

# Isatuximab Updates for Nurses: Isatuximab Plus Carfilzomib and Dexamethasone Versus Carfilzomib and Dexamethasone in Relapsed Multiple Myeloma Patients (IKEMA)

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## INTRODUCTION

- Multiple myeloma (MM) is the second most frequent hematologic malignancy after lymphoma, contributing to 1% of all cancers and approximately 10% of all hematologic malignancies<sup>1,2</sup>
- Despite the introduction of targeted therapies and combination regimens, patients with MM continue to experience multiple relapses and/or become refractory to treatment<sup>3</sup>
- CD38 is a transmembrane glycoprotein highly expressed in MM cells and at relatively low levels in other tissues, making this a desirable target for therapeutic antibodies to treat MM<sup>4</sup>
- Isatuximab is an IgG1 monoclonal antibody that targets a specific epitope on CD38 and inhibits its CD38 ectoenzyme activity. Isatuximab triggers death of MM cells through a combination of mechanisms of action, including antibody-dependent cellular cytotoxicity, antibody-dependent cellular phagocytosis, complement-dependent cytotoxicity, and direct apoptosis in the absence of cross-linking agents<sup>5-7</sup>
- Isatuximab is approved in combination with pomalidomide and dexamethasone in the United States, Canada, the European Union, and other countries for the treatment of adult patients with relapsed/refractory MM who have received at least 2 prior therapies, including lenalidomide and a proteasome inhibitor<sup>8-10</sup>
- Oncology nurses are pivotal members of the hematologic team providing care in this patient population
- In this poster, we present the results from IKEMA (NCT03275285), a Phase 3 isatuximab study in relapsed MM, together with clinical management considerations specific to oncology nurses

## METHODS<sup>11,12</sup>

- Eligible patients had relapsed MM and 1 to 3 prior lines of therapy
- 302 patients were randomized to receive either isatuximab plus carfilzomib (K) and dexamethasone (d) (Isa-Kd; n=179) or Kd alone (n=123). Randomization was stratified by number of prior lines of therapy (1 vs >1) and Revised International Staging System (Stage I or II vs III vs not classified), at study entry
- Patients in the isatuximab arm received isatuximab 10 mg/kg intravenously (Days 1, 8, 15, and 22 in the first 28-day cycle; Days 1 and 15 in subsequent cycles). In both arms, carfilzomib was administered intravenously at 20 mg/m<sup>2</sup> on Days 1 and 2; 56 mg/m<sup>2</sup> on Days 8, 9, 15, and 16 of cycle 1; and then 56 mg/m<sup>2</sup> on Days 1, 2, 8, 9, 15, and 16 of subsequent cycles. Dexamethasone 20 mg was administered intravenously or orally on Days 1, 2, 8, 9, 15, 16, 22, and 23
- Treatment continued until disease progression or unacceptable toxicities
- The primary endpoint was progression-free survival (PFS). Key secondary efficacy endpoints included: (i) overall response rate, (ii) very good partial response or better (≥ VGPR), (iii) minimal residual disease (MRD) negativity rate, (iv) complete response (CR) rate, and (v) overall survival
- Adverse events (AEs) were graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) v4.03
- Quality of life assessments were completed on Day 1 of each cycle before treatment was started, and at end of study treatment visit and 90 days after the last study treatment

## RESULTS

- Patient baseline characteristics are described in **Table 1**
- Efficacy parameters were calculated at the cutoff date of February 7, 2020 (**Table 2**)
- Health-related quality of life, was maintained with Isa-Kd. **Figure 1** shows the mean change in the QLQ-C30 Global Health Status score from baseline for each cycle for the Isa-Kd and the Kd arms. A higher score represents a better level of global health status. Error bars represent 95% confidence intervals. Numbers underneath the curve describe the sample size for each cycle in the Isa-Kd and Kd arms
- A safety summary is shown in **Table 3**
- Grade ≥3 AEs were observed in 76.8% patients (Isa-Kd) versus 67.2% (Kd). Serious AEs were reported in 59.3% patients (Isa-Kd) versus 57.4% (Kd). A total of 8.5% Isa-Kd patients versus 13.9% Kd patients discontinued due to AEs
- Most frequent AEs (any grade) were infusion reactions (IRs) and hypertension (**Table 3**)
- The most common laboratory abnormality was anemia (any grade), which occurred in 99.4% Isa-Kd vs 99.2% Kd patients. Neutropenia and infections were reversible and manageable with granulocyte colony-stimulating factors and antibiotics (**Table 3**)

