Data Management Report

Study name: SAFER3

Report creation date: 2025-02-27

# Study Recruitment status

## Number of subjects with initiated visits

|  | **Recruited** | **Signed Consent** | **Screened** | **Enrolled** | **Completed the study** | **Screen Failure** |
| --- | --- | --- | --- | --- | --- | --- |
| **Site** |  |  |  |  |  |  |
| AB02 | 15 (65%) | 15 (65%) | 15 (65%) | 13 (72%) | 12 (80%) | 0 (NA%) |
| AB05 | 7 (30%) | 7 (30%) | 7 (30%) | 5 (28%) | 3 (20%) | 0 (NA%) |
| CD01 | 1 (4.3%) | 1 (4.3%) | 1 (4.3%) | 0 (0%) | 0 (0%) | 0 (NA%) |
| **N (%)** | 23 (100%) | 23 (100%) | 23 (100%) | 18 (100%) | 15 (100%) | 0 (NA%) |

# Subject’s Eligibility status

## Number of subjects:

| **Eligibility Criteria meet on V1** | |
| --- | --- |
| **Characteristic** | **N = 181** |
| Site |  |
| AB02 | 13 (72.2%) |
| AB05 | 5 (27.8%) |
| Subject meet all criteria one hour prior to administration of the study drug (V1) |  |
| Yes | 18 (100.0%) |
| 1n (%) | |

## Eligibility Criteria - not met or empty:

| **Subject No** | **Site** | **Eligibility Criteria nr (not meet or empty)** | **Patient Qualified** |
| --- | --- | --- | --- |
| AB02-00006 | AB02 | Empty Ex 1 |Empty Ex 1A |Empty Ex 1B |Empty Ex 2 |Empty Ex 3 |Empty Ex 4 |Empty Ex 5 |Empty Ex 6 |Empty Ex 7 |Empty Ex 8 |Empty Ex 9 |Empty Ex 10 | | Missing |
| AB02-00024 | AB02 | Empty Ex 1 |Empty Ex 1A |Empty Ex 1B |Empty Ex 2 |Empty Ex 3 |Empty Ex 4 |Empty Ex 5 |Empty Ex 6 |Empty Ex 7 |Empty Ex 8 |Empty Ex 9 |Empty Ex 10 | | Yes |
| AB05-00006 | AB05 | Empty Ex 1 |Empty Ex 1A |Empty Ex 1B |Empty Ex 2 |Empty Ex 3 |Empty Ex 4 |Empty Ex 5 |Empty Ex 6 |Empty Ex 7 |Empty Ex 8 |Empty Ex 9 |Empty Ex 10 | | Yes |
| AB05-00011 | AB05 | Empty Ex 1 |Empty Ex 1A |Empty Ex 1B |Empty Ex 2 |Empty Ex 3 |Empty Ex 4 |Empty Ex 5 |Empty Ex 6 |Empty Ex 7 |Empty Ex 8 |Empty Ex 9 |Empty Ex 10 | | Yes |
| CD01-00010 | CD01 | Empty Ex 1 |Empty Ex 1A |Empty Ex 1B |Empty Ex 2 |Empty Ex 3 |Empty Ex 4 |Empty Ex 5 |Empty Ex 6 |Empty Ex 7 |Empty Ex 8 |Empty Ex 9 |Empty Ex 10 | | Missing |

# End of study status

## EOS

| **End of Study** | | | | |
| --- | --- | --- | --- | --- |
| **Characteristic** | **Overall** | **AB02, N = 15** | **AB05, N = 7** | **CD01, N = 1** |
| **Subject completed entire course of study** | 15 (79%) | 12 (92%) | 3 (60%) | 0 (0%) |
| **Primary reason for premature study termination** |  |  |  |  |
| Lost to follow-up | 1 (25%) | 0 (0%) | 1 (50%) | 0 (0%) |
| Withdrawal by Subject | 3 (75%) | 1 (100%) | 1 (50%) | 1 (100%) |

## EOS listing

| **Subject No** | **Site** | **Subject completed entire course of study** | **Primary reason for premature study termination** | **Date of last data collected** | **Date of premature study termination** | **Time of premature study termination** | **If Investigator's decision, please describe** | **If Protocol Violation, please describe** | **Other reason, please describe** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| AB02-00001 | AB02 | Yes |  | 2024-10-04 |  |  |  |  |  |
| AB02-00002 | AB02 | Yes |  | 2024-07-11 |  |  |  |  |  |
| AB02-00004 | AB02 | Yes |  | 2024-10-20 |  |  |  |  |  |
| AB02-00005 | AB02 | Yes |  | 2024-08-08 |  |  |  |  |  |
| AB02-00008 | AB02 | Yes |  | 2024-05-19 |  |  |  |  |  |
| AB02-00010 | AB02 | Yes |  | 2024-06-05 |  |  |  |  |  |
| AB02-00011 | AB02 | Yes |  | 2024-05-14 |  |  |  |  |  |
| AB02-00012 | AB02 | Yes |  | 2024-08-07 |  |  |  |  |  |
| AB02-00013 | AB02 | Yes |  | 2024-04-26 |  |  |  |  |  |
| AB02-00019 | AB02 | No | Withdrawal by Subject | 2024-05-25 | 2024-05-25 | 11:00 |  |  |  |
| AB02-00020 | AB02 | Yes |  | 2024-06-10 |  |  |  |  |  |
| AB02-00022 | AB02 | Yes |  | 2024-09-06 |  |  |  |  |  |
| AB02-00025 | AB02 | Yes |  | 2024-05-05 |  |  |  |  |  |
| AB05-00005 | AB05 | No | Withdrawal by Subject | 2024-05-31 | 2024-05-31 | 19:00 |  |  |  |
| AB05-00008 | AB05 | No | Lost to follow-up | 2024-10-21 | 2024-10-22 | 08:00 |  |  |  |
| AB05-00009 | AB05 | Yes |  | 2024-07-30 |  |  |  |  |  |
| AB05-00012 | AB05 | Yes |  | 2024-06-24 |  |  |  |  |  |
| AB05-00024 | AB05 | Yes |  | 2024-07-22 |  |  |  |  |  |
| CD01-00010 | CD01 | No | Withdrawal by Subject | 2024-10-31 | 2024-11-01 | 14:00 |  |  |  |

