COMPASS Pathfinder Limited / ICON Clinical Research Limited

22 April 2024

Subject	**Request for subsequent addition of a Member State Concerned to an authorised clinical trial under the regulatory framework of Regulation (EU) No 536/2014**
EU CT Number	2023-505268-12-00
Protocol Code	COMP 006
Protocol Title	A Phase III, multicentre, randomised, double-blind, controlled study to investigate the efficacy, safety, and tolerability of two initial administrations of COMP360 in participants with treatment-resistant depression
Sponsor	COMPASS Pathfinder Limited, 3rd Floor, 1 Ashley Road, Altrincham, Cheshire, WA14 2DT, UK

Dear Sir or Madam,

ICON Clinical Research Limited hereby submits a request for clinical trial authorization on behalf of COMPASS Pathfinder Limited under the regulatory framework of Regulation (EU) No 536/2014.

This application includes:

- A request for extension of an authorised clinical trial to an additional Member State Concerned (MSC); Czech Republic in accordance with Articles 14 and 89.

Trial population

The trial subject population includes vulnerable population groups such as women of childbearing potential using contraceptives. Please refer to the “Trial information – Population of trial subjects” section in Part I of the EU application form for further information.

First administration of a new substance to humans

The clinical trial does not involve first administration of a new active substance to humans. Please refer to the “Trial information – Trial category” section of the EU application form for further information.

Scientific Advice

Scientific Advice has been given for this clinical trial or the Investigational Medicinal Product(s) (IMP(s)) by EMA, a Member State Concerned or by a third country.

A copy of each summary of Scientific Advice can be found in the “Scientific advice and Paediatric Investigation Plan (PIP)” section of the Part I application dossier for further information.

Regulatory Authority	Type of Scientific Advice
Medical Products Agency, Sweden	Scientific Advice
Federal Institute for Drugs and Medical Devices, Germany	Scientific Advice
Medicines Evaluation Board, The Netherlands	Scientific Advice

Paediatric Investigation Plan

The clinical trial is not part of a Paediatric Investigation Plan (PIP), nor is it intended to be part of a PIP.

IMPs and Auxiliary Medicinal Products (AxMPs)

The following table provides information on the regulatory status (e.g., Marketing Authorisation (MA)), of the medicinal products, their special characteristics and sourcing strategy, if applicable. Please refer to the "Products" section in the EU application form for further information.

There are no Auxiliary Medicinal Products used in this clinical trial.

Medicinal products - Regulatory status and special characteristics					Sourcing of Authorised Medicinal Products		
Type	**Name/Code**	**MA Status**	**Orphan Designation Status**	**Special Characteristics**	**Sourcing Type**	**Source Country**	**Product Identification**
Test	Psilocybin	Not Authorised	No	☐ Narcotic ☒ Psychotropic ☐ Radiopharmaceutical ☐ Consists of genetically-modified organism(s) (GMOs) ☐ Contains genetically-modified organism(s) (GMOs) ☐ None of the above	N/A	N/A	N/A

Medical Devices to be investigated in this clinical trial

There are no medical devices being investigated in this clinical trial that are not part of the investigational medicinal product or products.

In-Vitro Diagnostics Device

There are no in-vitro diagnostics device(s) being investigated in this clinical trial that are not part of the investigational medicinal product(s).

Low-intervention clinical trial

The clinical trial is not considered to be a low-intervention clinical trial by the sponsor.

Informed Consent for Cluster Trial

This is not a cluster trial. Informed consenting by simplified means is not applicable.

Reference Safety Information (RSI)

Please refer to the below table for the location of the IMP / AxMP specific RSI in the application dossier:

Product	Name	RSI location
Test	Psilocybin	Please refer to section 6 Reference Safety Information of the Investigator's Brochure (IB).

Annual Safety Report (ASR)

A single ASR on all IMP used in the trial will be submitted. The submission of the first ASR was submitted on 02 February 2024.

We thank you in advance for validating and assessing the application.

Yours faithfully,

ICON Clinical Research Limited Representative,
For and on behalf of COMPASS Pathfinder Limited