ARTICLE CITATION

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Meta-analysis of phase II trials in metastatic uveal melanoma (MUM) to determine progression-free (PFS) and overall survival (OS) benchmarks for future phase II trials: An irci-ocular melanoma initiative.

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Abstract Disclosures

Abstract

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Background: Multiple phase II trials in MUM have reported a range of survival outcomes with limited meaningful benefit. We conducted a meta-analysis to establish benchmarks of PFS and OS for future phase II trials **Methods:** Individual patient data was obtained from 29 trials with a total of 970 patients (pts). Trials were identified from a literature search and were conducted from 1988 to 2015. Univariable (UA) and multivariable (MA) prognostic factor analyses were performed. 6-month PFS and 1-year OS were determined controlling for identified prognostic factors **Results:** Data from 677 pts enrolled onto 19 trials were available at the time of analysis. Therapy consisted of immunotherapy, kinase inhibitors, chemotherapy and liver directed therapy; the table below details patient characteristics. Superior 6 month PFS (UA) was associated with LDH ≤ ULN (OR 2.05 $p < 0.01$) and ALP ≤ ULN (OR 2.56 $p < 0.01$) but each millimeter increase in diameter of the largest liver lesion (DLL) (OR 0.99 $p = 0.007$) decreased PFS. LDH ≤ ULN (OR 2.14 $p < 0.01$) and ALP ≤ ULN (OR 1.97 $p = 0.015$) were significant by MA. Predictive factors of superior 1 year OS by UA were LDH ≤ ULN (OR 2.88 $p < 0.001$) and ALP ≤ ULN (OR 2.45 $p < 0.001$). Male sex (OR 0.65 $p = 0.008$), older age (OR 0.99 $p = 0.07$), ECOG ≥ 1 (OR 0.45 $p < 0.001$) and larger DLL (0.98 $p < 0.001$) predicted inferior OS. Significant prognostic factors by MA were LDH ≤ ULN (OR 2.95 $p < 0.001$), ALP ≤ ULN (OR 2.07 $p = 0.012$), and larger DLL (OR 0.98 $p < 0.001$). Using pooled data controlled for prognostic factors the 6-month PFS rate was 25% and the 1-year OS rate was 40%. **Conclusions:** Key prognostic factors were identified and benchmarks of PFS and OS were explored. Analysis of the complete dataset

(n~900) will be presented and the final results will guide the design of future trials in this rare disease.

Characteristic	Categories	Number (%)
Sex	M/F	352/325 (52/48)
ECOG	0/ ≥ 1	399/157 (72/28)
LDH	≤ ULN/ > UNL	257/309 (45/55)
ALP	≤ ULN/ > UNL	348/150 (70/30)
Line of therapy	0/1/ ≥ 2	33/399/85 (6/77/17)
Liver involvement (%)	< 20/ ≥ 20	62/76 (45/55)
Extrahepatic disease	No/yes	391/214 (65/35)
Age	Median (Range)	61 (19-90)
DLL (mm)	Median (Range)	35 (0-225)