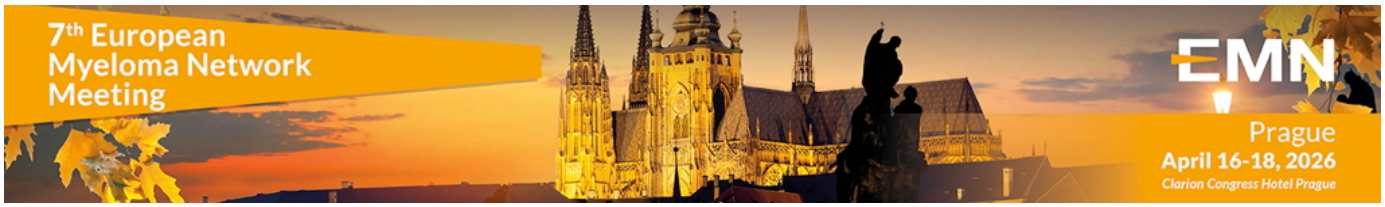

3. RELAPSED/REFRACTORY MULTIPLE MYELOMA

NATIONWIDE EXPERIENCE WITH STANDARD OF CARE IDECABTAGENE VICLEUCEL IN RELAPSED/REFRACTORY MULTIPLE MYELOMA: A REAL WORLD STUDY ON BEHALF OF THE *GRUPPO ITALIANO MALATTIE EMATOLOGICHE DELL'ADULTO* FOUNDATION

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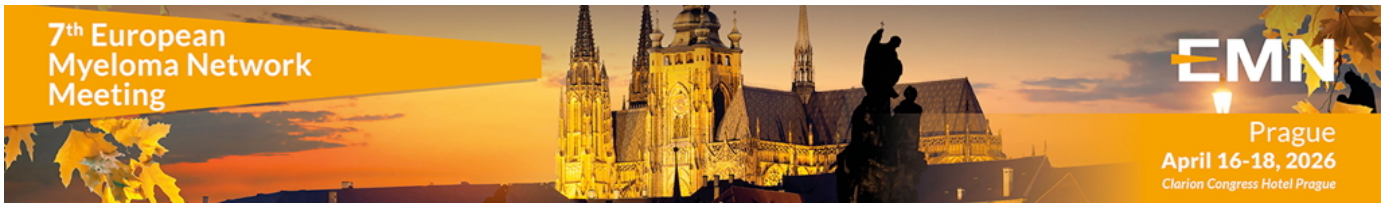
The treatment landscape of relapsed refractory multiple myeloma (RRMM) has recently been enriched by the introduction of chimeric antigen receptor T-cells (CAR-T). Since their approval stemmed from controlled clinical trials, real-world validation on a national level in unselected cohorts of patients (pts) is warranted. Hence, we designed an ambispective, national, multicentric, observational study with the aim of exploring the feasibility, efficacy and toxicity profiles of CAR-T within the Italian national healthcare system. The study is sponsored by and conducted on behalf of the Gruppo Italiano Malattie EMatologiche dell'Adulto (GIMEMA) foundation. Herein, we present the experience provided by the first 50 pts who consecutively underwent leukapheresis for idecabtagene vicleucel (ide-cel), from 28/05/2024 to 12/06/2025. Median age was 59 years (range 47-74). Extramedullay disease was observed in 14% of pts. Previous high risk cytogenetic abnormalities were reported in 34% of pts. Median number of previous lines was 3 (range 2-6). Triple and penta-class refractory disease was noted in 74% and 24% of pts, respectively. Five pts (10%) were exposed to talquetamab as last previous line, with a median time from last dose to leukapheresis of 1,4 months (mos). Poor performance status (PS) at the time of leukapheresis was present in 6% of pts. Manufacturing failure occurred in 1 pt , while 5 pts (10%) received an out of specification product. One pt did not undergo infusion due to unpermissive PS. Bridging therapy (BT) was used in 80% of pts: overall response rate (ORR) to BT was 35,9%. Median vein-to-vein time was 2,4 mos (range 42-170 days). Median follow-up (FU) from infusion was 6,3 mos. Cytokine release syndrome (CRS) and immune effector-cells associated neurotoxicity syndrome (ICANS) occured in 90% (6% grade 3-4) and 4% (1 grade 3) of pts, respectively. Hemophagocytic syndrome (IEC-HS) occurred in 8% of pts (1 grade 3). All the CRS, ICANS and IEC-HS events resolved. Tocilizumab and steroids were used in 46% of pts. Median hospital stay was 19 days (range 12-68). Incidence of grade 3-4 cytopenia decreased over time, being 99%, 24% and 16% at 1,3 and 6 mos, respectively. Serious infectious events were rare (grade 3-4 6%). The need for immunoglobulin supplementation decreased over time (64%, 56% and 44% at 1, 3, 6 mos, respectively). Non-relapse mortality was 2%. Among pts with available data, ORR at 1 and 3 mos was 88% and 85%, respectively, with a trend toward increase depth (complete responses being 24% and 35% respectively). Median progression free survival (PFS) was not reached; PFS at 5 mos was 82% (95% CI 0,7-0,95). On univariable analysis, the presence of progressive disease at infusion correlated with unfavourable PFS (HR 9,2; p 0,013 95% CI 1,1-76,3). A the time of the data cut-off, further subgroup analysis' were not feasible, due to limited FU. Median overall survival was not reached, being 88% at 5 mos (95% CI 0,78-1). In summary, our data recapitulated the expected toxicity and efficacy profiles of ide-cel within a national, real-world setting, aligning to similar experiences. Disease control before infusion appears critical to ensue prolonged responses, thus highliting the need for effective BT and adequate pts selection. Further data informing on the proper sequencing of therapies in the evolving



scenario of RRMM immunotherapy are awaited. Updated da- ta with longer FU will be presented at the meeting.