**Table 1.** Demographics and patient characteristics (intent-to-treat population)

|                                                      | Isa-Kd<br>(n=179) | Kd<br>(n=123) |
|------------------------------------------------------|-------------------|---------------|
| <b>Age in years, median (range)</b>                  | 65 (37–86)        | 63 (33–90)    |
| <b>Age in years, by category, n (%)</b>              |                   |               |
| <65                                                  | 88 (49.2)         | 66 (53.7)     |
| 65–74                                                | 74 (41.3)         | 47 (38.2)     |
| ≥75                                                  | 17 (9.5)          | 10 (8.1)      |
| <b>eGFR* &lt;60 mL/min/1.73 m<sup>2</sup>, n (%)</b> | 43 (26.1)         | 18 (16.2)     |
| <b>ECOG performance status, n (%)</b>                |                   |               |
| 0                                                    | 95 (53.1)         | 73 (59.3)     |
| 1                                                    | 73 (40.8)         | 45 (36.6)     |
| 2                                                    | 10 (5.6)          | 5 (4.1)       |
| 3                                                    | 1 (0.6)           | 0             |
| <b>ISS stage at study entry<sup>†</sup>, n (%)</b>   |                   |               |
| Stage I                                              | 89 (49.7)         | 71 (57.7)     |
| Stage II                                             | 63 (35.2)         | 31 (25.2)     |
| Stage III                                            | 26 (14.5)         | 20 (16.3)     |
| Unknown                                              | 1 (0.6)           | 1 (0.8)       |

|                                                           |                      |           |
|-----------------------------------------------------------|----------------------|-----------|
| <b>Cytogenetic risk at study entry<sup>‡</sup>, n (%)</b> |                      |           |
| High-risk                                                 | 42 (23.5)            | 31 (25.2) |
| Standard risk                                             | 114 (63.7)           | 78 (63.4) |
| Missing                                                   | 23 (12.8)            | 14 (11.4) |
| <b>Prior ASCT, n (%)</b>                                  | 116 (64.8)           | 69 (56.1) |
| <b>Prior lines of therapy, median (range)</b>             | 2 (1–4)              | 2 (1–4)   |
| <b>Number of prior lines, n (%)</b>                       |                      |           |
| 1                                                         | 79 (44.1)            | 55 (44.7) |
| 2                                                         | 64 (35.8)            | 36 (29.3) |
| 3                                                         | 33 (18.4)            | 30 (24.4) |
| >3                                                        | 3 (1.7) <sup>§</sup> | 2 (1.6)   |

|                                      |            |            |
|--------------------------------------|------------|------------|
| <b>Prior alkylating agent</b>        | 169 (94.4) | 101 (82.1) |
| <b>Prior PI</b>                      | 166 (92.7) | 105 (85.4) |
| <b>Prior lenalidomide</b>            | 72 (40.2)  | 59 (48.0)  |
| <b>Patients refractory to, n (%)</b> |            |            |
| Last line of therapy                 | 89 (49.7)  | 73 (59.3)  |
| IMiD                                 | 78 (43.6)  | 58 (47.2)  |
| Lenalidomide                         | 57 (31.8)  | 42 (34.1)  |
| Lenalidomide as the last line        | 36 (20.1)  | 31 (25.2)  |
| PI                                   | 56 (31.3)  | 44 (35.8)  |
| IMiD and PI                          | 35 (19.6)  | 27 (22.0)  |

\*Patients were required to have eGFR ≥15 mL/min/1.73 m<sup>2</sup> as per modification of diet in renal disease (MDRD) equation  
<sup>†</sup>ISS staging is derived based on the combination of serum β2-microglobulin and albumin  
<sup>‡</sup>High-risk was defined as del(17p), t(4;14), or t(14;16) by FISH. Cytogenetics was performed by a central laboratory with cut-off 50% for del(17p), 30% for t(4;14) and t(14;16)  
<sup>§</sup>For 2 patients, the number of prior lines was overestimated by the algorithm due to complex specific cases. The number of prior lines was reviewed by a clinician and confirmed to be equal to 3  
 ASCT, autologous stem cell transplant; d, dexamethasone; ECOG, Eastern Cooperative Oncology Group; eGFR, estimated glomerular filtration rate; IMiD, immunomodulatory drug; Isa, isatuximab; ISS, International Staging System; K, carfilzomib; PI, proteasome inhibitor

