Joint feasibility assessment of Bionomics' BNC210 and EmpathBio's MDMA derivative EMP-01 treatment regimen for PTSD

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ADELAIDE, Australia, Feb. 17, 2021 /PRNewswire/ -- Bionomics Limited (ASX: BNO,OTCQB: BNOEF, Germany: AU000000BNO5) (**Bionomics**) today announced that it has entered into a Memorandum of Understanding with EmpathBio Inc (**EmpathBio)**, a wholly owned subsidiary of Germany-based CNS clinical development company, atai Life Sciences (**atai**). Under the Memorandum of Understanding, Bionomics and EmpathBio propose to collectively explore a combination drug treatment regimen with Bionomics' BNC210 and EmpathBio's 3,4-Methylenedioxymethamphetamine (MDMA) derivative EMP-01. The parties will explore whether the different mechanisms of action of EMP-01 and BNC210 may offer the potential for developing an improved treatment regimen for the treatment of Post-Traumatic Stress Disorder (PTSD).

BNC210 is Bionomics' lead drug candidate, which has been granted Fast Track designation by the US Food and Drug Administration (FDA) for the treatment of PTSD and other trauma-related and stress-related disorders. A new solid dose formulation of BNC210 has recently been developed and will be used in a Phase 2 study in PTSD, projected to commence in the middle of 2021.

MDMA-assisted psychotherapy (two to three treatment sessions) has demonstrated significant symptom improvement in PTSD patients which continued at least 12 months post-treatment (*Jerome et al., Psychopharmacology 237: 2485-2497, 2020*). The FDA has granted a Breakthrough Therapy designation to MDMA-assisted psychotherapy, which is currently in Phase 3 trials being conducted by US not-for-profit organization, the Multidisciplinary Association for Psychedelic Studies (MAPS).

EmpathBio's EMP-01 is one of 11 programs in atai's pipeline. EmpathBio specifically focuses on developing MDMA derivatives that EmpathBio believes may permit the entactogenic effects of MDMA to be separated from some of the known adverse effects. If successful, such an approach could help minimize some of the transient physiological changes caused by MDMA, potentially expanding the pool of PTSD patients who will be medically eligible for the therapy.

Bionomics' Executive Chairman, Dr Errol De Souza, said "We are delighted to have entered into this exploratory collaboration with EmpathBio, which is looking at novel approaches to the treatment of PTSD. We consider that EMP-01, a derivative of MDMA, being developed by EmpathBio could be a very interesting treatment regimen when combined with BNC210 for the treatment of PTSD. Our entry into a Memorandum of Understanding with EmpathBio has drawn together an initial collaborative framework of preclinical studies, in which we can develop some deeply informed views about the possibility of a combination treatment regimen warranting clinical evaluation at a later date."

EmpathBio CEO, Glenn Short, said "We look forward to collaborating with Bionomics and the possibility of expanding the development potential of EMP-01 in combination with BNC210. Current clinical trials for MDMA carry a significant psychotherapy protocol which we could possibly re-evaluate with Bionomics' BNC210 to reduce some of the unwanted side effects and improve patient outcomes. We are fortunate to be working with a Bionomics team that brings a wealth of scientific and clinical experience to the collaboration. Should the results of our exploratory studies support progressing to clinical trials, we will look to negotiate a legally binding definitive Agreement with Bionomics to conduct combination treatment regimen trials."

atai CEO, Florian Brand, said "We are extremely excited for Bionomics and EmpathBio to have entered into this collaboration, bringing incredible expertise together to explore how we might increase the efficacy of treatments for PTSD. This shared goal will allow us to advance our understanding of treatments as we evaluate this specific treatment regimen and the ways in which it may reduce unwanted side effects, with the ultimate mission of delivering increased optionality for patients."

About Bionomics Limited

Bionomics (ASX: BNO) is a global, clinical stage biopharmaceutical company leveraging its proprietary platform technologies to discover and develop a deep pipeline of best in class, novel drug candidates. Bionomics' lead drug candidate BNC210 is a novel, proprietary negative allosteric modulator of the alpha-7 (α7) nicotinic acetylcholine receptor. Beyond BNC210, Bionomics has a strategic partnership with MSD (known as Merck & Co in the US and Canada) and a pipeline of clinical-stage ion channel programs targeting pain, depression, cognition and epilepsy.

www.bionomics.com.au

About EmpathBio

EmpathBio, a wholly-owned subsidiary of atai Life Sciences, is a clinical-stage biopharmaceutical company developing derivatives of 3,4-methylenedioxy-methamphetamine (MDMA) for the treatment of post-traumatic stress disorder (PTSD) and other indications.

https://www.empath.bio/

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Factors Affecting Future Performance

This announcement contains "forward-looking" statements within the meaning of the United States' Private Securities Litigation Reform Act of 1995. Any statements contained in this announcement that relate to prospective events or developments, including, without limitation, statements made regarding Bionomics' drug candidates (including BNC210), its licensing agreements with MSD and any milestone or royalty payments thereunder, drug discovery programs, ongoing and future clinical trials, and timing of the receipt of clinical data for our drug candidates are deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "projects," "forecasts," "will" and similar expressions are intended to identify forward-looking statements.

There are a number of important factors that could cause actual results or events to differ materially from those indicated by these forward-looking statements, including unexpected safety or efficacy data, unexpected side effects observed in clinical trials, risks related to our available funds or existing funding arrangements, our failure to introduce new drug candidates or platform technologies or obtain regulatory approvals in a timely manner or at all, regulatory changes, inability to protect our intellectual property, risks related to our international operations, our inability to integrate acquired businesses and technologies into our existing business and to our competitive advantage, as well as other factors. Results of studies performed on our drug candidates and competitors' drugs and drug candidates may vary from those reported when tested in different settings.

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