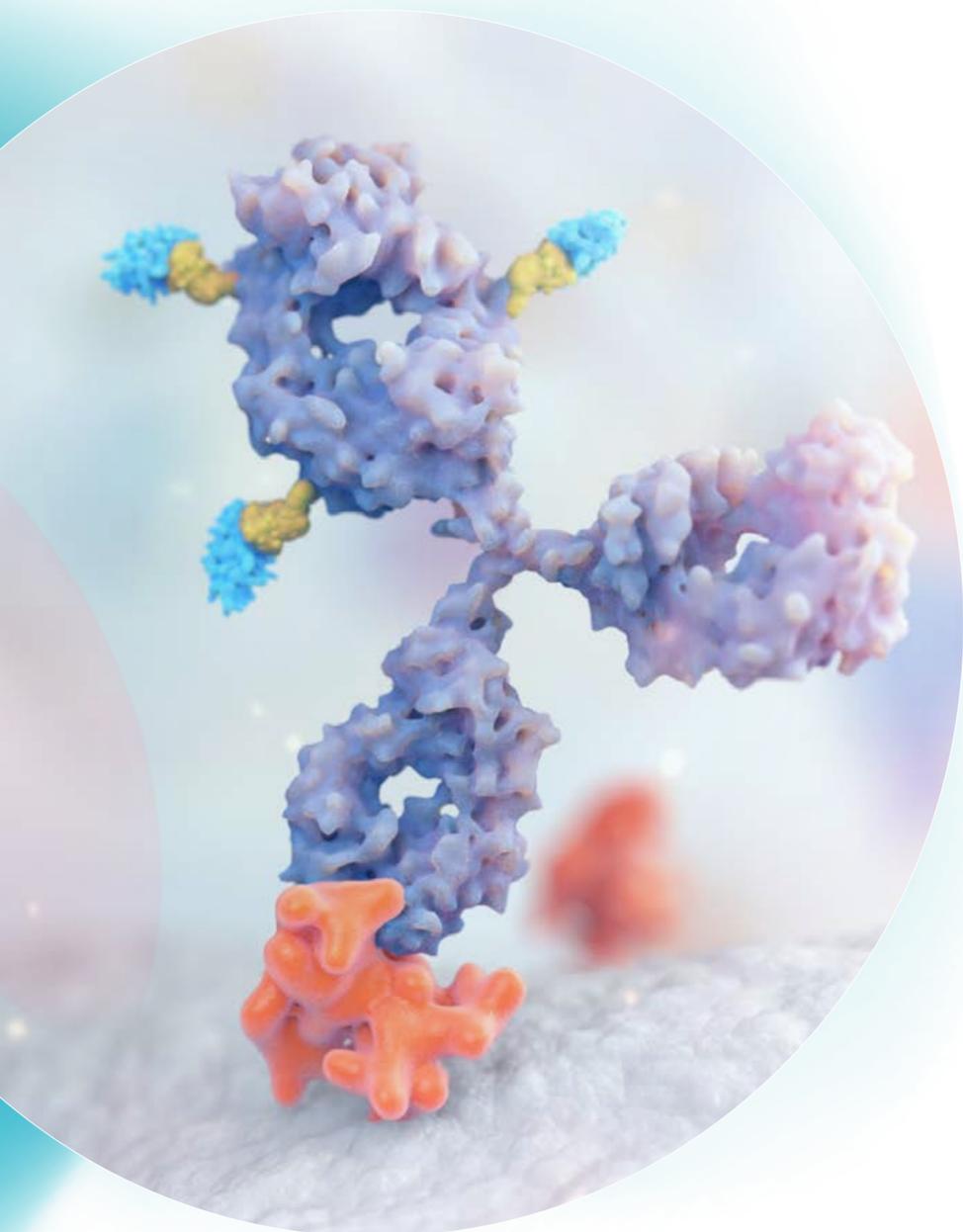


# Belantamab Mafodotin Clinical Trials Program

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Belantamab Mafodotin: Anti-BCMA  
Antibody-drug conjugate (ADC)



