical evidence which matches the scientific evidence, and supports the ProMIS view that PMN310, which is highly selective for toxic oligomers, will likely avoid the ARIA-E side effect, can be dosed higher, and have "best in class efficacy".

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.

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Source: ProMIS Neurosciences Inc.