

## GRAFT: SAE by MedDRA preferred term & system organ class per arm

|       |   | G-CSF+ Std.-ther. |        | Standard therapy |        | total |        |
|-------|---|-------------------|--------|------------------|--------|-------|--------|
|       |   | No                | %      | No               | %      | No    | %      |
| Blood | Anaemia                                 | 0                 | 0,0%   | 2                | 100,0% | 2     | 100,0% |
|       | Coagulopathy                            | 1                 | 100,0% | 0                | 0,0%   | 1     | 100,0% |
|       | Total                                   | 1                 | 33,3%  | 2                | 66,7%  | 3     | 100,0% |
| Card  | Atrial flutter                          | 1                 | 100,0% | 0                | 0,0%   | 1     | 100,0% |
|       | Cardiovascular insufficiency            | 0                 | 0,0%   | 1                | 100,0% | 1     | 100,0% |
|       | Pulseless electrical activity           | 1                 | 100,0% | 0                | 0,0%   | 1     | 100,0% |
|       | Right ventricular failure               | 0                 | 0,0%   | 1                | 100,0% | 1     | 100,0% |
|       | Total                                   | 2                 | 50,0%  | 2                | 50,0%  | 4     | 100,0% |
|       |   |                   |        |                  |        |       |        |
| Gastr | Acute abdomen                           | 0                 | 0,0%   | 1                | 100,0% | 1     | 100,0% |
|       | Ascites                                 | 2                 | 66,7%  | 1                | 33,3%  | 3     | 100,0% |
|       | Dieulafoy`s vascular malformation       | 1                 | 100,0% | 0                | 0,0%   | 1     | 100,0% |
|       | Duodenal ulcer perforation              | 1                 | 100,0% | 0                | 0,0%   | 1     | 100,0% |
|       | Gastrointestinal haemorrhage            | 6                 | 60,0%  | 4                | 40,0%  | 10    | 100,0% |
|       | Haemoperitoneum                         | 0                 | 0,0%   | 1                | 100,0% | 1     | 100,0% |
|       | Haemorrhoidal haemorrhage               | 1                 | 100,0% | 0                | 0,0%   | 1     | 100,0% |
|       | Ileus                                   | 0                 | 0,0%   | 1                | 100,0% | 1     | 100,0% |
|       | Intestinal haemorrhage                  | 0                 | 0,0%   | 1                | 100,0% | 1     | 100,0% |
|       | Intestinal ischaemia                    | 1                 | 100,0% | 0                | 0,0%   | 1     | 100,0% |
|       | Intestinal varices haemorrhage          | 0                 | 0,0%   | 2                | 100,0% | 2     | 100,0% |
|       | Oesophageal varices haemorrhage         | 2                 | 100,0% | 0                | 0,0%   | 2     | 100,0% |
|       | Upper gastrointestinal haemorrhage      | 0                 | 0,0%   | 2                | 100,0% | 2     | 100,0% |
|       | Total                                   | 14                | 51,9%  | 13               | 48,1%  | 27    | 100,0% |
|       |   |                   |        |                  |        |       |        |
|       |   |                   |        |                  |        |       |        |
| Genrl | General physical health deterioration   | 1                 | 50,0%  | 1                | 50,0%  | 2     | 100,0% |
|       | Multiple organ dysfunction syndrome     | 11                | 55,0%  | 9                | 45,0%  | 20    | 100,0% |
|       | Systemic inflammatory response syndrome | 0                 | 0,0%   | 1                | 100,0% | 1     | 100,0% |
|       | Ulcer haemorrhage                       | 0                 | 0,0%   | 1                | 100,0% | 1     | 100,0% |
|       | Total                                   | 12                | 50,0%  | 12               | 50,0%  | 24    | 100,0% |
| Hepat | Acute on chronic liver failure          | 8                 | 53,3%  | 7                | 46,7%  | 15    | 100,0% |

