



NEWS RELEASE

## BioVie Presents Data for NE3107 at 2023 International Congress of Parkinson's Disease and Movement Disorders

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- New preclinical data characterizing NE3107 mechanism of action featured in oral presentation
- Pharmacokinetic data from Phase 2a study supports potential co-administration of NE3107 with carbidopa/levodopa
- Separate analysis of Phase 2a study data shows evidence of motor effects of NE3107 independent of levodopa/ carbidopa, supporting further investigation of NE3107 as first line therapy in Parkinson's Disease

CARSON CITY, Nev., Aug. 28, 2023 (GLOBE NEWSWIRE) -- BioVie Inc., (NASDAQ: BIVI) ("BioVie" or the "Company") a clinical-stage company developing innovative drug therapies for the treatment of advanced liver disease and neurological and neurodegenerative disorders, today announced details of three presentations given from studies of NE3107 in the treatment of Parkinson's Disease (PD) at the 2023 International Congress of Parkinson's Disease and Movement Disorders (MDS), being held in Copenhagen, Denmark August 27-31, 2023 .

"The results and analysis we are presenting at the MDS this week add to the growing body of data for NE3107 that support our core understanding of this molecule and its potential in diseases such as PD," said Cuong Do, President and CEO of BioVie. "The presentations include new pre-clinical data that support the relationship between neuroinflammation and insulin resistance in diseases like PD, and new analyses from our Phase 2a clinical trial that further characterize the pharmacokinetics of NE3107 and its potential as an adjunctive or first-line therapy. We are pleased to see these results highlighted at the MDS Congress this week, which provide confidence in the potential of this asset as we look ahead to topline data readout from our Phase 3 Alzheimer's trial later this fall."

Details of the three presentations are as follows:

Effects of NE3107 Anti-Inflammatory Treatment on Motor Activity and Neurodegenerative Features of Parkinson's Disease in a Marmoset Monkey Model (Ingrid H.C.H.M. Philoippens, Clarence Ahlem, Christopher L Reading) –

presented as a poster and oral presentation on Wednesday, 30 August 2023 13:00 CEST

- Objectives of this pre-clinical study were to evaluate the safety, tolerability, and the extent of anti-inflammatory effects of NE3107 treatment, specifically on the major features of PD in marmosets with Parkinson's-like disease.
- Results showed that mean immobility scores with NE3107 monotherapy (during weeks 8 and 9 on therapy) were significantly lower, indicating improved mobility, than comparison treatment with amantadine HCl or vehicle only. These improvements within 24 hours of initiating NE3107 monotherapy, suggesting a direct influence on neuro-motor signaling, as opposed to an effect that increased with time of treatment, which might imply a link to neuroprotection.
- Investigators concluded that the findings corroborate the involvement of chronic neuroinflammation and insulin resistance in PD clinical symptoms, in addition to neurodegenerative pathways, support the continued investigation of therapies like NE3107 nondopaminergic therapies.

Safety and Pharmacokinetics of Anti-Inflammatory NE3107 Treatment in Carbidopa/Levodopa-Treated Patients with Parkinson's Disease: A Phase 2a, Double-Blind, Placebo-Controlled Study (Jason Aldred, Ramon Rodriguez, et al) – presented as a poster Monday, 28 August 2023 at 13:00 – 15:00 CEST

- The objectives of this clinical trial were to evaluate the safety, tolerability, and exploratory effects of anti-inflammatory NE3107 treatment adjunctive to concomitantly administered carbidopa/levodopa (C/L) in patients with PD and examine its effects on the pharmacokinetics (PK) of levodopa.
- Results showed that in comparison of Day 1 and Day 14 of treatment, PK parameters demonstrated that NE3107 administration did not affect the PK profile of levodopa:
  - In patients who received NE3107 + C/L, levodopa AUC was 4243.08 ( $\pm$ 1913.81) ng·h/mL and 4127.41 ( $\pm$ 1568.47) ng·h/mL on day 1 and day 14, respectively.
  - In patients who received placebo + C/L, levodopa AUC was 3175.55 ( $\pm$ 2526.68) ng·h/mL and 3093.19 ( $\pm$ 1919.73) ng·h/mL on day 1 and day 14, respectively.
  - PK analysis on day 14 showed that levodopa reached a maximum serum concentration (C<sub>max</sub>) of 2089.15 ( $\pm$ 973.08) ng/mL and 3093.19 ( $\pm$ 1919.73) ng/mL in patients treated with NE3107 + C/L and placebo + C/L, respectively.
- Investigators concluded that the findings of the NM201 study, together with the results of the marmoset pre-clinical study, suggest that through its anti-inflammatory and insulin-sensitizing properties, NE3107 may possess intrinsic pro-motoric and potentially levodopa-enhancing activities, while having a favorable safety profile, and support further investigation of the safety and clinical benefit of nondopaminergic therapies in late-phase clinical trials.

