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PATIENT EXPECTATIONS AND PERCEPTIONS OF TREATMENT IN CARTITUDE-1: PHASE 1B/2 STUDY OF CILTACABTAGENE AUTOLEUCEL (CILTA-CEL) BCMA-DIRECTED CAR-T CELL THERAPY, IN RELAPSED/REFRACTORY MULTIPLE MYELOMA (RRMM)

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INTRODUCTION

- Patients with multiple myeloma (MM) experience health-related quality-of-life (HRQoL) decrements due to symptoms such as fatigue, pain, and insomnia¹
- Patients' perspectives of their disease and treatment expectations are an important part of clinical decision-making²
- In the phase 1b/2 CARTITUDE-1 study (NCT03548207), a single infusion of ciltacabtagene autoleucel (cilta-cel; JNJ-68284528) yielded deep and durable responses in patients with relapsed/refractory MM (RRMM)³
 - An exploratory objective of CARTITUDE-1 is to describe pretreatment goals and expectations and post-treatment experience of cilta-cel using qualitative interviews

METHODS

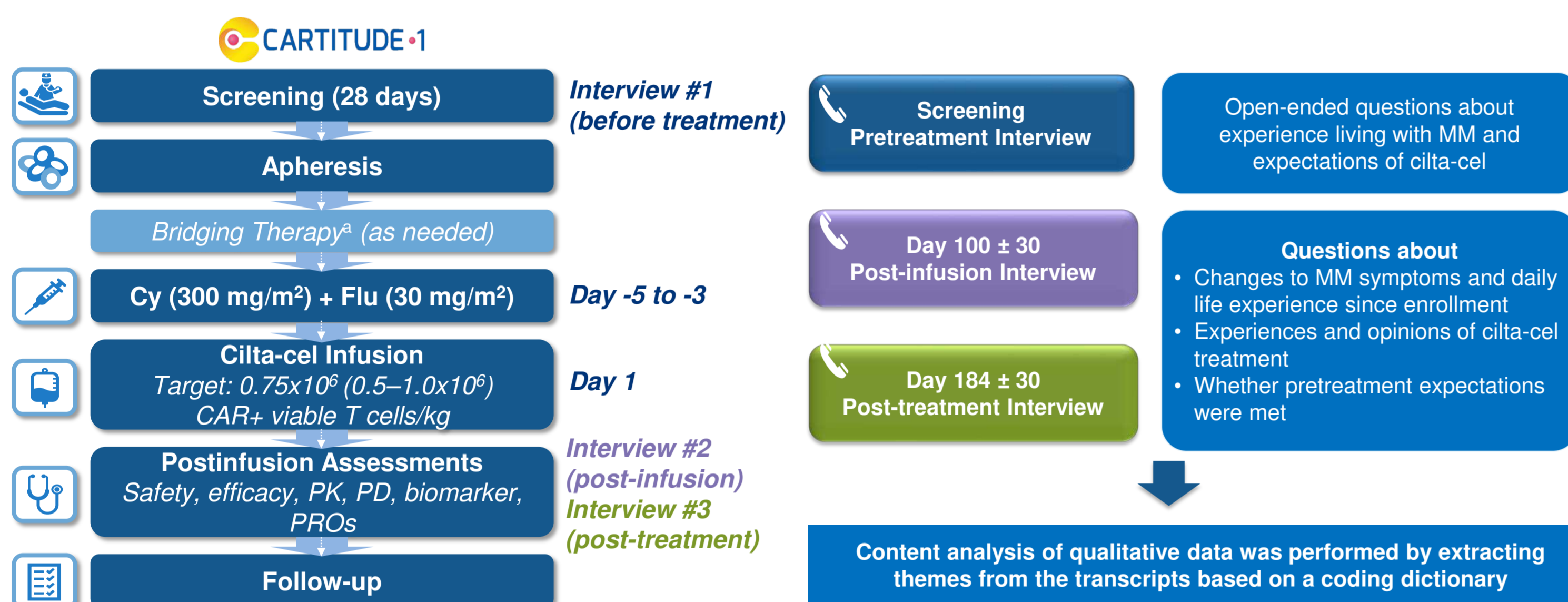
Study Design

- The CARTITUDE-1 study design is shown in **Figure 1**
- Qualitative interviews (~30 minutes) were conducted as an optional component of phase 2 portion of CARTITUDE-1 (**Figure 1**)