|       |                             |    |        |    |        |    |        |
|-------|-----------------------------|----|--------|----|--------|----|--------|
|       | Hepatic cirrhosis           | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
|       | Hepatic failure             | 5  | 45,5%  | 6  | 54,5%  | 11 | 100,0% |
|       | Hepatic function abnormal   | 2  | 100,0% | 0  | 0,0%   | 2  | 100,0% |
|       | Hepatorenal syndrome        | 6  | 60,0%  | 4  | 40,0%  | 10 | 100,0% |
|       | Total                       | 21 | 53,8%  | 18 | 46,2%  | 39 | 100,0% |
| Infec | Abdominal wall infection    | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
|       | Infection                   | 0  | 0,0%   | 2  | 100,0% | 2  | 100,0% |
|       | Influenza                   | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
|       | Peritonitis                 | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
|       | Peritonitis bacterial       | 1  | 25,0%  | 3  | 75,0%  | 4  | 100,0% |
|       | Pneumonia                   | 1  | 20,0%  | 4  | 80,0%  | 5  | 100,0% |
|       | Pulmonary sepsis            | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
|       | Sepsis                      | 3  | 50,0%  | 3  | 50,0%  | 6  | 100,0% |
|       | Septic shock                | 1  | 50,0%  | 1  | 50,0%  | 2  | 100,0% |
|       | Urosepsis                   | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
|       | Total                       | 9  | 37,5%  | 15 | 62,5%  | 24 | 100,0% |
| Inj&P | Post procedural haemorrhage | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
|       | Subdural haematoma          | 1  | 50,0%  | 1  | 50,0%  | 2  | 100,0% |
|       | Total                       | 1  | 33,3%  | 2  | 66,7%  | 3  | 100,0% |
| Inv   | Blood sodium decreased      | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
|       | Transaminases increased     | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
|       | Total                       | 1  | 50,0%  | 1  | 50,0%  | 2  | 100,0% |
| Metab | Acidosis                    | 0  | 0,0%   | 2  | 100,0% | 2  | 100,0% |
|       | Fluid overload              | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
|       | Hyponatraemia               | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
|       | Lactic acidosis             | 2  | 100,0% | 0  | 0,0%   | 2  | 100,0% |
|       | Total                       | 4  | 66,7%  | 2  | 33,3%  | 6  | 100,0% |
| Neopl | Choroid melanoma            | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
|       | Total                       | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |

|       |                                     |    |        |    |        |    |        |
|-------|-------------------------------------|----|--------|----|--------|----|--------|
| Nerv  | Cerebral haemorrhage                | 1  | 50,0%  | 1  | 50,0%  | 2  | 100,0% |
|       | Coma hepatic                        | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
|       | Disturbance in attention            | 1  | 33,3%  | 2  | 66,7%  | 3  | 100,0% |
|       | Encephalopathy                      | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
|       | Generalised tonic-clonic seizure    | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
|       | Hepatic encephalopathy              | 5  | 33,3%  | 10 | 66,7%  | 15 | 100,0% |
|       | Seizure                             | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
|       | Status epilepticus                  | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
|       | Subarachnoid haemorrhage            | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
|       | Total                               | 11 | 42,3%  | 15 | 57,7%  | 26 | 100,0% |
| Renal | Acute kidney injury                 | 1  | 50,0%  | 1  | 50,0%  | 2  | 100,0% |
|       | Anuria                              | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
|       | Renal failure                       | 1  | 50,0%  | 1  | 50,0%  | 2  | 100,0% |
|       | Renal impairment                    | 1  | 50,0%  | 1  | 50,0%  | 2  | 100,0% |
|       | Total                               | 4  | 57,1%  | 3  | 42,9%  | 7  | 100,0% |
| Resp  | Acute respiratory distress syndrome | 1  | 50,0%  | 1  | 50,0%  | 2  | 100,0% |
|       | Asphyxia                            | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
|       | Aspiration                          | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
|       | Epistaxis                           | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
|       | Pleural effusion                    | 1  | 33,3%  | 2  | 66,7%  | 3  | 100,0% |
|       | Pulmonary oedema                    | 1  | 33,3%  | 2  | 66,7%  | 3  | 100,0% |
|       | Respiratory failure                 | 3  | 33,3%  | 6  | 66,7%  | 9  | 100,0% |
|       | Total                               | 8  | 40,0%  | 12 | 60,0%  | 20 | 100,0% |
| Surg  | Endotracheal intubation             | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
|       | Haemodialysis                       | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
|       | Liver transplant                    | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
|       | Portal shunt procedure              | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
|       | Resuscitation                       | 2  | 66,7%  | 1  | 33,3%  | 3  | 100,0% |
|       | Thoracic cavity drainage            | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
|       | Total                               | 5  | 62,5%  | 3  | 37,5%  | 8  | 100,0% |
| Vasc  | Bleeding varicose vein              | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
|       | Circulatory collapse                | 1  | 33,3%  | 2  | 66,7%  | 3  | 100,0% |
|       | Haemorrhage                         | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
|       | Hypotension                         | 2  | 50,0%  | 2  | 50,0%  | 4  | 100,0% |
|       | Shock haemorrhagic                  | 0  | 0,0%   | 3  | 100,0% | 3  | 100,0% |
|       | Total                               | 3  | 25,0%  | 9  | 75,0%  | 12 | 100,0% |

