Appendix Table C37. KQ1 Outcome VI. Antibodies: Epoetin versus control

|  |  |  |  |
| --- | --- | --- | --- |
| **Study ID** | **Antibodies Reported** | **Numbers** | **Comments** |
| **Aapro 2008** | Not reported |  |  |
| **Antonadou 2001** | Not reported |  |  |
| **Bamias 2003** | Not reported |  |  |
| **Blohmer 2004** | Not reported |  |  |
| **Boogaerts 2003** | Not reported |  |  |
| **Case 1993** | Yes |  | Serum samples for the determination of antibodies against rHuEPO were obtained at entry and after completion of the study's 12-week double blind phase or when a patient prematurely withdrew from the study. |
| **Chang 2005** | Not reported |  |  |
| **Christodoulou 2009** | Not reported |  |  |
| **Dammacco 2001** | Not reported |  |  |
| **Debus 2006** | Not reported |  |  |
| **Engert 2009** | Not reported |  |  |
| **EPO INT-1** | Not reported |  |  |
| **EPO INT-3** | Not reported |  |  |
| **Fujisaka 2011** | Not reported |  |  |
| **Goss 2005** | Not reported |  |  |
| **Grote 2005** | Not reported |  |  |
| **Gupta 2009** | Not reported |  |  |
| **Henke 2003** | Not reported |  |  |
| **Henry 1995** | Yes | Evaluated: 60 (30/30). Negative: 56 (28/28). Positive: 4 (2/2) | Assays for anti-r-HuEPO antibodies before and after therapy were done on **56** patients (28 in each group) and none had a positive titer to the r-HuEPO. Four patients (2 r-HuEPO, 2 placebo) had a positive titer both before and during the study, suggesting a reaction to the albumin containing vehicle. |
|
| **Hoskin 2009** | Not reported |  |  |
| **Iconomou 2003** | Not reported |  |  |

Appendix Table C37. KQ1 Outcome VI. Antibodies: Epoetin versus control (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| **Study ID** | **Antibodies Reported** | **Numbers** | **Comments** |
| **Leyland-Jones 2005** | Not reported |  |  |
| **Littlewood 2001** | Not reported |  |  |
| **Machtay 2007** | Not reported |  |  |
| **Moebus 2007** | Not reported |  |  |
| **Milroy 2003** | Not reported |  |  |
| **ML17620** | Not reported |  |  |
| **Oberhoff 1998** | Yes |  | Anti-EPO antibodies were measured at baseline and at the end of the controlled treatment phase. No anti-bodies against rhEPO developed during therapy in the study. |
| **Osterborg 2002** | Yes |  | No antibodies to erythropoietin were detected in any patient. |
| **Porter 1996** | Not reported |  |  |
| **Pronzato 2002** | Not reported |  |  |
| **Ray-Coquard 2009** | Not reported |  |  |
| **Razzouk 2006** | Not reported |  |  |
| **Rose 1994** | Not reported |  |  |
| **Savonije 2005** | Not reported |  |  |
| **Thomas 2002** | Not reported |  |  |
| **Thomas 2008** | Not reported |  |  |
| **Tsuboi 2009** | Yes |  | Anti-erythropoietin antibodies were masured by enzyme-linked immunosorbent assay and radioimmunoprecipitation assay and compared with the data of the last observation. Detection by either method was judged as positive. No anti-erythropoietin antibodies were reported |
| **Wagner 2004** | Not repored |  |  |
| **Wilkinson 2006** | Not repoted |  |  |
| **Witzig 2005** | Not reported |  |  |