## Belantamab mafodotin:

### Anti-BCMA Antibody-drug conjugate\*

B-cell maturation antigen (BCMA), a membrane protein expressed on malignant plasma cells in all patients with multiple myeloma, supports myeloma cell proliferation and survival.<sup>1-4</sup>

Belantamab mafodotin is the first BCMA-targeted antibody-drug conjugate (ADC) with a humanized anti-BCMA monoclonal antibody (mAb) conjugated to the microtubule inhibitor mafodotin.<sup>2,5</sup>

Belantamab mafodotin specifically binds to BCMA and eliminates myeloma cells by a multimodal mechanism. Mafodotin delivered to BCMA-expressing malignant cells inhibits microtubule polymerization, resulting in immune-independent apoptosis that is accompanied by release of markers of immunogenic cell death (ICD), which may contribute to an adaptive immune response. The antibody component of belantamab mafodotin enhances antibody-dependent cellular cytotoxicity and phagocytosis (ADCC/ADCP).<sup>2,5</sup>

\*In-license or other partnership with third party.

Belantamab mafodotin (BLENREP) is approved in the EU as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least 4 prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. In Spain, belantamab mafodotin is now under price and reimbursement process and its not commercialised yet. Any other intended use of belantamab mafodotin reviewed in this display is investigational. Information about all GSK-sponsored trials can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). All clinical study information updated as of July 22, 2020.

#### References:

1. Tai KC. Immunotherapy. 2015;7(11):1187-11999. 2. Tai YT et al. Blood. 2014;123(20):3128-3138. 3. O'Connor BP et al. J Med. 2004;199(1):91-98. 4. Cho SF et al. Front Immunol. 2018; 9:1821. doi: 10.3389/fimmu.2018.01821. 5. Montes de Oca R *et al.* The anti-BCMA antibody-drug conjugate belantamab mafodotin (GSK2857916) drives immunogenic cell death and immune-mediated anti-tumor response, and in combination with an OX40 agonist potentiates in vivo activity. Presented at: European Hematology Meeting (EHA); June 13-16, 2019; Amsterdam, Netherlands.

**DREAMM-1 (NCT02064387)**

First-time-in-human study, dose escalation study of belantamab mafodotin in patients with relapsed/refractory multiple myeloma.

**DREAMM-2 (NCT03525678)\***

Study of two doses of belantamab mafodotin in patients with relapsed/refractory multiple myeloma.

**DREAMM-3 (NCT04162210)\***

Belantamab mafodotin monotherapy compared with pomalidomide and dexamethasone in patients with relapsed/refractory multiple myeloma.

**DREAMM-4 (NCT03848845)\***

Study of belantamab mafodotin in combination with pembrolizumab in patients with relapse/refractory multiple myeloma.

**DREAMM-5 (NCT04126200)\***

Belantamab mafodotin alone and in combination with GSK3174998 (OX40 agonist antibody) or GSK3359609 (ICOS agonist IgG4 antibody) in patients with relapsed/refractory multiple myeloma.

**DREAMM-6 (NCT03544281)\***

Study of belantamab mafodotin in combination with lenalidomide and dexamethasone or with bortezomib and dexamethasone in patients with relapsed/refractory multiple myeloma.

**DREAMM-7 (NCT04246047)\***

Belantamab mafodotin in combination with bortezomib and dexamethasone compared with daratumumab, bortezomib, and dexamethasone in patients with relapsed/refractory multiple myeloma.

**DREAMM-8 (NCT04484623)\***

Belantamab mafodotin in combination with pomalidomide and dexamethasone vs pomalidomide, bortezomib, and dexamethasone in relapsed/refractory multiple myeloma.

