Haematologica HAEMATOL/2016/162321 Version 4 Double autophagy stimulation using chemotherapy and mTOR inhibition combined with hydroxychloroquine for autophagy modulation in patients with relapsed or refractory multiple myeloma

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Disclosures: Financial support University of Pennsylvania Institutional Clinical and Translational Science Award Research Center grant (UL1 RR024134) (ECS) The Knight Cancer Institute RAC CCSG grant: P30CA069533 (ECS) OCTRI (Oregon clinical translational research institute) resources (ECS) M. D. Anderson Cancer Center SPORE in Multiple Myeloma Developmental Research Program (DTV) The Abramson Cancer Center pilot grant #IRG-78-002-31 (DTV) NCI Cancer Clinical Investigator Team Leadership Award 5P30CA069533-17 (ECS) Disclosures ECS holds an IND for rapamycin, hydroxychloroquine, ixasomib (Takeda), receives research funding from Takeda and Amgen, and performed on advisory boards of Takeda, Amgen, Novartis and Incyte DTV receives research funding and has performed on advisory boards of Takeda, Acetylon RTM, SS, EM, JG, RKA, ES, GVT, JP, ML and MC: no relevant conflicts

Contributions: ECS, DTV conception of design and performed the clinical trial ECS, DTV, RA, SS analysis and interpretation of data RTM, SS, EM, JG, AK, JB, MG, MS performed the clinical trial and reviewed the manuscript ECS, ML, GT and RA developed the methodology for the correlative analyses BP performed statistical analysis SRH acquired and managed the data and assisted in writing the paper