Serious Adverse Event Reporting Format (Clinical trials)

 Ospedale Universitario di Roma

*(Name of the Institution)*

Logo of the Institute

Title of study: **A Randomized Phase III safety and tolerability Trial of Ivabradine in patients with chronic heart failure**

Principal Investigator (Name, Designation and Affiliation): **Dr. Antonio Rossi**

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1. Participant details :

Subject ID: **01-005** Age at the time of event: **75** Gender Weight:**86** (Kgs)

 Male  Height:**172** (cms)

 Female x

1. Report type: Initial x Follow-up  Final 

If Follow-up report, state date of Initial report

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

What was the Principal Investigator assessment of relatedness to the event?

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Unrelated  | Related x |  |

3. Describe the event and specify suspected SAE diagnosis:……………………………………………...……………………………………….............

**On 16.06.2025 the patient experienced severe bradycardia (HR < 40 bpm) associated with syncope and orthostatic hypotension. The patient was taken to the emergency department, cerebral hypoperfusion were found. The ECG showed sinus bradycardia.**

**CS-986(Ivabradine) has been stopped. The patient received emergency atropine therapy and hemodynamic support.**

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

|  |  |  |
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1. Date of onset of SAE: **16.06.2025**  Date of reporting: **17.06.2025**
2. Onset lag time after administration of intervention: Location of SAE (Clinic/Ward/Home/Other)

....…………………………………… **4weeks**…………………. .........**Hospital**............................

1. Details of suspected study drug/device/investigational procedure causing SAE:

I. Suspect study drug (include generic name) device/intervention: **CS-986(Ivabradine)**

* 1. Indication(s) for which suspect study drug was prescribed or tested: **Chronic Heart Failure**
	2. Route(s) of administration, daily dose and regimen, dosage form and strength : …**10 mg via os per day…………………………………………………….**
	3. Therapy start date: **16.05.2025**  Stop date: **16.06.2025**

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

|  |  |  |
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| dd | mm | yy |

1. Was study intervention discontinued due to event? Yes  No x

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1. Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? Yes  No  NAx

If yes, provide details about the reduced dose..........**Not Applicable**

1. Did the reaction reappear after reintroducing the study drug / procedure? Yes  No  NA x

If yes, provide details about the dose............................. **Not Applicable**

1. Concomitant drug (s) and date of administration:

Beta-blocker therapy

1. Relevant test/laboratory data with dates:

**ECG on 16 June 2025 (HR < 40 bpm)**

1. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc): **caucasian, no allergies, no pregnancies, no smoking or alcohol use history. Heart failure Class III (NYHA), arterial hypertension and mild chronic renal failure**

10.

Have any similar SAE occurred previously in this study? If yes, please provide details. Yes  No x

**........Not Applicable………………………………………………………………………………...........................…………………..................................................**

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11. Seriousness of the SAE:

|  |  |  |
| --- | --- | --- |
| Death |  Congenitial anomaly |  |
| Life threatening |  Required intervention to prevent |  |
| Hospitalization-initial or prolonged | x permanent impairment / damage | x |
| Disability |  Others *(specify)* |  |

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12. Describe the medical management provided for adverse reaction (if any) to the research participant.

**atropine therapy and hemodynamic support**.……………………………………………………………………...........................…………………..................................................

13. Outcome of SAE:

|  |  |  |
| --- | --- | --- |
| Fatal |  Recovered |  |
| Continuing | x Unknown |  |
| Recovering |  Other *(specify)* |  |

........................................................................................................................................……………………………………........................................

14. Was the research participant continued on the trial? Yes x No  NA 

15. Provide details about PI’s final assessment of SAE relatedness to trial.

.....**Adverse event severe bradycardia is considered related to the suspect drug** ...........……………………………………………………………………………………………...........................…………………..................................................

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16. Does this report require any alteration in trial protocol? Yes  No x

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

Signature of PI: ………………………………………………………………………………………………… **17.06.2025**

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