- The majority of IRs occurred at first infusion and were reversible; 0.6% of patients had Grade ≥3 IRs. No delayed IRs were reported. 1.4% of isatuximab infusions were interrupted, with a median time to interruption of 63 minutes. The most frequently reported IR symptoms involved respiratory, thoracic, and mediastinal disorders (**Table 4**)

**Table 2.** Endpoints assessed by an independent response committee (intent-to-treat population)

| Endpoint           | Isa-Kd<br>(n=179) | Kd<br>(n=123) | Isa-Kd vs Kd                                             |
|--------------------|-------------------|---------------|----------------------------------------------------------|
| <b>mPFS, mo</b>    | NC                | 19.15         | HR 0.531 (99% CI 0.318–0.889); p=0.0007*                 |
| <b>CR, %</b>       | 39.7              | 27.6          | –                                                        |
| <b>≥VGPR, %</b>    | 72.6              | 56.1          | Stratified Cochran-Mantel-Haenszel p=0.0011 <sup>†</sup> |
| <b>MRD–, %</b>     | 29.6              | 13.0          | Stratified Cochran-Mantel-Haenszel p=0.0004 <sup>†</sup> |
| <b>12-mo OS, %</b> | 90.8              | 88.4          | –                                                        |

\*One-sided p value  
<sup>†</sup>For descriptive purposes  
 CI, confidence interval; CR, complete response rate; d, dexamethasone; HR, hazard ratio; Isa, isatuximab; K, carfilzomib; mo, months;  
 mPFS, median progression-free survival; MRD–, minimal residual disease negative; n, number of patients; NC, not calculable; NR, not reached; OS, overall survival; VGPR, very good partial response rate

**Table 3.** AEs and hematologic laboratory abnormalities (safety population)

| AEs                                                                                    | All grades n (%) | Grade ≥3 n (%) | All grades n (%) | Grade ≥3 n (%) |
|----------------------------------------------------------------------------------------|------------------|----------------|------------------|----------------|
| <b>Most common AEs (occurring in at least 20% of isatuximab patients, worst grade)</b> |                  |                |                  |                |
| <b>Gastrointestinal disorders</b>                                                      |                  |                |                  |                |
| Diarrhea                                                                               | 64 (36.2)        | 5 (2.8)        | 35 (28.7)        | 3 (2.5)        |
| <b>General disorders and administration site conditions</b>                            |                  |                |                  |                |
| Fatigue                                                                                | 50 (28.2)        | 6 (3.4)        | 23 (18.9)        | 1 (0.8)        |
| <b>Infections and infestations</b>                                                     |                  |                |                  |                |
| Bronchitis                                                                             | 40 (22.6)        | 4 (2.3)        | 15 (12.3)        | 1 (0.8)        |
| Pneumonia                                                                              | 42 (23.7)        | 29 (16.4)      | 24 (19.7)        | 15 (12.3)      |
| URTI                                                                                   | 64 (36.2)        | 6 (3.4)        | 29 (23.8)        | 2 (1.6)        |
| <b>Injury, poisoning, and procedural complications</b>                                 |                  |                |                  |                |
| Infusion reaction*                                                                     | 79 (44.6)        | 1 (0.6)        | 4 (3.3)          | 0              |
| <b>Musculoskeletal and connective tissue disorders</b>                                 |                  |                |                  |                |
| Back pain                                                                              | 39 (22.0)        | 3 (1.7)        | 25 (20.5)        | 1 (0.8)        |
| <b>Psychiatric disorders</b>                                                           |                  |                |                  |                |
| Insomnia                                                                               | 42 (23.7)        | 9 (5.1)        | 28 (23.0)        | 3 (2.5)        |
| <b>Respiratory, thoracic, and mediastinal disorders</b>                                |                  |                |                  |                |
| Dyspnea                                                                                | 49 (27.7)        | 9 (5.1)        | 26 (21.3)        | 1 (0.8)        |
| <b>Vascular disorders</b>                                                              |                  |                |                  |                |
| Hypertension                                                                           | 65 (36.7)        | 36 (20.3)      | 38 (31.1)        | 24 (19.7)      |
| <b>Other AEs of interest</b>                                                           |                  |                |                  |                |
| Thromboembolic events <sup>†</sup>                                                     | 27 (15.3)        | 7 (4.0)        | 20 (16.4)        | 7 (5.7)        |
| Cardiac failure <sup>†</sup>                                                           | 13 (7.3)         | 7 (4.0)        | 8 (6.6)          | 5 (4.1)        |
| Ischemic heart disease <sup>†</sup>                                                    | 8 (4.5)          | 2 (1.1)        | 5 (4.1)          | 2 (1.6)        |
| Second primary malignancy <sup>‡</sup>                                                 | 13 (7.3)         | 4 (2.3)        | 6 (4.9)          | 4 (3.3)        |

