

Busulfan dose and blood levels, PTX CIPRO dosing, Regimen Related Toxicity, Deaths

| Dose level | Patient numbers | Doses of BU CY | Average BU level *(n) | % CIPRO pre-post | % PTX pre/post | Grade 3-4 Toxicity / cause of death | Patient BU level + |
|------------|-----------------|----------------|-----------------------|------------------|----------------|---|--------------------|
| -- | 16 | 16/120 | ND | NA | NA | pulmonary hemorrhage/day 14. Pulmonary IPS/day 14. | ND |
| 1 | 12 | 15/150 | ND | 88/88 | 79/70 | renal and hepatic/fungal pneumonia day 26 | ND |
| 2 | 10 | 16/160 | 1162 (2) | 95/70 | 79/65 | none | |
| 3 | 12 | 17/160 | 729 (2) | 94/66 | 86/69 | none | |
| 4 | 8 | 18/150 | 926 (7) | 92/56 | 83/53 | cardiac and renal/cardiomyopathy day 35 [Hamilton] | 1194 |
| 5 | 10 | 19/150 | 1278 (4) | 94/73 | 89/61 | none | |
| 6 | 4 | 20/150 | 1292 (4) | 96/66 | 52/69 | none | |
| 6 | 10 | 1350T/150 | 1340 (10) | 93/80 | 86/67 | pulmonary/falve in CR | 1344 |
| | | | | | | hepatic/VOD day 68 | 1494 |
| 7 | 2 | 21/150 | 1559 (2) | 95/53 | 70/25 | skin/progressive DZ day 137 Cardiac/cardiomyopathy day 6 | 1510, 1608 |
| | | [84] | | | | | |

Code

T = BU level adjusted to target nanogram/milliliter

NA not administered

ND not done

PTX pentoxifyllene

% of prescribed doses taken pre and post transplant

* average level nanogram/milliliter (n) = number of patients with BU blood level measurement

(+) BU CSS, nanogram/milliliter level of individual patients experiencing grade 3-4 RRT

Note toxicity grades:

- grade 3 life threatening