|       |                                       |   |        |   |        |    |        |
|-------|---------------------------------------|---|--------|---|--------|----|--------|
| Total | Abdominal wall infection              | 1 | 100,0% | 0 | 0,0%   | 1  | 100,0% |
|       | Acidosis                              | 0 | 0,0%   | 2 | 100,0% | 2  | 100,0% |
|       | Acute abdomen                         | 0 | 0,0%   | 1 | 100,0% | 1  | 100,0% |
|       | Acute kidney injury                   | 1 | 50,0%  | 1 | 50,0%  | 2  | 100,0% |
|       | Acute on chronic liver failure        | 8 | 53,3%  | 7 | 46,7%  | 15 | 100,0% |
|       | Acute respiratory distress syndrome   | 1 | 50,0%  | 1 | 50,0%  | 2  | 100,0% |
|       | Anaemia                               | 0 | 0,0%   | 2 | 100,0% | 2  | 100,0% |
|       | Anuria                                | 1 | 100,0% | 0 | 0,0%   | 1  | 100,0% |
|       | Ascites                               | 2 | 66,7%  | 1 | 33,3%  | 3  | 100,0% |
|       | Asphyxia                              | 1 | 100,0% | 0 | 0,0%   | 1  | 100,0% |
|       | Aspiration                            | 1 | 100,0% | 0 | 0,0%   | 1  | 100,0% |
|       | Atrial flutter                        | 1 | 100,0% | 0 | 0,0%   | 1  | 100,0% |
|       | Bleeding varicose vein                | 0 | 0,0%   | 1 | 100,0% | 1  | 100,0% |
|       | Blood sodium decreased                | 0 | 0,0%   | 1 | 100,0% | 1  | 100,0% |
|       | Cardiovascular insufficiency          | 0 | 0,0%   | 1 | 100,0% | 1  | 100,0% |
|       | Cerebral haemorrhage                  | 1 | 50,0%  | 1 | 50,0%  | 2  | 100,0% |
|       | Choroid melanoma                      | 1 | 100,0% | 0 | 0,0%   | 1  | 100,0% |
|       | Circulatory collapse                  | 1 | 33,3%  | 2 | 66,7%  | 3  | 100,0% |
|       | Coagulopathy                          | 1 | 100,0% | 0 | 0,0%   | 1  | 100,0% |
|       | Coma hepatic                          | 0 | 0,0%   | 1 | 100,0% | 1  | 100,0% |
|       | Dieulafoy's vascular malformation     | 1 | 100,0% | 0 | 0,0%   | 1  | 100,0% |
|       | Disturbance in attention              | 1 | 33,3%  | 2 | 66,7%  | 3  | 100,0% |
|       | Duodenal ulcer perforation            | 1 | 100,0% | 0 | 0,0%   | 1  | 100,0% |
|       | Encephalopathy                        | 1 | 100,0% | 0 | 0,0%   | 1  | 100,0% |
|       | Endotracheal intubation               | 0 | 0,0%   | 1 | 100,0% | 1  | 100,0% |
|       | Epistaxis                             | 0 | 0,0%   | 1 | 100,0% | 1  | 100,0% |
|       | Fluid overload                        | 1 | 100,0% | 0 | 0,0%   | 1  | 100,0% |
|       | Gastrointestinal haemorrhage          | 6 | 60,0%  | 4 | 40,0%  | 10 | 100,0% |
|       | General physical health deterioration | 1 | 50,0%  | 1 | 50,0%  | 2  | 100,0% |
|       | Generalised tonic-clonic seizure      | 1 | 100,0% | 0 | 0,0%   | 1  | 100,0% |
|       | Haemodialysis                         | 1 | 100,0% | 0 | 0,0%   | 1  | 100,0% |
|       | Haemoperitoneum                       | 0 | 0,0%   | 1 | 100,0% | 1  | 100,0% |
|       | Haemorrhage                           | 0 | 0,0%   | 1 | 100,0% | 1  | 100,0% |
|       | Haemorrhoidal haemorrhage             | 1 | 100,0% | 0 | 0,0%   | 1  | 100,0% |
|       | Hepatic cirrhosis                     | 0 | 0,0%   | 1 | 100,0% | 1  | 100,0% |

