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Characterization and outcomes of Spanish Patients with Relapsed/Refractory Multiple Myeloma in the MajesTEC-1 and REALiTEC Studies

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INTRODUCTION AND METHODS

Relapsed and/or refractory multiple myeloma (RRMM) remains a therapeutic challenge, particularly in patients previously treated with proteasome inhibitors (PIs), immunomodulatory drugs (IMiDs), and anti-CD38 monoclonal antibodies or triple-class exposed (TCE). Teclistamab, the first-in-class bispecific antibody targeting B-cell maturation antigen (BCMA) and CD3, has demonstrated clinically meaningful efficacy in this heavily pre-treated patient population and stands as the bispecific antibody with most real-world experience¹⁻¹⁰.

- In the pivotal phase 1/2 MajesTEC-1 study, rapid, deep and durable responses were observed in patients with TCE RRMM, with an overall response rate (ORR) of 63%, a complete response or better (\geq CR) rate of 46.1%, and a median progression-free survival (PFS) of 11.4 months^{1,2}.
- The REALiTEC study, an international observational retrospective study, corroborated teclistamab's effectiveness in clinical practice in a heavily pre-treated patient population mainly treated via pre-approval access programs, validating teclistamab as a standard of care in a difficult-to-treat broader population^{8,9,10}.

Here we present a post hoc analysis of the Spanish cohorts of MajesTEC-1 and REALiTEC to describe the effectiveness of teclistamab monotherapy in the Spanish patient population included in these studies. The primary efficacy endpoints assessed were response rates and PFS. No safety analysis was conducted.

RESULTS

A total of 24 Spanish patients were included in this analysis: 16/165 (9.7%) from MajesTEC-1 and 8/113 (7.1%) from REALiTEC.

- Overall, baseline characteristics and high-risk features were balanced between the Spanish cohorts and the overall populations of both studies.
- In the Spanish cohort, the median age was 66.5 years (47-80) in MajesTEC-1 and 74.5 years (48-81) in REALiTEC. The median number of prior lines was 4 (3-8) and 3 (2-6), respectively.
- With a median follow-up of 30.9 months in MajesTEC-1 and 19.1 months in REALiTEC in the Spanish cohorts:
 - High ORR were observed (75% and 87.5%, respectively), with all the responses being \geq VGPR. A large proportion of patients achieved \geq CR, with 50% and 75% \geq CR rates, respectively. (**Figure 1**).
 - Median PFS was 13.1 months in MajesTEC-1 (**Figure 2**). Notably, patients achieving deep responses (\geq CR) experienced sustained disease control, with a median PFS exceeding two years (25.9 months). (**Figure 3**).
 - In REALiTEC, median PFS was not reached (0.85-NE), with an 18-month estimate of 75%. (**Figure 4**).