Key Eligibility Criteria

- Progressive MM per International Myeloma Working Group criteria
- Eastern Cooperative Oncology Group performance status ≤1
- Measurable disease
- ≥3 prior therapies or double refractory
- Prior proteasome inhibitor, immunomodulatory drug, and anti-CD38 therapy

Figure 1. CARTITUDE-1 Study Design and Interview Procedure



ClinicalTrials.gov number NCT03548207; 01 Sept 2020 data cutoff. *Treatment with previously used agent resulting in at least stable disease. CAR, chimeric antigen receptor; Cy, cyclophosphamide; Flu, fludarabine; MM, multiple myeloma; PD, pharmacodynamics; PK, pharmacokinetics; PRO, patient-reported outcome.

RESULTS

Patients

- In total, 36 patients who were recruited across 11 clinical sites in the United States (**Table 1**) completed 74 interviews in the phase 2 part of CARTITUDE-1 (**Figure 2**)

Pretreatment Symptoms, Goals, and Expectations

- The most common pretreatment symptoms were pain and fatigue (**Table 2**)
 - Pain and fatigue were also the pretreatment symptoms with the greatest impact on patients' lives and most important to improve
- The most frequently patient reported HRQoL impacts during the pretreatment interviews included impacts on relationships, psychological and emotional state, and activities of daily living (**Table 3**)

Table 1. Baseline Characteristics

| Characteristic | Interview | | | Total ^a (N=36) |
|------------------------|----------------------|----------------|----------------|---------------------------|
| | Pre-treatment (n=27) | Day 100 (n=23) | Day 184 (n=24) | |
| Sex, n (%) | | | | |
| Male | 16 (59.3) | 12 (52.2) | 12 (50.0) | 20 (55.6) |
| Female | 11 (40.7) | 11 (47.8) | 12 (50.0) | 16 (44.4) |
| Age, y, median (range) | 60.0 (46-77) | 63.0 (46-77) | 63.0 (46-77) | 62.5 (46-77) |

^aIncludes the number of unique patients who completed ≥1 interview.