A Randomized, Phase 2a, Double-Blind, Placebo-Controlled Clinical Trial with NE3107 Adjunctive to

Carbidopa/Levodopa in Patients with Parkinson's Disease (Jason Aldred, Ramon Rodriguez, et al) -presented as a poster Monday, 28 August 2023 at 13:00 – 15:00 CEST

- This separate analysis of the Phase 2a trial examined the exploratory efficacy of NE3107, specifically improvement of motor function, in C/L-treated patients with PD.
- Clinical efficacy was assessed by evaluating changes in motor control as assessed by MDS-UPDRS scores, between visit 1 and visits 2, 5, and 6, and between visit 2 and visits 5 and 6.
- Results showed that on day 28, patients treated with NE3107 + C/L demonstrated a lower (3+ points) MDS-UPDRS Part III (motor) score than patients treated with placebo + C/L at the 2- and 3-hour marks, indicating improved motor control.
  - Patients who received NE3107 + C/L had a lower Part III disease score at time 0 (before medication administration) compared to patients treated with placebo + C/L
- On day 28, patients <70 years old treated with NE3107 + C/L experienced improvements that were ~6 points better than those who received placebo + C/L at the 2- and 3-hour marks
  - NE3107 +C/L-treated patients <70 years old had lower morning OFF state MDS-UPDRS Part III scores prior to medication administration (t=0) compared to those treated with placebo + C/L.
- 80% of NE3107 + C/L-treated patients and 88.9% of NE3107 + C/L-treated patients <70 years of age demonstrated >30% improvement in their MDS-UPDRS Part III scores 2 hours post administration from baseline, compared with 63.6% and 66.7% of all patients and patients <70 years of age, respectively, treated with placebo + C/L.
- Investigators concluded that the NE3107 + C/L combination treatment was associated with clinically meaningful and superior improvements (3+ points) on the motor examination part (Part III) of the MDS-UPDRS, and demonstrate the potential intrinsic and levodopa-enhancing, pro-motoric activity of NE3107 that is consistent with data from pre-clinical trials and support further clinical investigation of nondopaminergic therapies in late-phase clinical trials.

#### About BioVie

BioVie Inc. (NASDAQ: BIVI) is a clinical-stage company developing innovative drug therapies for the treatment of neurological and neurodegenerative disorders and advanced liver disease. In neurodegenerative disease, the Company's drug candidate NE3107 inhibits inflammatory activation of ERK and NFkB (e.g., TNF signaling) that leads to neuroinflammation and insulin resistance, but not their homeostatic functions (e.g., insulin signaling and neuron growth and survival). Both are drivers of Alzheimer's and Parkinson's diseases. The Company is conducting a potentially pivotal Phase 3 randomized, double-blind, placebo-controlled, parallel-group, multicenter study to evaluate NE3107 in patients who have mild to moderate probable Alzheimer's disease (NCT04669028). Results of a Phase 2 investigator-initiated trial (NCT05227820) showing NE3107-treated patients experienced improved

cognition and biomarker levels were presented at the Clinical Trial in Alzheimer's Disease (CTAD) annual conference in December 2022. An estimated six million Americans suffer from Alzheimer's. A Phase 2 study of NE3107 in Parkinson's disease (NCT05083260) has completed, and data presented at the International Conference on Alzheimer's and Parkinson's Disease and Related Neurological Disorders conference in Gothenburg, Sweden in March 2023 showed significant improvements in "morning on" symptoms and clinically meaningful improvement in motor control in patients treated with a combination of NE3107 and levodopa vs. patients treated with levodopa alone, and no drug-related adverse events. 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 2b study for the treatment of refractory ascites due to liver cirrhosis. BIV201 is administered as a patent-pending liquid formulation. The active agent is approved in the U.S. and in about 40 countries for related complications of advanced liver cirrhosis. For more information, visit <http://www.bioviepharma.com/>.

#### Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the Company's strategy, plans and objectives, such as statements regarding the Company's anticipated timeline for announcing topline data readout for our NM101 product candidate. Forward-looking statements may generally 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 risks associated with conducting and completing clinical trials, including our reliance on third parties to conduct our clinical trials, to successfully defend potential future litigation, our ability to raise capital when needed on reasonable terms, 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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