**Hematologic laboratory abnormalities (worst grade)**

|                           |            |           |            |           |
|---------------------------|------------|-----------|------------|-----------|
| <b>Evaluable patients</b> |            |           |            |           |
| Anemia                    | 176 (99.4) | 39 (22.0) | 121 (99.2) | 24 (19.7) |
| Neutropenia               | 97 (54.8)  | 34 (19.2) | 53 (43.4)  | 9 (7.4)   |
| Thrombocytopenia          | 167 (94.4) | 53 (29.9) | 107 (87.7) | 29 (23.8) |

\*As reported by the investigator in the specific form of an AE, including infusion related reaction, cytokine release syndrome, drug hypersensitivity.  
<sup>†</sup>Groupings using MedDRA SMO (narrow terms): thromboembolic events, cardiac failure, ischemic heart disease  
<sup>‡</sup>Isa-Kd arm: 1 patient each with adenocarcinoma of appendix, colon cancer, pancreatic carcinoma metastatic, squamous cell carcinoma, uterine cancer; 6 patients with basal cell carcinoma, 3 patients with squamous cell carcinoma of the skin, 1 patient with malignant melanoma in situ, and 1 patient with skin cancer; Kd arm: 1 patient with colon cancer, 1 patient with bladder neoplasm, 1 patient with large cell lung cancer, 1 patient with lung neoplasm malignant, 2 patients with basal cell carcinoma, and 1 patient with squamous cell carcinoma of the skin  
 AE, adverse event; d, dexamethasone; Isa, isatuximab; K, carfilzomib; URTI, upper respiratory tract infection

## DISCLOSURES

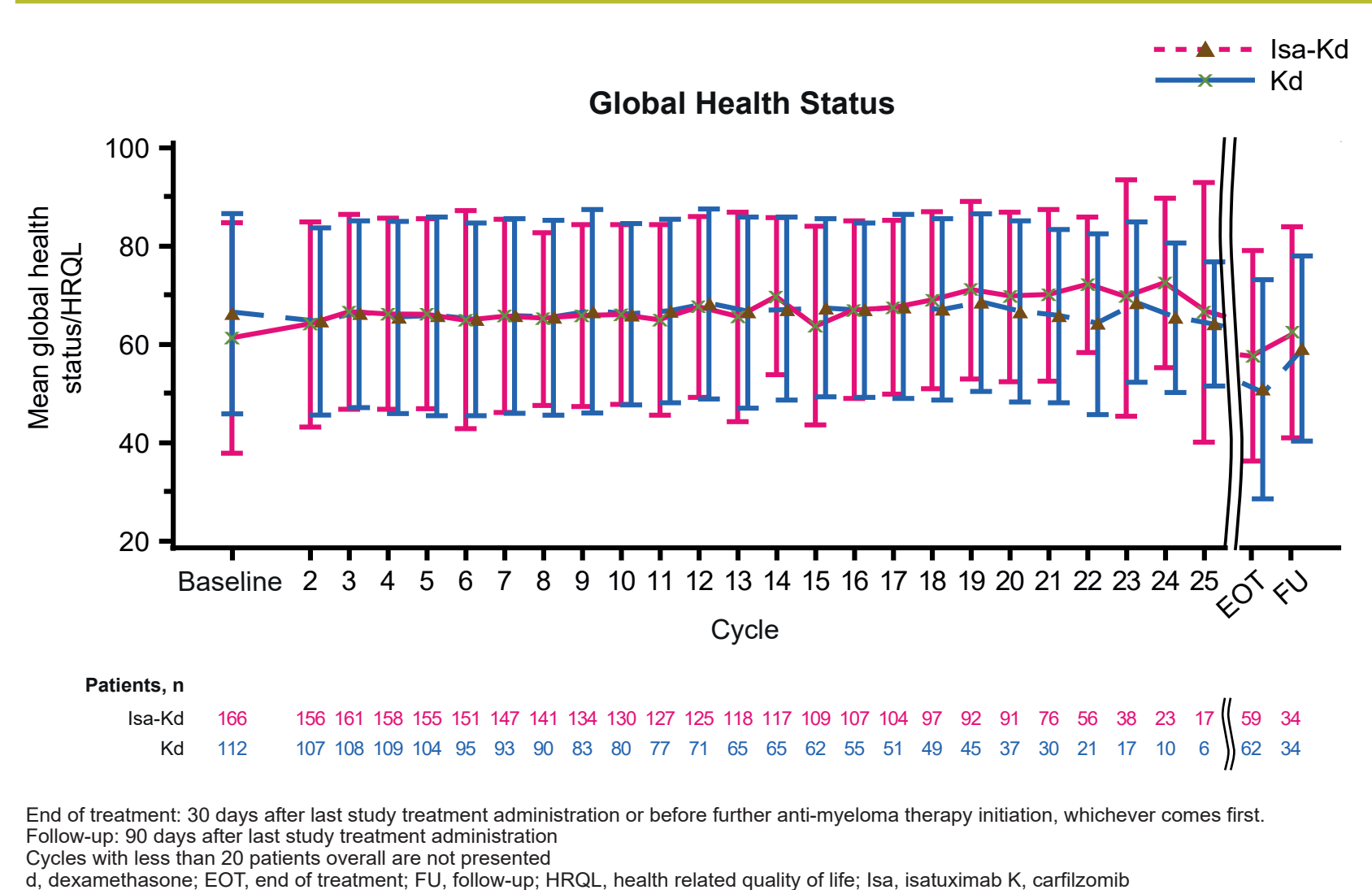
JW: reports honorarium for participation in an advisory board, Sanofi.  
 SM: is employed by Sanofi and might hold company shares.  
 CK: reports honorarium for participation in an advisory board, Sanofi.

