**Title : A phase III randomized prospective trial, comparing the efficacy and safety between etoposide plus G-CSF and G-CSF only, followed by peripheral blood CD34+ cell count-adapted plerixafor mobilization for autologous transplantation–eligible patients with multiple myeloma**

**CASE REPORT FORM**

**1. Patients’ baseline demographics and disease-related characteristics at diagnosis**

|  |  |  |  |
| --- | --- | --- | --- |
| UPN | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| Age | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Sex | Male / Female |
| ECOG PS | 0 / 1 / 2 / 3 / 4 |  |  |
| Ig heavy chain type | G / A / M / D / E | Ig light chain type | Kappa / lambda |
| Hemoglobin | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ g/dL | Creatinine | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ mg/dL |
| Calcium | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ mg/dL | Osteolytic lesion | None / 1 / ≥2 |
| LDH | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ U/L | β2**-**microglobulin | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ µg/mL |
| Serum PEP | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ g/dL | Urine PEP | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ g/24hrs |
| Serum FLC kappa | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ mg/dL | Serum FLC lambda | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ mg/dL |
| BM aspiration PC | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ % | FISH t(4;14)(p16;q32) | Yes / No |
| Chromosome | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| FISH t(14;16)(q32;q32) | Yes / No | FISH del(17p) | Yes / No |
| D-S stage | I / II / III, A / B | ISS stage | I / II / III |
| R-ISS stage | I / II / III |  |  |

Abbreviations: UPN; unique patient number, ECOG PS; Eastern Cooperative Oncology Group performance status, Ig; immunoglobulin, LDH; lactate dehydrogenase, PEP; protein electrophoresis, FLC; free light chain, BM; bone marrow, PC; plasma cell, FISH; Fluorescence in situ hybridization, D-S; Durie-Salmon, ISS; international staging system

**2. Induction chemotherapy**

|  |  |  |  |
| --- | --- | --- | --- |
| 1st Regimen | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Cycle # | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| First response | PD / SD / PR / VPGR / CR / sCR | First response date | \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_ |
| Best response | PD / SD / PR / VGPR / CR / sCR | Best response date | \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_ |
| Final response | PD / SD / PR / VGPR / CR / sCR | Final response date | \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_ |
| 2nd Regimen | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Cycle # | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| First response | PD / SD / PR / VPGR / CR / sCR | First response date | \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_ |
| Best response | PD / SD / PR / VGPR / CR / sCR | Best response date | \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_ |
| Final response | PD / SD / PR / VGPR / CR / sCR | Final response date | \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_ |
| 3rd Regimen | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Cycle # | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| First response | PD / SD / PR / VPGR / CR / sCR | First response date | \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_ |
| Best response | PD / SD / PR / VGPR / CR / sCR | Best response date | \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_ |
| Final response | PD / SD / PR / VGPR / CR / sCR | Final response date | \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_ |

Abbreviations: PD; progressive disease, SD; stable disease, PR; partial response, VGPR; very good partial response, CR; complete response, sCR; stringent complete response

**3. Pre-transplant bone marrow aspiration and biopsy**

|  |  |  |  |
| --- | --- | --- | --- |
| BM aspiration PC | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ % | FISH t(4;14)(p16;q32) | Yes / No |
| Chromosome | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| FISH t(14;16)(q32;q32) | Yes / No | FISH del(17p) | Yes / No |

Abbreviations: BM; bone marrow, PC; plasma cell, FISH; Fluorescence in situ hybridization

**4. Screening**

|  |  |  |  |
| --- | --- | --- | --- |
| Height | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ cm | Weight | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ kg |
| BSA | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ m2 |  |  |
| CBC c diff. | | | |
| WBC | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ×109/L | ANC | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ×109/L |
| Hemoglobin | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ g/dL | Platelet | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ×109/L |
| Blood chemistry | | | |
| Creatinine | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ mg/dL | eGFR | \_\_\_\_\_\_ mL/min/1.73m2 |
| Total bilirubin | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ mg/dL |  |  |
| AST | U/L | ALT | U/L |
| Pregnancy test | (+) / (-) / ND |  |  |

Abbreviations: CBC; complete blood count, ANC; absolute neutrophil count, AST; aspartate aminotransferase, ALT; alanine aminotransferase

**5. PBSC mobilization**

|  |  |  |  |
| --- | --- | --- | --- |
| Etoposide adm. date | \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_ | G-CSF adm. date | \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_ |
| PB CD34+ cell count | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ /µL |  |  |
| Plerixafor adm. | Yes / No | Plerixafor adm. date | \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_ |
| Reason for Plerixafor | Low PB CD34+ cell count / Low CD34+ collection at day 1 | | |
| Pheresis date | \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_ | Duration of pheresis | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ days |
| 1st day CD34+ count | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ×106/kg | 2nd day CD34+ count | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ×106/kg |
| 3rd day CD34+ count | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ×106/kg | Total CD34+ count | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ×106/kg |
| Optimal collection | Yes / No | Adequate collection | Yes / No |
| Collection failure | Yes / No |  |  |
| Adverse events during SC mobilization | | | |
| Leukopenia | I / II / III / IV / V | Thrombocytopenia | I / II / III / IV / V |
| Neutropenic fever | I / II / III / IV / V | Nausea | I / II / III / IV / V |
| Vomiting | I / II / III / IV / V | Diarrhea | I / II / III / IV / V |
| Others |  |  |  |
|  | I / II / III / IV / V |  | I / II / III / IV / V |
|  | I / II / III / IV / V |  | I / II / III / IV / V |
|  | I / II / III / IV / V |  | I / II / III / IV / V |
|  | I / II / III / IV / V |  | I / II / III / IV / V |
| Adverse events during pheresis | | | |
| Paresthesia | I / II / III / IV / V | Hypotension | I / II / III / IV / V |
| Pyrexia | I / II / III / IV / V | Nausea | I / II / III / IV / V |
| Vomiting | I / II / III / IV / V |  |  |
| Others |  |  |  |
|  | I / II / III / IV / V |  | I / II / III / IV / V |
|  | I / II / III / IV / V |  | I / II / III / IV / V |
|  | I / II / III / IV / V |  | I / II / III / IV / V |
|  | I / II / III / IV / V |  | I / II / III / IV / V |

Abbreviations: adm.; admission, G-CSF; Granulocyte colony-stimulating factor, PB; peripheral blood, SC; stem cell

**6. Autologous stem cell transplantation**

|  |  |  |  |
| --- | --- | --- | --- |
| Conditioning regimen | Mel 140 m2 / 200 m2 | Conditioning date | \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_ |
| Neu. engraft. | Yes / No | Neu. engraft. date | \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_ |
| Platelet engraft. | Yes / No | Platelet engraft. date | \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_ |

Abbreviations: Mel; melphalan, engraft; engraftment

**7. Others**