**S2 Table.** Results from Multivariable Cox Regression Models of Trial Completion

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Characteristic** | **HR (95% CI)**  ***All Trials*** | *P value* |  | **HR (95% CI)**  ***Efficacy/Safety*** | *P value* |
| PIP opinion year |  |  |  |  |  |
| 2008 | 1 [Reference] |  |  | 1 [Reference] |  |
| 2009 | 0.62 (0.24-1.56) | 0.31 |  | 0.55 (0.20-1.57) | 0.27 |
| 2010 | 1.26 (0.50-3.22) | 0.62 |  | 0.76 (0.30-1.93) | 0.57 |
| 2011 | 1.05 (0.40-2.75) | 0.92 |  | 0.61 (0.18-1.99) | 0.41 |
| 2012 | 0.72 (0.16-3.18) | 0.66 |  | 0.41 (0.10-1.72) | 0.22 |
| 2013 | –b | –b |  | –b | –b |
| Therapeutic area a |  |  |  |  |  |
| Alimentary and metabolism | 1 [Reference] |  |  | 1 [Reference] |  |
| Blood | 1.86 (0.79-4.34) | 0.15 |  | 1.63 (0.52-5.09) | 0.40 |
| Cardiovascular | 0.56 (0.18-1.72) | 0.31 |  | 0.30 (0.06-1.54) | 0.15 |
| Genitourinary | 0.75 (0.29-1.93) | 0.55 |  | –b | –b |
| Anti-infective | 1.55 (0.63-3.82) | 0.34 |  | 2.11 (0.66-6.73) | 0.21 |
| Antineoplastic | 0.48 (0.18-1.24) | 0.13 |  | 0.19 (0.05-0.74) | 0.02 |
| Neurologic | 0.83 (0.29-2.33) | 0.72 |  | 1.14 (0.34-3.83) | 0.83 |
| Respiratory | 2.25 (0.85-5.92) | 0.10 |  | 1.80 (0.58-5.57) | 0.31 |
| Musculoskeletal and others | 0.73 (0.07-7.91) | 0.80 |  | 0.51 (0.05-5.81) | 0.59 |
| Planned completion after MA |  |  |  |  |  |
| Yes | 0.11 (0.06-0.19) | <0.001 |  | 0.09 (0.05-0.18) | <0.001 |
| No | 1 [Reference] |  |  | 1 [Reference] |  |
| Orphan drug status |  |  |  |  |  |
| Yes | 0.88 (0.50-1.53) | 0.64 |  | 0.92 (0.49-1.71) | 0.79 |
| No | 1 [Reference] |  |  | 1 [Reference] |  |
| Study type |  |  |  |  |  |
| PK/PD only | 1 [Reference] |  |  |  |  |
| Primarily efficacy | 0.81 (0.39-1.68) | 0.56 |  | 1 [Reference] |  |
| Efficacy and safety | 0.98 (0.37-2.58) | 0.97 |  | 1.26 (0.54-2.94) | 0.59 |
| Primarily safety | 0.76 (0.39-1.50) | 0.43 |  | 0.77 (0.41-1.44) | 0.41 |
| Planned study enrolment (N) | 1.00 (1.00-1.00) | 0.12 |  | 1.00 (1.00-1.00) | 0.85 |