GH Research

# Clinical and regulatory questions in the development of psychedelics

## Experience from the GH001 (5-MeO-DMT) program in treatment-resistant depression (TRD)

INVITATION

Industry session financially supported by GH Research during the 36th ECNP Congress

**Mon 9 Oct 2023,**
11.15 - 11.45am,
Session Room 118

## Programme Outline

The development of psychedelic treatments for psychiatric conditions introduces novel clinical and regulatory questions. In this 30-minute Industry Interactive Discussion we will talk about key aspects of psychedelic drug development, such as individualized dosing, timing of the primary endpoint, characterization of the durability of the treatment effect, and re-treatment and psychological support concepts. Context will be provided through discussion of the GH001 clinical development program in TRD. GH001 is a pulmonary inhalation formulation of the classical psychedelic mebufotenin (5-MeO-DMT), with two completed Phase 1 trials in healthy subjects (NCT04640831, NCT05163691), one completed Phase 1/2 trial in TRD (NCT04698603), and one ongoing randomized, double-blind, placebo-controlled Phase 2b trial in TRD (NCT05800860). Active audience participation will be encouraged.

## Speakers

**Prof R Hamish McAllister-Williams, PhD, MD, FRCPsych**
Senior Research Advisor, Newcastle University
Deputy Medical Director for Research, Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust, UK

**Dr Jan Ramaekers**
Professor of Psychopharmacology and Behavioral Toxicology
Faculty of Psychology and Neuroscience
Maastricht University, NL

## Organising Committee

**Dr Velichka Valcheva, MD, MSc**
GH Research, IE

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