Figure 2. Interview Completion Flow Chart^a

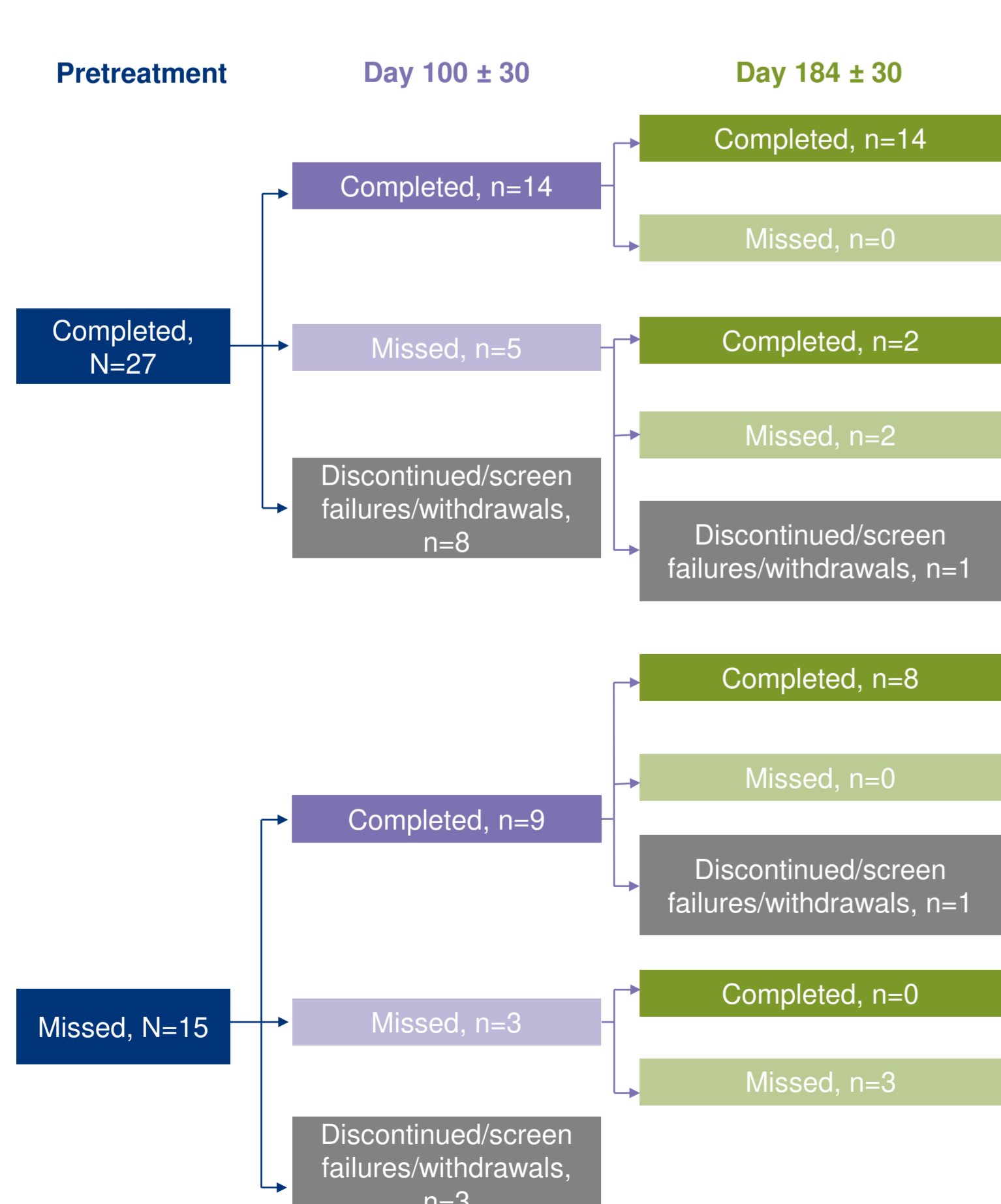


Table 2. Pretreatment Symptoms

| MM Symptoms, n (%) | Pretreatment (n=27) | | |
|--------------------------------------|---------------------|-------------------------------|------------------------------------|
| | Symptoms Reported | Symptoms With Greatest Impact | Symptoms Most Important to Improve |
| Pain ^c | 23 (85.2) | 8 (29.6) | 7 (25.9) |
| Fatigue | 20 (74.1) | 7 (25.9) | 9 (33.3) |
| Bone fractures | 9 (33.3) | 0 | 0 |
| Gastrointestinal issues ^d | 8 (29.6) | 0 | 1 (3.7) |
| Neuropathy | 7 (25.9) | 0 | 0 |
| Weakness | 6 (22.2) | 1 (3.7) | 1 (3.7) |

^aOnly includes symptoms/topics reported by >20% of patients; ^bSome patients reported ≥1 symptom as the most important, most important symptom to improve, and/or symptom with the biggest impact, which is reflected in the percentages; ^cIncludes leg, back, and arm pain; ^dIncludes nausea, diarrhea, constipation, and gastrointestinal pain. MM, multiple myeloma.

Table 3. Impact of MM on HRQoL

| HRQoL Topic, n (%) | Pretreatment (n=27) |
|------------------------------------|---------------------|
| Impact on relationships | 25 (92.6) |
| Psychological and emotional impact | 24 (88.9) |
| Activities of daily living | 18 (66.7) |
| Social functioning | 17 (63.0) |
| Work | 17 (63.0) |
| Exercise and sport | 16 (59.3) |
| Physical functioning | 12 (44.4) |
| Vacations | 8 (29.6) |
| Risk aversion ^b | 6 (22.2) |
| Changes to diet | 6 (22.2) |

^aOnly includes symptoms/topics reported by >20% of patients; ^bIncludes avoiding crowds, strenuous activity. HRQoL, health-related quality of life; MM, multiple myeloma.

