



CCMO
PO Box 16302
2500 BH The Hague
The Netherlands

29 May 2019

Subject: Closure of the FRIENDS Study in the Netherlands
Eudamed-No.: CIV-18-08-025366
Your Reference No.: VGR2010792

Dear Sir/Madam,

The FRIENDS study (Eudamed N. CIV-PT-18-08-025366; your ref. VGR2010792) is a pre-market approval, interventional, prospective, longitudinal, international (European), multicenter, single arm study, whose aim is to evaluate the safety and the electrical performance of the InVICTA leads, tachycardia leads equipped with a quadripolar DF4 connector, with both active and passive fixation.

A maximum total number of 224 enrolled patients were required in order to evaluate the study endpoints (112 subjects enrolled for the InVICTA lead with active fixation and a maximum of 112 subjects enrolled for InVICTA lead with passive fixation).

Thirty-three (33) patients have been included in the FRIENDS study from 27 December 2018 to 27 February 2019. Thirty-two (32) patients were implanted with an active fixation InVICTA lead and one (1) patient with a passive fixation InVICTA lead, at ten investigational sites in France, Italy, Spain and Portugal.

On 4 March 2019, the Sponsor informed the National Competent Authorities (NCAs), the Ethics Committees (ECs), and the Principal Investigators (PIs) actively involved in the study, about the decision to temporarily suspend of the enrolments in the study, following the occurrence of a series of adverse events related to the investigation device, in order to perform a root cause analysis and obtain the advice from the independent Data Safety Monitoring Board (DSMB).

NCAs, ECs, and PIs have been informed about the final decision of the Sponsor to prematurely terminate the enrolments in the FRIENDS study, according to the DSMB's advice, since 10 April.

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Considering that:

- No sites have been activated in the Netherlands
- No patients have been enrolled in the Netherlands

and that the Sponsor has:

- No intention to resume the study
- No intention to apply for the CE mark with the current lead design

the Sponsor asks CCMO to consider the FRIENDS study as officially closed in the Netherlands.

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Yours faithfully,


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