**Table 4.** Infusion reaction symptoms

| IR Symptom organ class preferred term, n (%)                | Isa-Kd<br>(n=179) | Kd<br>(n=123) |
|-------------------------------------------------------------|-------------------|---------------|
| <b>Respiratory, thoracic, and mediastinal disorders</b>     |                   |               |
| All grades                                                  | 52 (29.4)         | 1 (0.8)       |
| Grade 1                                                     | 23 (13.0)         | 0             |
| Grade 2                                                     | 28 (15.8)         | 1 (0.8)       |
| Grade ≥3                                                    | 1 (0.6)           | 0             |
| <b>General disorders and administration site conditions</b> |                   |               |
| All grades                                                  | 24 (13.6)         | 2 (1.6)       |
| Grade 1                                                     | 11 (6.2)          | 0             |
| Grade 2                                                     | 13 (7.3)          | 2 (1.6)       |
| Grade ≥3                                                    | 0                 | 0             |
| <b>Gastrointestinal disorders</b>                           |                   |               |
| All grades                                                  | 18 (10.2)         | 2 (1.6)       |
| Grade 1                                                     | 11 (6.2)          | 1 (0.8)       |
| Grade 2                                                     | 7 (4.0)           | 1 (0.8)       |
| Grade ≥3                                                    | 0                 | 0             |
| <b>Vascular disorders</b>                                   |                   |               |
| All grades                                                  | 10 (5.6)          | 0             |
| Grade 1                                                     | 1 (0.6)           | 0             |
| Grade 2                                                     | 6 (3.4)           | 0             |
| Grade ≥3                                                    | 3 (1.7)           | 0             |

d, dexamethasone; IR, infusion reaction; Isa, isatuximab; K, carfilzomib

**Figure 1.** Global Health Status Quality of Life Score Over Time (EORTC-QLQ-C30, Intent-to-Treat Population)



## Nursing considerations for Isa administration and the management of IRs

- Oncology nurses are at the cornerstone of patient care and play a pivotal role in the administration of isatuximab
- Guidance pertaining to the administration of isatuximab and the management of IRs is shown in **Figure 2**
- Due to potential interference with indirect Coombs testing, it is important that patients undergo blood typing and screening tests prior to the first infusion. In IKEMA, 64% of patients treated with isatuximab had false-positive indirect Coombs test results and there was no evidence of hemolysis
- To reduce the chance of patients developing IRs, premedication should be administered 15 to 60 minutes before infusions