- The most frequently reported treatment expectation and hope was achieving remission (40.7%; **Figure 3**)
 - More than 70% of the patients considered improvement in their MM symptoms as a meaningful change
- The proportion of patients reporting common symptoms was lower after cilta-cel treatment (**Figure 4**)

Figure 3. Expectations, Hopes, and Considerations of Meaningful Changes in Relation to Treatment

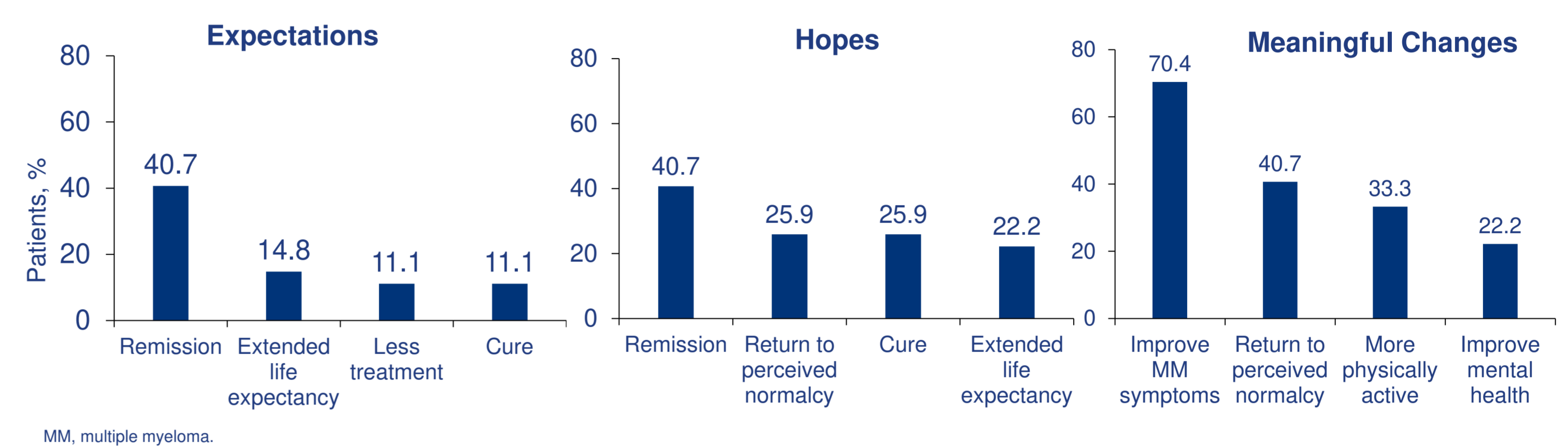
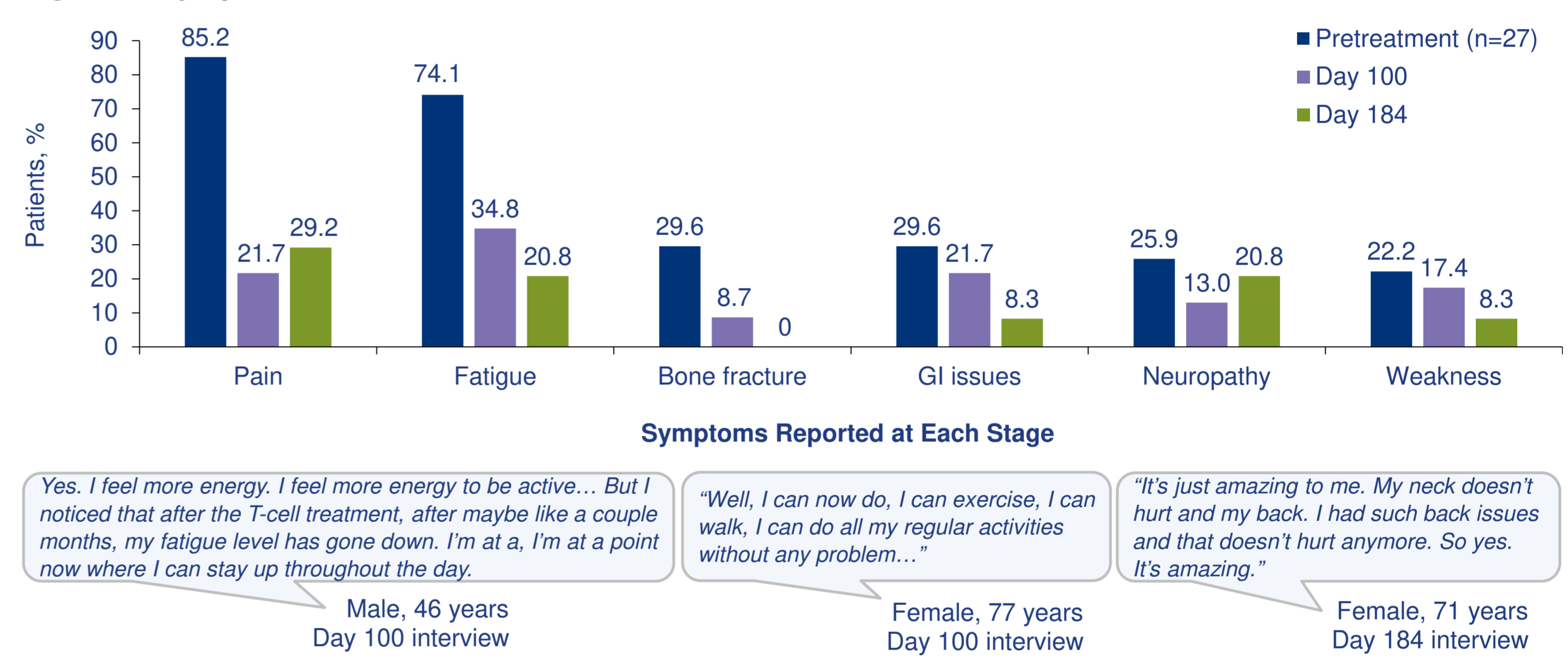


