



NEWS RELEASE

## Development of BioVie's NE3107 Asset Featured by the American Diabetes Association

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SANTA MONICA, Calif., June 29, 2021 (GLOBE NEWSWIRE) -- BioVie Inc., a clinical-stage company developing innovative drug therapies for the treatment of liver disease and neurological and neurodegenerative disorders and certain cancers, announced today that a video documentary detailing the development history of the Company's newly acquired NE3107 asset will be featured in the American Diabetes Association's Thought Leadership Film Series on **ADA TV**, a production of the ADA providing news and updates for its 81<sup>st</sup> Annual Scientific Sessions held virtually from June 25-29, 2021.

The video can be viewed [here](#).

NE3107, a new drug candidate in development for Alzheimer's and Parkinson's Diseases and other conditions, is an ERK inhibitor that selectively inhibits neuroinflammation and insulin resistance. The relationship between inflammation and insulin resistance is well established in type 2 diabetes. This relationship has been further advanced for Alzheimer's disease, which is being referred in the scientific literature as "type 3 diabetes," and is being intensively studied by diabetes and neurodegeneration experts. NE3107 is an anti-inflammatory insulin sensitizer that previously showed improvement in insulin sensitivity, and restoration of inflammation-driven systems dysregulation in clinical trials in both impaired glucose tolerance and advanced type 2 diabetic subjects.

"It is now known that up to 81% of Alzheimer's subjects have impaired glucose tolerance or type 2 diabetes," said Cuong Do, Chief Executive Officer of BioVie. "The systems dysregulation in diabetes can presage Alzheimer's disease. Neuroinflammation in Alzheimer's appears to increase insulin resistance in the brain by the same molecular mechanism as peripheral inflammation increases peripheral insulin resistance in diabetes. In preclinical models NE3107 blocks insulin resistance and neuroinflammation at the right time and place, without inhibiting homeostatic activity. We are excited that NE3107 may now provide improvement in both inflammation and insulin resistance in our upcoming pivotal phase 3 trial in Alzheimer's subjects."



BioVie plans to launch a pivotal Phase 3 trial in Alzheimer's this summer to assess how treatment with NE3107 could slow cognitive decline and improve function and behavior compared to standard of care as measured by Alzheimer's Disease Assessment Scale Cognitive Subscale 12 (ADAS-Cog12) and the Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC). The study will have a number of secondary endpoints involving additional neuropsychological endpoints, glycemic control, and insulin sensitivity.

#### About BioVie

BioVie Inc. (NASDAQ: BIVI) is a clinical-stage company developing transformative therapies to overcome unmet medical needs in chronic debilitating conditions. In liver disease, the Company's Orphan drug candidate BIV201 (continuous infusion terlipressin), with FDA Fast Track status, is being evaluated in a US Phase 2 study for the treatment of refractory ascites with top-line results expected in early 2022. The Company is also planning a pivotal Phase 3 study of BIV201 in the treatment of hepatorenal syndrome-acute kidney injury (HRS-AKI) in 2022. BIV201 is administered as a patent-pending liquid formulation. The active agent is approved in about 40 countries for related complications of advanced liver cirrhosis but is not available in the US or Japan. In neuro-degenerative disease, BioVie recently acquired the assets of NeurMedix Inc., including NE3107, an ERK inhibitor that selectively reduces neuroinflammation and insulin resistance. Both are drivers of Alzheimer's and Parkinson's diseases. The FDA has authorized a pivotal Phase 3 randomized, double blind, placebo controlled, parallel group, multicenter study to evaluate NE3107 in subjects who have mild to moderate Alzheimer's disease (NCT04669028). An estimated six million Americans suffer from Alzheimer's. BioVie is planning to initiate this trial in mid-2021 and targeting primary completion in late 2022. A Phase 2 trial of NE3107 in Parkinson's Disease is planned for later this year, and related compounds have additional potential to treat certain cancers. NE3107 and related compounds are globally patented, first-in-class molecules. For more information, visit <http://www.biovieinc.com>.

#### Forward-Looking Statements

This press release contains forward-looking statements, which may be identified by words such as "expect," "look forward to," "anticipate" "intend," "plan," "believe," "seek," "estimate," "will," "project" or words of similar meaning. Although BioVie Inc. believes such forward-looking statements are based on reasonable assumptions, it can give no assurance that its expectations will be attained. Actual results may vary materially from those expressed or implied by the statements herein due to the Company's ability to successfully raise sufficient capital on reasonable terms or at all, available cash on hand and contractual and statutory limitations that could impair our ability to pay future dividends, our ability to complete our clinical trials and to obtain approval for our product candidates, to successfully defend potential future litigation, changes in local or national economic conditions as well as various additional risks, many of which are now unknown and generally out of the Company's control, and which are detailed from time to time in reports filed by the Company with the SEC, including quarterly reports on Form 10-Q,

reports on Form 8-K and annual reports on Form 10-K. BioVie Inc. does not undertake any duty to update any statements contained herein (including any forward-looking statements), except as required by law.

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