- Patient actual body weight should be measured prior to each infusion to facilitate the accurate dosing of isatuximab
- Oncology nurses are responsible for the prompt identification of IR symptoms and should be aware of how to manage these, and other, adverse effects. Detailed information regarding the management of IRs is included in **Figure 2**
- Patients experiencing Grade ≥3 IRs should have their isatuximab treatment permanently discontinued

## Patient education

- Key nursing considerations for the education of patients receiving isatuximab are detailed in **Figure 2**
- Nurses must ensure that patients starting treatment with isatuximab are aware of the treatment schedule and duration, in order to manage patient expectations. The first isatuximab infusion will be the longest, so patients should be prepared to spend most of the day in the clinic
- Patient counseling should also include discussion of the risks of the most common AEs associated with isatuximab with patients and caregivers, such as neutropenia and thrombocytopenia, and the need for periodic transfusions when clinically indicated
- Oncology nurses should review preventive lifestyle measures to help reduce potential complications of infections, including to wash hands thoroughly, maintain good oral hygiene, care for cuts and scrapes, avoid contact with anyone with infectious symptoms, and report a fever above 100.4°F (38°C) to the care team

**Figure 2.** Nursing considerations for the use of isatuximab

|                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Before first infusion</b>           | <ul style="list-style-type: none"> <li>Isa can interfere with indirect Coombs test, therefore, nurses should make sure that the patient has had blood typing and screening tests</li> <li>Patients should be given a wallet card indicating their blood type and blood banks should be notified</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Administration of premedication</b> | <ul style="list-style-type: none"> <li>Acetaminophen oral (650–1000 mg), H2 antagonist IV (50 mg), and diphenhydramine (25–50 mg IV or equivalent)</li> <li>15 to 60 minutes prior to Isa infusion</li> <li>Dexamethasone is administered as part of premedication and backbone treatment</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Isa infusion</b>                    | <ul style="list-style-type: none"> <li>Reuspend Isa in the appropriate dose (10 mg/kg actual body weight)</li> <li>Day 1, 8, 15, 22 in Cycle 1, then Q2W</li> <li>250-mL fixed-volume infusion</li> <li>No post-infusion corticosteroid or bronchodilator prophylaxis are required</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Management of IRs</b>               | <ul style="list-style-type: none"> <li>Prompt identification of IRs symptoms so they can be addressed and treated immediately; signs and symptoms of IRs can range from mild rash to anaphylaxis-like symptoms</li> <li>Patients experiencing Grade 2 IRs should be given symptomatic treatment (diphenhydramine 25 mg IV or equivalent and methylprednisolone 100 mg IV)</li> <li>Once a Grade 2 IR leading to interruption improves to Grade ≤1, the infusion can be restarted at half the initial infusion rate, after consultation with a provider</li> <li>If symptoms do not recur after 30 minutes, the infusion rate can be increased every 30 minutes to a maximum of 200 mL/h</li> <li>Treatment with Isa should be permanently discontinued in patients experiencing Grade ≥3 IRs</li> </ul>     |
| <b>Patient education</b>               | <ul style="list-style-type: none"> <li>Isa treatment schedule and infusion duration, as well as schedule for carfilzomib and dexamethasone</li> <li>The use of premedications and the major symptoms of a possible IR, as well as the need to report them should they occur</li> <li>Immediately inform the care team if fevers, chills, rigors, chest pain, shortness of breath, nasal congestion, or a cough develop, as well as any persistent AE</li> <li>The risks of the most common AEs associated with Isa, such as neutropenia, thrombocytopenia, and the possibility of worsening of pre-existing cardiac failure with carfilzomib</li> <li>Recommendations for prevention of infection</li> <li>Stress the importance of keeping appointments and commitment to follow-ups/monitoring</li> </ul> |

AEs, adverse events; Isa, isatuximab; IRs, infusion reactions; IV, intravenously; Q2W, every other week subsequent doses

## CONCLUSIONS

- The clinical activity and manageable safety profile observed in IKEMA highlight isatuximab as an important new treatment option for patients with relapsed MM
- Among patients receiving isatuximab treatment, oncology nurses are critical team members in facilitating patient care through education, clinical supervision/decision-making, and IR management

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