Figure 4. Symptoms Before and After Treatment With Cilta-cel



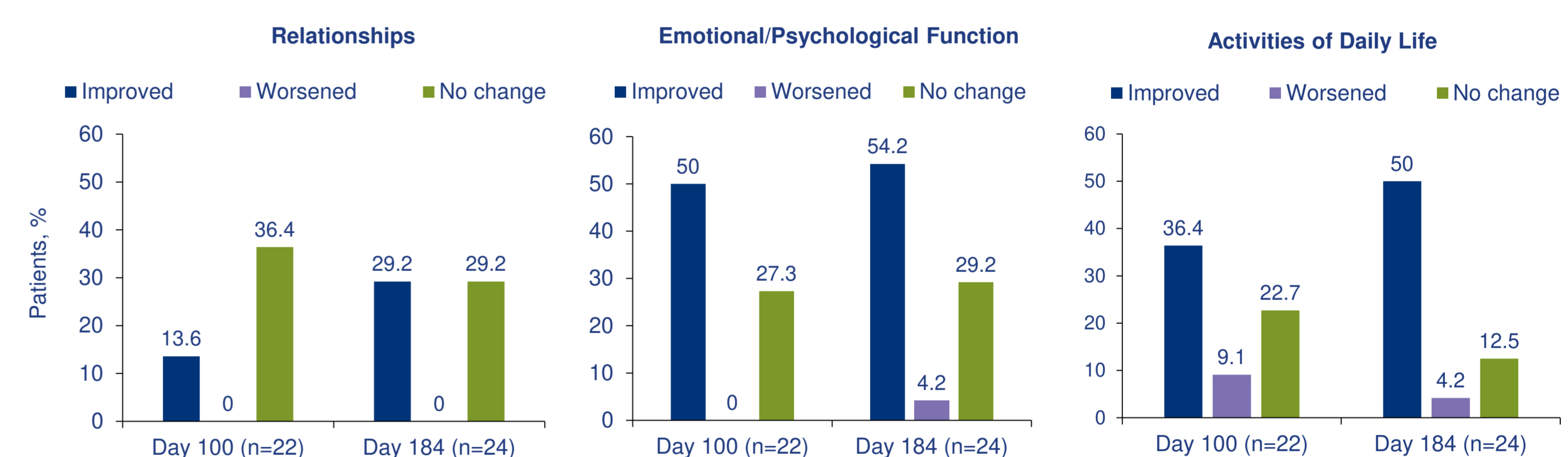
Yes, I feel more energy. I feel more energy to be active... But I noticed that after the T-cell treatment, after maybe like a couple months, my fatigue level has gone down. I'm at a, I'm at a point now where I can stay up throughout the day. (Male, 46 years Day 100 interview)

"Well, I can now do, I can exercise, I can walk, I can do all my regular activities without any problem..." (Female, 77 years Day 100 interview)

"It's just amazing to me. My neck doesn't hurt and my back. I had such back issues and that doesn't hurt anymore. So yes. It's amazing." (Female, 71 years Day 184 interview)