# AE

## AE summary

| **Characteristic** | **Overall** | **AB02, N = 6** | **AB05, N = 1** |
| --- | --- | --- | --- |
| **AE** |  |  |  |
| Yes | 7 (100%) | 6 (100%) | 1 (100%) |
| **Severity** |  |  |  |
| mild | 2 (29%) | 1 (17%) | 1 (100%) |
| moderate | 2 (29%) | 2 (33%) | 0 (0%) |
| severe | 3 (43%) | 3 (50%) | 0 (0%) |

## AE listing

| **Subject No** | **Site** | **Adverse Event occurred on** | **Short description of AE** | **Start Date** | **Ongoing** | **End Date** | **Adverse event related to IMP** | **Severity** | **Action taken** | **Serious adverse event** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| AB02-00004 | AB02 | Other | Ventricular arrhythmia found on Holter ECG | 2024-08-26 | Yes |  | No | moderate | none | No |
| AB02-00010 | AB02 | ICA | VENTRICULAR FIBRILLATION WITH CARDIAC ARREST | 2024-05-24 | No | 2024-05-24 | No | severe | other action | Yes |
| AB02-00010 | AB02 | ICA | CARDIAC ARREST DUE TO VENTRICULAR FIBRILLATION | 2024-05-25 | No | 2024-05-25 | No | severe | other action | Yes |
| AB02-00010 | AB02 | ICA | COMPLETE ATRIO-VENTRICULAR BLOCK | 2024-05-28 | No | 2024-05-29 | No | severe | other action | Yes |
| AB02-00011 | AB02 | V2 - Follow-up 1 | diabetes mellitus | 2024-05-06 | Yes |  | No | mild | Concomitant therapy | No |
| AB02-00020 | AB02 | ICA | forearm hematoma | 2024-06-08 | Yes |  | No | moderate | other action | No |
| AB05-00024 | AB05 | V2 - Follow-up 1 | trace swelling around the ankles of the lower limbs | 2024-06-27 | Yes |  | No | mild | Concomitant therapy | No |

1. SAE

## SAE summary

| **Characteristic** | **Overall** | **AB02, N = 3** |
| --- | --- | --- |
| **SAE** |  |  |
| Yes | 3 (100%) | 3 (100%) |
| **Expectedness** |  |  |
| unexpected | 3 (100%) | 3 (100%) |

## SAE listing

| **Subject No** | **Site** | **AE definition** | **Seriousness criteria** | **Causes of the Adverse Event** | **AE start date** | **AE end date** | **Relation to the IMP** | **Expectedness** | **CTCAE grade** | **SAE Outcome** | **Date of Resolution** | **Action taken** | **AE Description** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| AB02-00010 | AB02 | VENTRICULAR FIBRILLATION WITH CARDIAC ARREST | Life-threatening | Medical conditions | 2024-05-24 | 2024-05-24 | Not Related | unexpected | Grade 4 | Resolved | 2024-05-24 | Not applicable (NA) | After admission to the hospital for planned coronary angiography, on 24 MAY 2024 at 16.35 , cardiac arrest occured- succesfully defibrillated. Coronary angiography performed after this event- multivessel coronary artery disesase found with 70% stenosis of LAD, chronic occlusion of TCA and Cx-marginal branch. PCI of LAD was ad hoc performed. |
| AB02-00010 | AB02 | CARDIAC ARREST DUE TO VENTRICULAR FIBRILLATION | Life-threatening | Medical conditions | 2024-05-25 | 2024-05-25 | Not Related | unexpected | Grade 4 | Resolved | 2024-05-25 | Not applicable (NA) | Second VF occured on 25MAY 2024 at 3:29 AM, succesfully defibrillated. COntrol angiography showed normal flow in LAD. Ad hoc PCI of CTO in RCA was performed.  FInally, CRT-D was implanted on 29 of May 2024 and patient was discharged home on 03of June 2024 |
| AB02-00010 | AB02 | COMPLETE ATRIOVENTRICULAR BLOCK | Life-threatening | Medical conditions | 2024-05-28 | 2024-05-29 | Not Related | unexpected | Grade 4 | Resolved | 2024-05-29 | Not applicable (NA) | COMPLETE ATRIOVENTRICULA BLOCK OCCURED ON 28 MAY 00:43 (ECG MONITORIN PRINTOUT AVAILABLE)  AS PATIENT WAS QUALIFIED DO ICD (BECAUSE OF TWO EPISODES OF VF, CRT-D WAS IMPLANTED ( WITH DDD STIMULATION OPTION) ON 29 MAY 2024  PATIENT WAS DISCHARGED HOME ON 3 OF JUNE 2024 |