|                                     |    |        |    |        |    |        |
|-------------------------------------|----|--------|----|--------|----|--------|
| Hepatic encephalopathy              | 5  | 33,3%  | 10 | 66,7%  | 15 | 100,0% |
| Hepatic failure                     | 5  | 45,5%  | 6  | 54,5%  | 11 | 100,0% |
| Hepatic function abnormal           | 2  | 100,0% | 0  | 0,0%   | 2  | 100,0% |
| Hepatorenal syndrome                | 6  | 60,0%  | 4  | 40,0%  | 10 | 100,0% |
| Hyponatraemia                       | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
| Hypotension                         | 2  | 50,0%  | 2  | 50,0%  | 4  | 100,0% |
| Ileus                               | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
| Infection                           | 0  | 0,0%   | 2  | 100,0% | 2  | 100,0% |
| Influenza                           | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
| Intestinal haemorrhage              | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
| Intestinal ischaemia                | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
| Intestinal varices haemorrhage      | 0  | 0,0%   | 2  | 100,0% | 2  | 100,0% |
| Lactic acidosis                     | 2  | 100,0% | 0  | 0,0%   | 2  | 100,0% |
| Liver transplant                    | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
| Multiple organ dysfunction syndrome | 11 | 55,0%  | 9  | 45,0%  | 20 | 100,0% |
| Oesophageal varices haemorrhage     | 2  | 100,0% | 0  | 0,0%   | 2  | 100,0% |
| Peritonitis                         | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
| Peritonitis bacterial               | 1  | 25,0%  | 3  | 75,0%  | 4  | 100,0% |
| Pleural effusion                    | 1  | 33,3%  | 2  | 66,7%  | 3  | 100,0% |
| Pneumonia                           | 1  | 20,0%  | 4  | 80,0%  | 5  | 100,0% |
| Portal shunt procedure              | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
| Post procedural haemorrhage         | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
| Pulmonary oedema                    | 1  | 33,3%  | 2  | 66,7%  | 3  | 100,0% |
| Pulmonary sepsis                    | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
| Pulseless electrical activity       | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
| Renal failure                       | 1  | 50,0%  | 1  | 50,0%  | 2  | 100,0% |
| Renal impairment                    | 1  | 50,0%  | 1  | 50,0%  | 2  | 100,0% |
| Respiratory failure                 | 3  | 33,3%  | 6  | 66,7%  | 9  | 100,0% |
| Resuscitation                       | 2  | 66,7%  | 1  | 33,3%  | 3  | 100,0% |
| Right ventricular failure           | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
| Seizure                             | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
| Sepsis                              | 3  | 50,0%  | 3  | 50,0%  | 6  | 100,0% |
| Septic shock                        | 1  | 50,0%  | 1  | 50,0%  | 2  | 100,0% |
| Shock haemorrhagic                  | 0  | 0,0%   | 3  | 100,0% | 3  | 100,0% |
| Status epilepticus                  | 1  | 100,0% | 0  | 0,0%   | 1  | 100,0% |
| Subarachnoid haemorrhage            | 0  | 0,0%   | 1  | 100,0% | 1  | 100,0% |
| Subdural haematoma                  | 1  | 50,0%  | 1  | 50,0%  | 2  | 100,0% |

|   |    |        |     |        |     |        |
|---|----|--------|-----|--------|-----|--------|
| Systemic inflammatory response syndrome | 0  | 0,0%   | 1   | 100,0% | 1   | 100,0% |
| Thoracic cavity drainage                | 1  | 100,0% | 0   | 0,0%   | 1   | 100,0% |
| Transaminases increased                 | 1  | 100,0% | 0   | 0,0%   | 1   | 100,0% |
| Ulcer haemorrhage                       | 0  | 0,0%   | 1   | 100,0% | 1   | 100,0% |
| Upper gastrointestinal haemorrhage      | 0  | 0,0%   | 2   | 100,0% | 2   | 100,0% |
| Urosepsis                               | 0  | 0,0%   | 1   | 100,0% | 1   | 100,0% |
| Total                                   | 97 | 47,1%  | 109 | 52,9%  | 206 | 100,0% |

Summary:

- 54 patients from G-CSF arm and 47 Patients from SMT (Standard medical treatment) arm
- 37 patients from G-CSF arm and 36 Patients from SMT (arm with fatal SAE outcome(s))