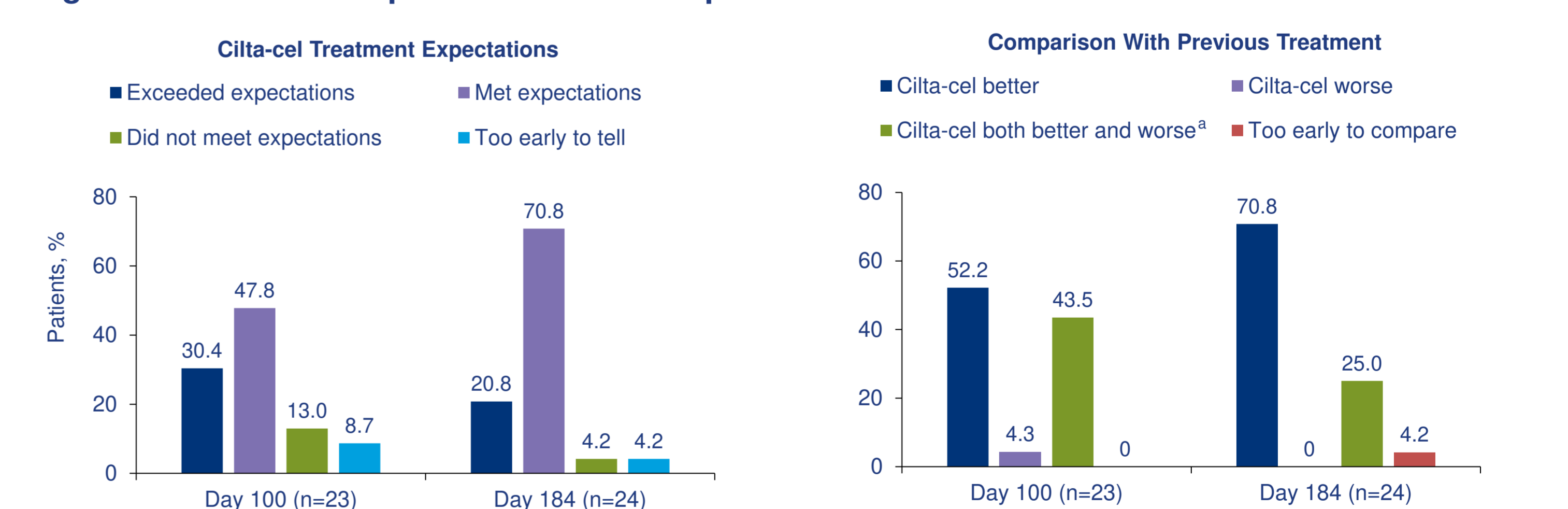
- For frequently reported pretreatment HRQoL topics, most patients reported improvements or no change following cilta-cel treatment (**Figure 5**)
- The majority of patients reported that cilta-cel met or exceeded their expectation (**Figure 6**)
 - Most patients perceived their experience with cilta-cel as exclusively better than their previous treatment experiences

Figure 5. Patients Reported an Improvement in HRQoL After Cilta-cel Treatment^{a,b}



^aLongitudinal analyses of patients who completed >1 interview; ^bThe 3 categories shown were most impacted. Cilta-cel, ciltacabtagene autoleucel; HRQoL, health-related quality of life.

Figure 6. Treatment Expectations and Comparison With Previous Treatment



^aPatients indicated during the interview that some aspects of cilta-cel were better than previous treatments (eg, effectiveness, administration), whereas other aspects were worse (eg, hospitalization, side effects). Cilta-cel, ciltacabtagene autoleucel.

CONCLUSION

- Patients treated with cilta-cel experienced reductions in both symptoms associated with RRMM and impact of MM on HRQoL
 - Pain and fatigue, respectively, were reported in 85.2% and 74.1% of patients before treatment versus 29.2% and 20.8% at Day 184
 - At Day 184, patients reported improvement in key HRQoL topics (relationships: 29.2%, psychological and emotional functioning: 54.2%, and activities of daily living: 50.0%)
- At Day 184, pretreatment expectations of cilta-cel were met or exceeded in 91.7% of patients, and 70.8% reported their experience was better than with prior MM treatments

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