Figure 1: Response rates in MajesTEC-1 and REALiTEC

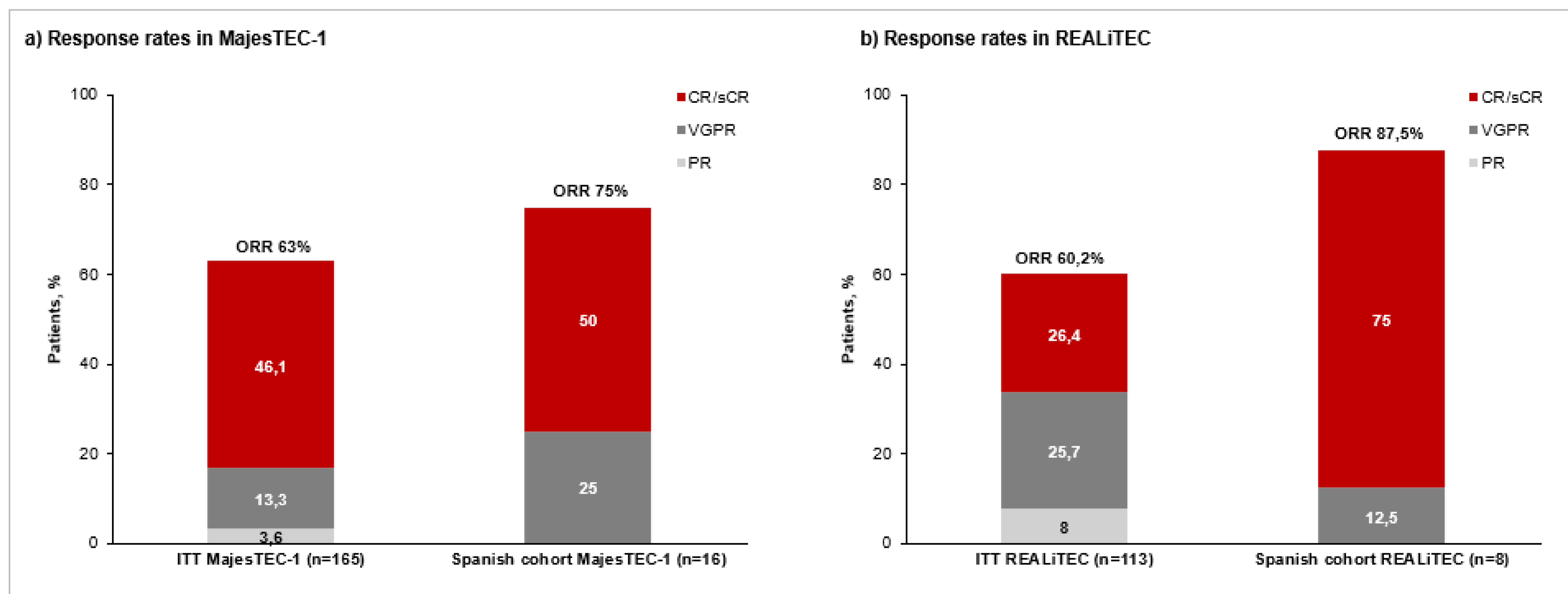


Figure 2: PFS in the Spanish cohort in MajesTEC-1

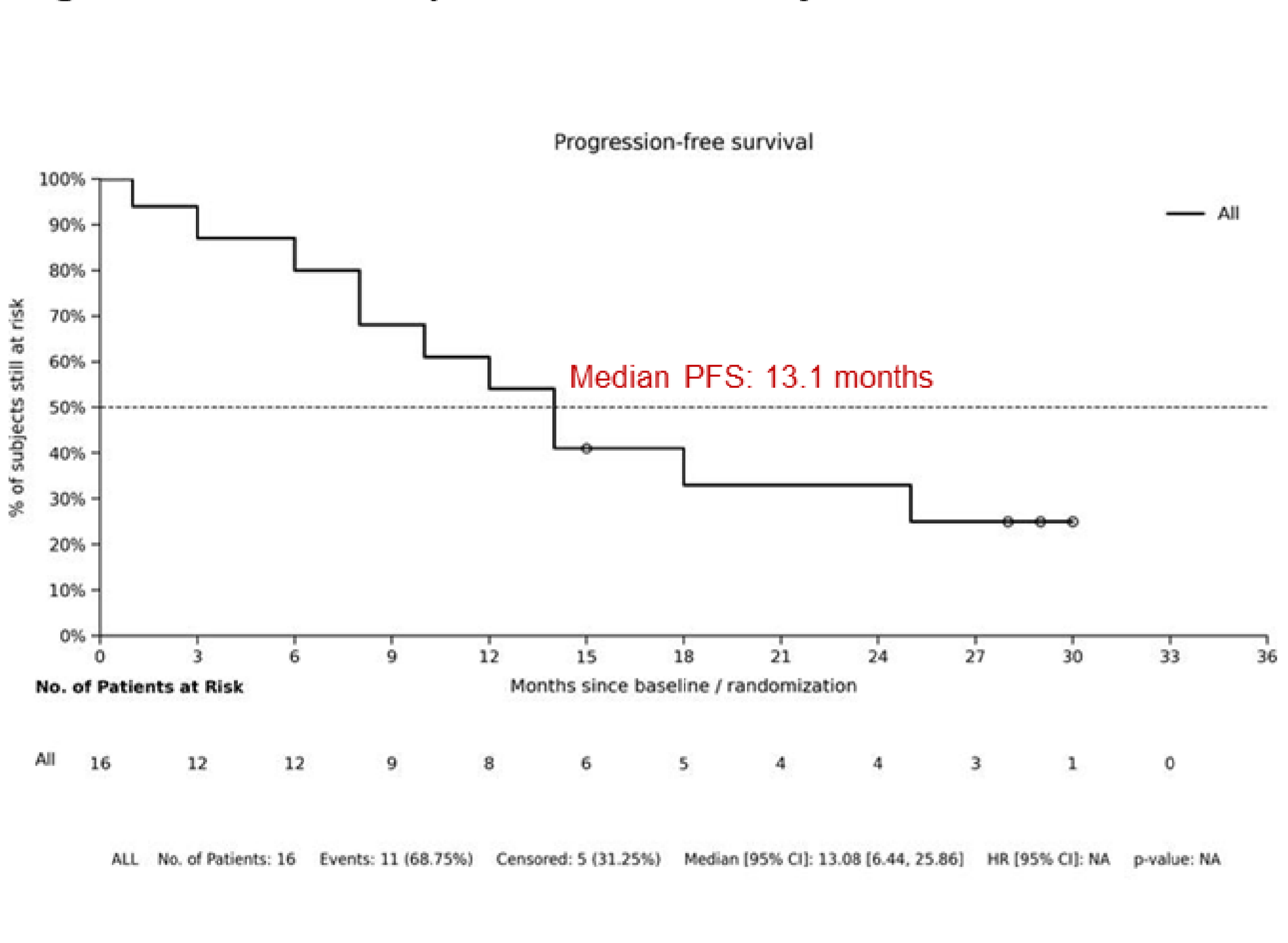


Figure 3: PFS in the Spanish cohort in patients achieving \geq CR in MajesTEC-1

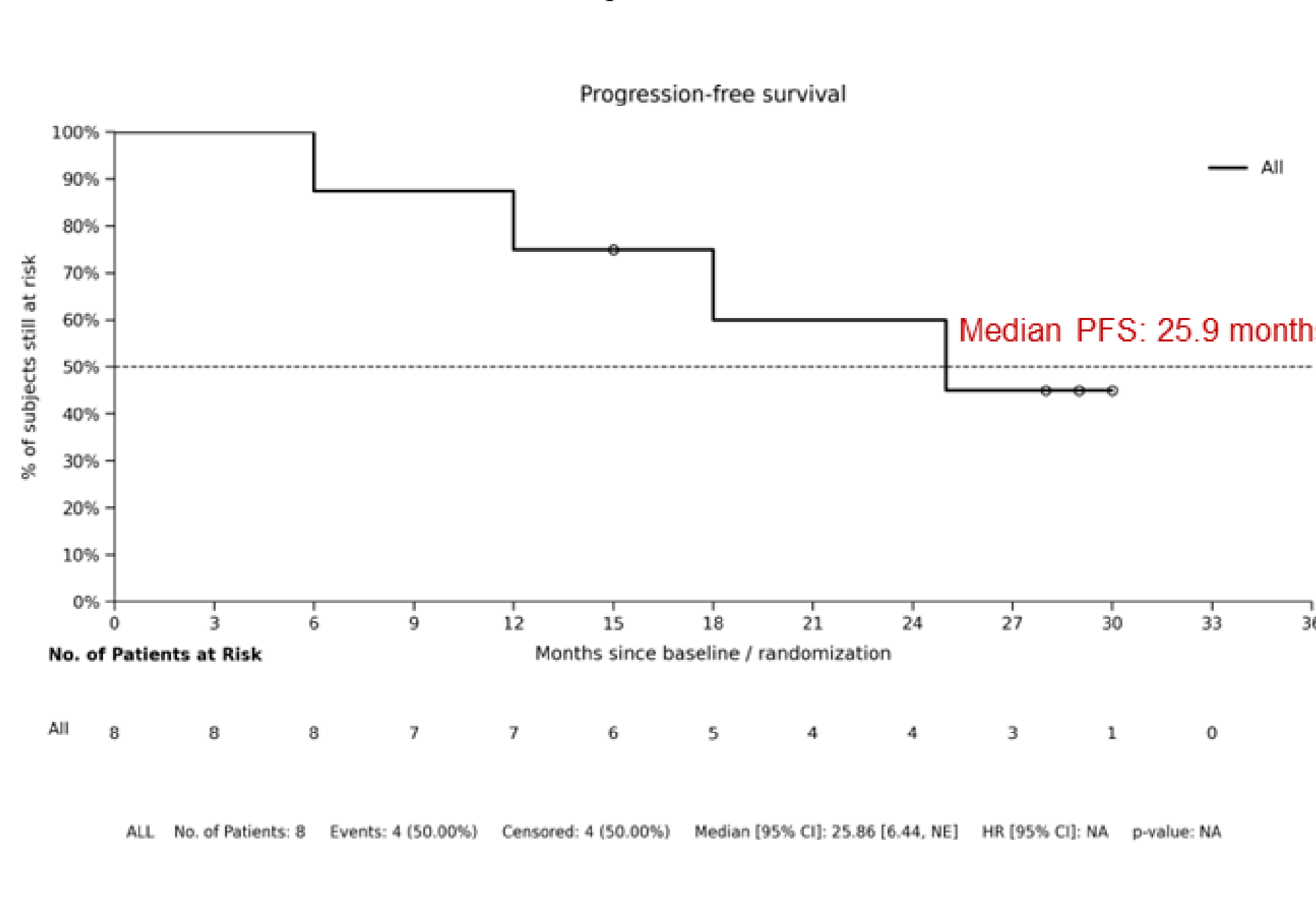
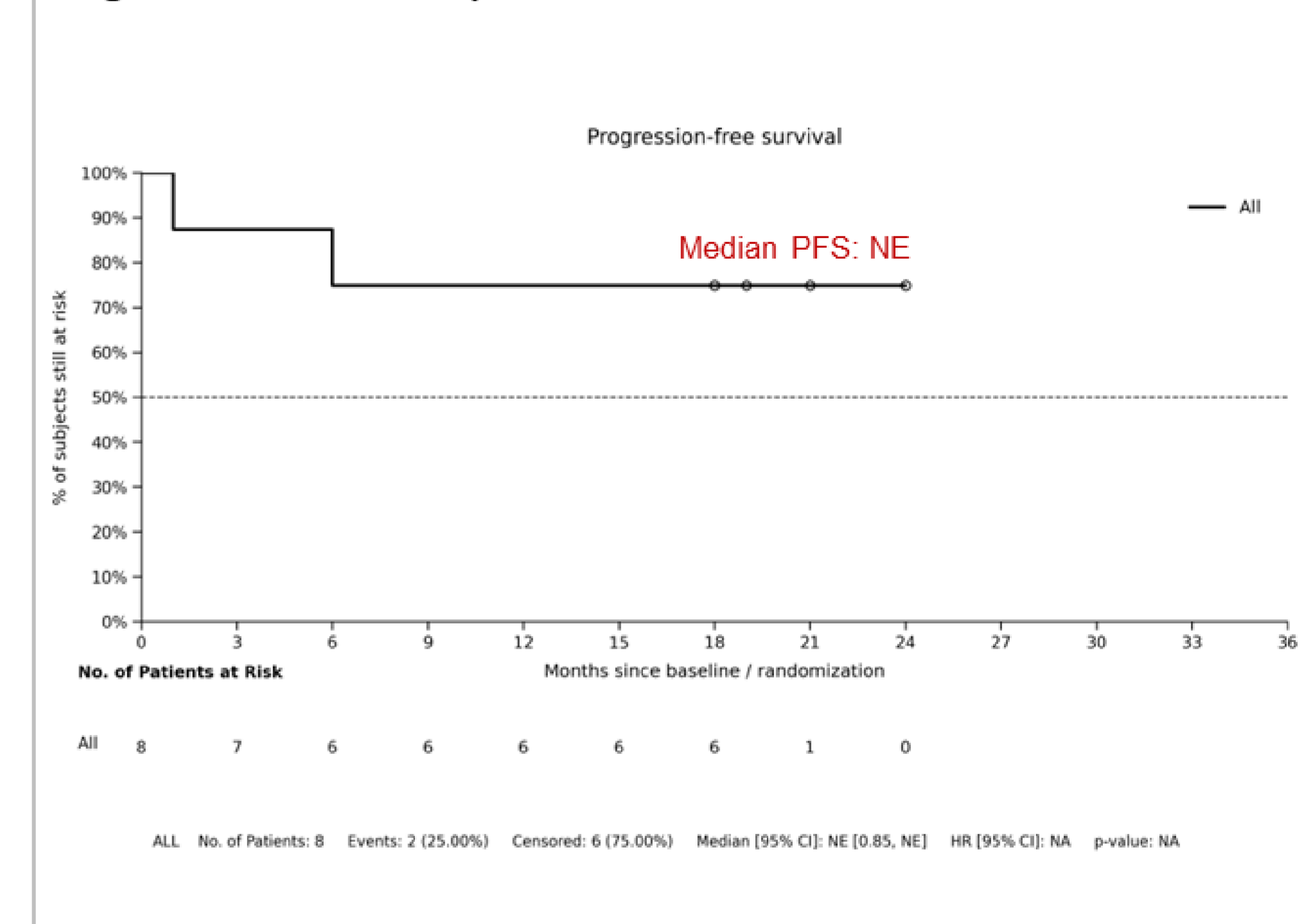


Figure 4: PFS in the Spanish cohort in REALiTEC



CONCLUSIONS

- Teclistamab demonstrated robust effectiveness outcomes in Spanish patients with TCE RRMM across both clinical trial and routine clinical practice settings, with outcomes suggesting real-world results may be comparable to, or potentially better than those observed in clinical trials.
- Teclistamab achieved high and deep response rates in Spanish RRMM patients, with a substantial proportion attaining \geq CR, translating into clinically meaningful disease control.
- These results reinforce the value of teclistamab as an effective standard of care for Spanish RRMM patients, underscoring its value in addressing unmet needs in this challenging population.

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