**DREAMM-9 (NCT04091126)\***

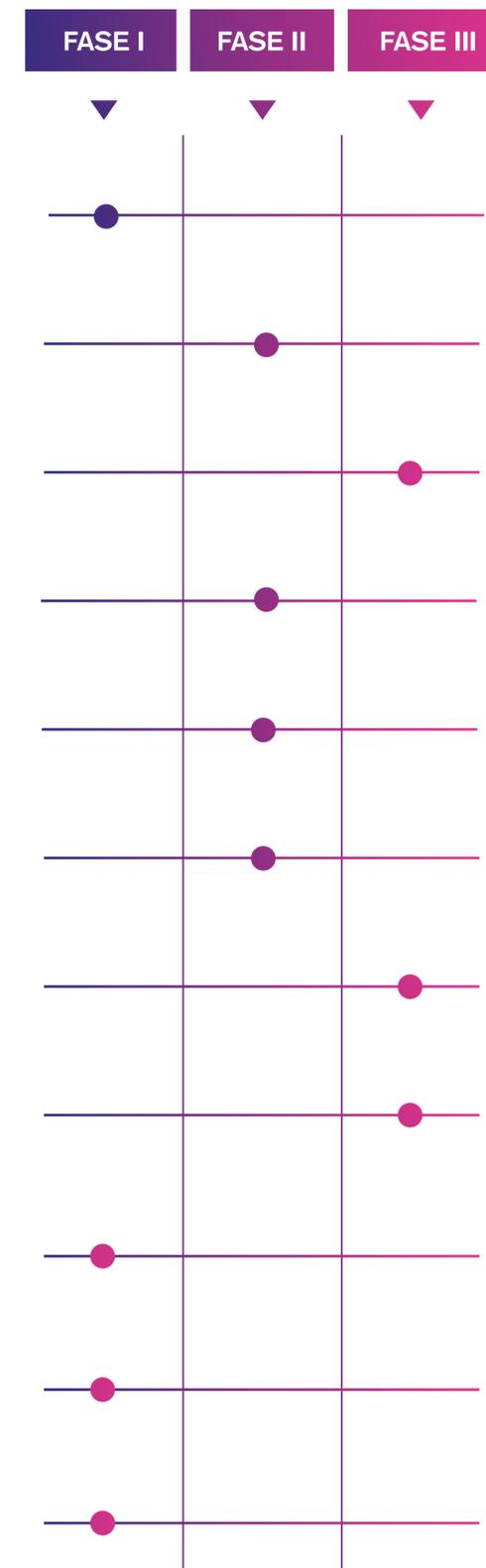
Belantamab mafodotin in combination with bortezomib, lenalidomide, and dexamethasone in patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplantation.

**DREAMM-12 (NCT04398745)**

A pharmacokinetics and safety study of belantamab mafodotin in patients with relapsed/refractory multiple myeloma with normal or varying degrees of impaired renal function.

**DREAMM-13 (NCT04398680)**

A pharmacokinetics and safety study of belantamab mafodotin in patients with relapsed/refractory multiple myeloma with normal or varying degrees of impaired hepatic function.



# DREAMM-1 (NCT02064387)

First-time-in-human study, dose escalation study of belantamab mafodotin in patients with relapsed/refractory multiple myeloma

