Single technology appraisal

Addendum 2 to the ERG report: Daratumumab in combination with bortezomib and dexamethasone for treating relapsed or refractory multiple myeloma. Survival estimates.

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(SHTAC)

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Commercial in confidence information relating to the Patient Access Schemes is <u>underlined</u> and <u>highlighted in green</u> for comparators and <u>underlined and highlighted in blue</u> for the CAA and Patient Access Scheme for daratumumab (monotherapy and combination therapy respectively).

Table 1 Overall survival: CS base case (CASTOR independently fitted, 2L)

OS distribution	DBd		Bd	
	5 year	10 year	5 year	10 year
Exponential	63.1%	39.7%	39.6%	15.6%
Weibull	58.0%	28.4%	33.5%	8.7%
Log normal	67.0%	51.6%	47.3%	30.6%
Log logistic	61.8%	40.5%	41.1%	22.7%
Gompertz	31.2%	0.0%	21.3%	0.0%
Generalised gamma	52.1%	1.9%	16.8%	0.0%

Table 2 Overall survival: Company base case and scenarios *

Scenario	Year	Percentage alive		
		DBd	Bd	Cd
Company base case: DBd log-logistic / Bd	5	61.8%	21.3%	27.6%
Gompertz/ HR Cd vs. Bd 0.83	10	40.5%	0.0%	0.1%
DBd Weibull / Bd Gompertz	5	58.0%	21.3%	27.6%
	10	28.4%	0.0%	0.1%
DBd exponential / Bd Gompertz	5	63.1%	21.3%	27.6%
	10	39.7%	0.0%	0.1%
DBd log-logistic / Bd Weibull	5	61.8%	33.5%	40.2%
	10	40.5%	8.7%	13.1%
DBd Weibull / Bd Weibull	5	58.0%	33.5%	40.2%
	10	28.4%	8.7%	13.1%
Unadjusted for subsequent treatment	5	59.9%	20.0%	26.2%
	10	38.5%	0.0%	0.0%
Adjusted for Bd duration: HR Cd vs. Bd 0.57	5	61.8%	21.3%	41.4%
	10	40.5%	0.0%	1.2%

^{*} No impact on other scenarios

Table 3 Overall survival: ERG preferred analysis and scenarios *

Scenario	Year	Percentage alive		
	leai	DBd	Bd	Cd
ERG base case: Bd Weibull /	5	56.0%	33.5%	54.8%
HR DBd vs. Bd 0.53 / Cd vs. Bd 0.55	10	27.4%	8.7%	26.1%
2L: HR DBd vs. Bd 0.50 / Cd vs. Bd 0.57	5	57.8%	33.5%	53.5%
	10	29.5%	8.7%	24.8%
Unadjusted for subsequent treatment	5	55.3%	32.7%	54.0%
	10	25.9%	7.8%	24.6%
Unadjusted for Bd duration: HR Cd vs. Bd 0.80	5	56.0%	33.5%	41.5%
	10	27.4%	8.7%	14.1%
Equal hazards from 5 years	5	56.0%	33.5%	54.8%
	10	14.6%	8.7%	14.3%

^{*} No impact on other scenarios

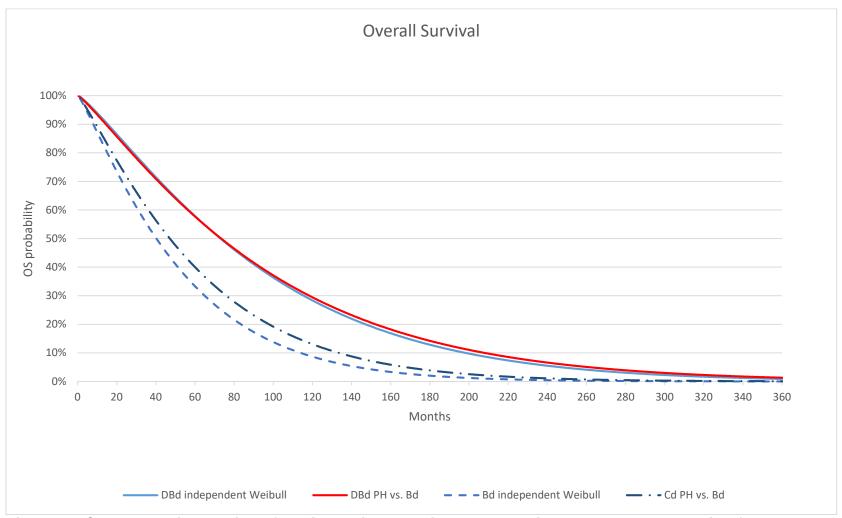


Figure 1 OS extrapolation: Weibull functions with and without proportional hazards assumption for DBd vs. Bd