

# Gabather

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## **Gabather Joins Forces with the Centre for Neuropsychiatric Schizophrenia Research in Denmark to Conduct a Clinical Phase II Study with GT-002**

**STOCKHOLM, April 10, 2024 -- Gabather AB (Nasdaq First North Growth Market: GABA) announces that the Company has signed a Collaborative Agreement with the Centre for Neuropsychiatric Schizophrenia Research at the Psychiatric Centre in Glostrup to conduct a so-called clinical phase II study with GT-002 in patients diagnosed with schizophrenia. The clinical trial has been made possible by a contribution from the Innovation Fund Denmark (IFD) and will test the effect of GT-002 on EEG patterns and cognitive parameters in schizophrenia. The total budget for the study corresponds to approximately 18.6 MSEK amounting to 12 MDKK. The findings of this study hold the promise of unveiling novel avenues for treating patients with schizophrenia.**

Funded by an Investment Agreement from the Innovation Fund Denmark (IFD), it will now be possible to conduct the first study with GT-002 in patients with schizophrenia. The study is a double-blind randomised so-called phase II study investigating the effect of GT-002 compared to placebo and an active comparator. The 3-year study, aiming at recruiting 20 patients and 30 healthy volunteers will be conducted by the Centre for Neuropsychiatric Schizophrenia Research (CNSR), with Professor Bjørn H. Ebdrup, head of research at the CNSR, as the Principal Investigator. CNSR is a well-recognised psychiatric centre with many years of experience seeing patients with different neuropsychiatric disorders.

"Rarely has the timing of a project been better than in this case; while within schizophrenia research we are uncovering several new connections between schizophrenia and the GABA system, the collaboration with Gabather gives us the opportunity to test the clinical significance of actively influencing the GABA system in patients with schizophrenia. If our studies show positive results, the collaboration will provide optimal conditions to quickly proceed with necessary additional studies, which will ultimately benefit patients" Professor Bjørn H. Ebdrup states.

GT-002 has completed 3 clinical trials in healthy volunteers and has been shown to be safe and well tolerated. The most recent target engagement study showed clinically relevant effects of GT-002 on modulation of EEG frequency band power with a significant increase in alpha band power. This effect spanned various brain regions, including frontal and occipital areas. The results suggest a distinct effects of GT-002 to modulate alpha band power across specific cortical regions. EEG alpha band power is recognised as a marker of cognitive activity such as attention and is associated with relaxation and reduced anxiety. Modulation of EEG alpha band power could be beneficial for several neuropsychiatric conditions, especially negative symptoms in schizophrenia that has been shown to be associated with reduced EEG alpha band power.

"This clinical trial in patients with schizophrenia represents a major step forward in the development of the main asset in our pipeline, GT-002. A positive study outcome could serve as a cornerstone for the development of innovative therapeutic options for the treatment of schizophrenia and improve the quality of life for individuals suffering from diverse neuropsychiatric disorders, a long term goal for the drug development projects at Gabather AB" says Michael-Robin Witt, CEO of Gabather AB.

## **About GT-002**

GT-002 is a small molecule GABA<sub>A</sub> receptor Positive Allosteric Modulator (PAM) eliciting both tonic and phasic inhibitory currents. GT-002 improves learning and memory in preclinical models. It restores ketamine induced cognitive deficits in a discrimination learning task model, and inhibits the behavioural effects induced by phencyclidine in an in-vivo model of schizophrenia. GT-002 has been shown to be anxiolytic and to promote social interaction in rats. GT-002 targets a novel binding site on GABA<sub>A</sub> receptors, different from benzodiazepines (BZDs), and has not shown any of the side effects known for BZDs. Long-term treatment (28 days) with GT-002 has not shown any withdrawal symptoms upon cessation of treatment both in mice and dogs, indicating no drug abuse liability associated with this drug candidate. GT-002 has completed 3 phase I clinical trials in healthy volunteers. Both single ascending dose (SAD) and multiple ascending dose (MAD) studies have been completed. The results from these studies show that GT-002 is safe and well tolerated and that it has excellent pharmacokinetics, allowing for once-a-day oral dosing. A recently completed EEG/fMRI target engagement study in healthy volunteers shows that GT-002 modulates brain activity across different brain regions and neuronal networks, indicating a unique profile of GT-002 for the treatment of different neuropsychiatric disorders.

## **Contact Information**

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## **About Gabather**

Gabather is a clinical-stage pharmaceutical company aiming to transform the treatment of neuropsychiatric disorders. The Company was founded as a response to the significant unmet need and lack of innovative therapeutics in the mental health treatment landscape. Gabather is dedicated to developing innovative therapeutics for the treatment of a broad range of neuropsychiatric disorders. The goal is to accelerate the development of new groundbreaking medicines to achieve clinically meaningful therapies for the patients.

For more information, please visit: [www.gabather.com](http://www.gabather.com)

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## **Forward-looking statement**

*This press release contains forward-looking statements that constitute subjective estimates and forecasts about the future. Assessments about the future are only valid on the date they are made and are, by their nature, similar to research and development work in the biotech field, associated with risk and uncertainty. In light of this, actual outcomes may differ substantially from what is described in this press release. Gabather is listed on First North Growth Market and Corpura Fondkommission AB is Certified Advisor.*