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To  
**Ufficio Sperimentazione Clinica  
AIFA  
Via del Tritone, 181  
00187 Roma**

Roma, 28/12/2022

**Object: request for authorization of a No-Profit Phase II Clinical Trial in Italy, according to the REGULATION (EU) No 536/2014.**

<b>EudraCT number</b>	2021-006274-23
<b>EU CT number</b>	2022-503016-16-00
<b>Protocol Title</b>	A double-blind, randomized, placebo-controlled trial to test the efficacy, safety and tolerability of Dimethyl Fumarate in Friedreich Ataxia.
<b>Protocol Code</b>	DMF-FA-201
<b>Phase</b>	II
<b>Sponsor</b>	Dipartimento di Neuroscienze, Scienze Riproduttive e Odontostomatologiche Università degli Studi di Napoli Federico II Via Sergio Pansini, 5 - 80131 Napoli, Italia
<b>Applicant</b>	Fullcro srl, Via Ignazio Guidi 5. 00147 Roma, Italia
<b>Coordinator Site</b>	UOS Centro Sclerosi Multipla AOU "Federico II" Via Pansini, 5 80131 Napoli

Fullcro srl, as representative of the Sponsor, requests to this Agency, identify as RMS, the authorization to conduct the above Clinical Trial, according to REGULATION (EU) No 536/2014.

This is a no-profit, monocentric, double-blind, randomized, placebo-controlled trial to test the efficacy, safety and tolerability of Dimethyl Fumarate in Friedreich Ataxia. The study is composed of a screening visit and two sequential phases of identical length of 12 weeks each: a core phase and an extension phase. During the core phase, patients will be randomly assigned to either DMF or placebo. During the extension phase, all patients will be treated with DMF. The study will begin with a screening visit where patients will sign the informed consent. We will then assess inclusion and exclusion criteria. Patients fulfilling all inclusion and none of the exclusion criteria will undergo endpoint measurement and will enter the core phase of the study. Entering the core phase, patients will be randomized to receive either DMF or placebo in a 1:1 ratio.



Moreover, the following information are communicated about the trial:

- The enrolment of patients with age  $\geq 12$  years is expected; then, also minors can be enrolled (*application dossier – part I - Population of trial subjects*);
- The clinical trial NOT involves the first administration of a new active substance to humans (*application dossier – part I - Trial category*);
- NO scientific advice relating to the clinical trial or the investigational medicinal product has been given by the Agency, a Member State or a third country (*application dossier – part I - Scientific advice and Paediatric Investigation Plan (PIP)*);
- The clinical trial is NOT part of a Paediatric Investigation Plan (PIP) (*application dossier – part I - Scientific advice and Paediatric Investigation Plan (PIP)*);
- Investigational medicinal products are NOT a narcotic, psychotropic or radiopharmaceutical; auxiliary medicinal products are not used in this trial. Moreover, the investigational medicinal products NOT consist of and NOT contain a genetically-modified organism or organisms. The following IMP and Placebo are used in this trial:
  - Placebo of dimethyl fumarate 120 mg gastro-resistant tablets
  - IMP Skilarence 120 mg gastro-resistant tablets with market authorization in Italy

(*Application dossier – part I – Products*);

- NOT orphan designation for the investigational medicinal product for an orphan condition (*application dossier – part I - Orphan Designation*);
- NO medical device is used in the trial (*application dossier – part I - Device associated with medicinal product*)

The clinical trial is NOT considered by the Sponsor to be a low-intervention clinical trial.

The informed consent will be NOT obtained by simplified means.

The information, necessary for assessing whether an adverse reaction is a suspected unexpected serious adverse reaction, is contained in the Skilarence 120 mg gastro-resistant tablets SmPC (*application dossier – part I - Investigator brochure for the medicinal product*).

Finally, we require that the Part II of the application will be evaluated by the following ethics committee:

Comitato Etico dell'Area Vasta Emilia Nord  
Segreteria Centrale di Modena  
Sede presso il Policlinico di Modena  
Largo del Pozzo 71, 41124  
Ingresso n. 3, Piano Terra presso Direzione Assistenza Farmaceutica

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FULLCRO S.r.l.  
Maira Cordisco  
Start-up Manager

**For every necessity, please contact:**

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