**Appendix Table C60. Adverse events: Treatment, germ cell tumor**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study (Investigator, country, year)** | **Record Number** | **Group (N)** | **Severity or Grade Infection** | **%** | **% Engraftment Failure** | **% TRM** |
| Burdach, Germany and Austria, 2000 | 14310 | 28 |  |  |  |  |
| Burdach, Germany, 2003 | 10030 | reported engr, TRM, infec compl, sec malig, and major organ tox, but not by age of < or > 17 yrs |  |  |  |  |
| Burke, USA 2007 | 4060 | 7 | sepsis n=1 |  | 0 | 0 |
| Costa, USA, 2008 | 1710 | 1 |  |  | 0 | 0 |
| Drabko, Poland 2005 | 6680 | 21 |  |  |  | 5% (n=1 day 35 from multiorgan failure secondary to infection) |
| Hara , Japan 1998 | 17950 | 3 |  |  |  | 0 NR |
| Harimaya, Japan, 2003 | 9850 | 2 |  |  | 0 | 0 |
| Kasper, Germany, 2006 | 2570 | 5 |  |  | 0 | 0 |
| Koscielniak Germany 2005 | 7860 |  |  |  | 0 | 0 |
| Kushner, USA, 2001 | 14240 | 1 HSCT pt died at 17 mos after HSCT with NED but pulmonary failure |  |  |  |  |
| Lucas, USA 2008 | 2450 | 1 |  |  | 0 | 0 |
| Lucidarme, France, 1998 | 17610 | 3 |  |  |  | 0 (NR) |
| Meyers, USA, 2001 | 13670 |  | sepsis leading to death | 4% n=1 patient from HSCT group (incl in TRM) |  | of HSCT group n=23 n=3 13% |
| Navid, US and Canada, 2006 | 5930 | 9 |  |  | 0 | 0 |
| Numata, Japan, 2002 | 12130 |  |  |  | 0 | 0 |
| Ozkaynak, USA 1998 | 18540 | 15 |  |  | 0 (one patient not assessable secondary to early toxic death) | n=2 ATN day 0 and septic shock day 8 |
| Pession, Italy, 1999 | 16120 | 3 |  |  |  | 0 NR |
| Prete, Italy 1998 | 17210 | 17 |  |  |  | 0 |
| Tanaka, Japan, 2002 | 11770 |  |  | 0 |  | 0 |

**Appendix Table C60. Adverse events: Treatment, germ cell tumor Continued**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study (Investigator,**  **country, year)** | **Record Number** | **Severity or Grade SM** | **F/U (mos) SM** | **% SM** | **Comments SM** | **Group (N)\_7** | **% Hepatic veno-occlusive disease (Hepatic Sinusoidal Obstruction)** | **Comments hVOD** | **Severity or Grade SHE** | **% SHE** |
| Costa, USA, 2008 | 1710 | AML at 53 months post HSCT |  |  |  |  |  |  |  |  |
| Drabko, Poland 2005 | 6680 |  |  |  |  |  | 10% | moderate to severe |  |  |
| Meyers, USA, 2001 | 13670 |  |  |  |  |  |  |  | HSCT pt died from hemorrhagic pericarditis (included in TRM) | 4% |
| Numata, Japan, 2002 | 12130 | CML chronic phase | 50 months after HSCT |  |  |  |  |  |  |  |
| Tanaka, Japan, 2002 | 11770 | CML |  | 14% | not clear if the 35 y/o pt or one of the 6 abstracted pts | 1 of 7 |  |  |  |  |