Phase I, non-randomized, open label study

**Study Status**  
Closed study: Completed

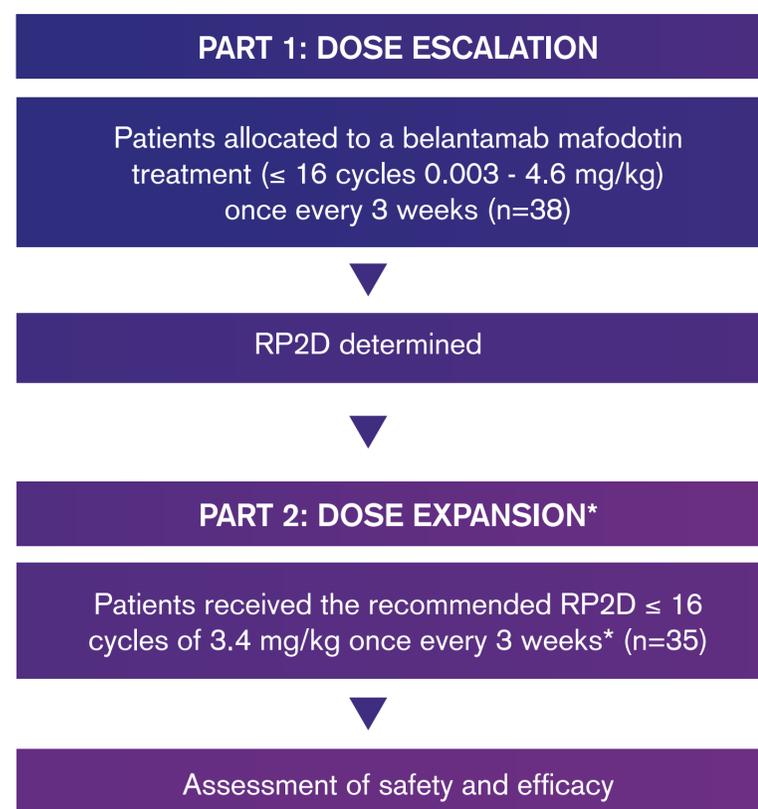
## Endpoints

**KEY INCLUSION CRITERIA**

- ECOG  $\leq$  1
- Multiple myeloma cohort:
  - Received prior treatment with alkylators, PIs and IMiDs
  - Progression on or within 60 days of completion of last therapy
- Other heme malignancies cohort:
  - Subjects with DLBCL/FL; positive BCMA expression;  $\geq$ 2 prior LOTs

**KEY EXCLUSION CRITERIA**

- Systemic antitumor therapy within 14 days, or plasmapheresis within 7 days
- Evidence of cardiovascular risk; current corneal disease/history of corneal disease



**PRIMARY**

- AEs, SAEs
- DLTs
- Baseline changes

**SECONDARY**

- PK parameters
- ADAs
- ORR

**EXPLORATORY**

Some exploratory endpoints included:

- DoR, TTR, PFS
- PROs

**Tumor type:**  
Relapsed/refractory multiple myeloma (RRMM)

**Study population:**  
Patients with RRMM who have been treated with at least 3 prior lines of therapy, including alkylators agents, immunomodulatory agents and proteasome inhibitors and have been refractory to last line of treatment.

\*Treatment until PD, intolerable toxicity, or a maximum of 16 max treatment cycles  
ADA = anti-drug antibody; AE = adverse event; DoR = duration of response; ORR = overall response rate; PD = progressive disease; PFS = progression free survival; PK = pharmacokinetic; PRO = patient reported outcome; RP2D = recommended phase 2 dose; RRMM = relapsed/refractory multiple myeloma; TTR = time to (best) response.

1. Trudel S, Lendvai N, Popat R *et al.* Targeting B-cell maturation antigen with GSK2857916 antibody-drug conjugate in relapsed or refractory multiple myeloma (BMA117159): a dose escalation and expansion phase 1 trial. *Lancet Oncol.* 2018;19(12):1641-1653. doi: [http://dx.doi.org/10.1016/S1470-2045\(18\)30576-X](http://dx.doi.org/10.1016/S1470-2045(18)30576-X); 2. Trudel S, Lendvai N, Popat R *et al.* Antibody-drug conjugate, GSK2857916, in relapsed/refractory multiple myeloma: an update on safety and efficacy from dose expansion phase I study. *Blood Cancer J.* 2019;9:37. doi: <http://dx.doi.org/10.1038/s41408-019-0196-6>.

Belantamab mafodotin (BLENREP) is approved in the EU as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least 4 prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. In Spain, belantamab mafodotin is now under price and reimbursement process and its not commercialised yet. Any other intended use of belantamab mafodotin reviewed in this display is investigational. All clinical study information updated as of July 22, 2020.

# DREAMM-2 (NCT03525678)

Study of two doses of belantamab mafodotin in patients with relapsed/refractory multiple myeloma

Phase II, randomized, open-label study

|   |
|---|
| <b>Study Status</b><br>Active, not recruiting |
| <b>Spain Status</b><br>Closed                 |

## Endpoints



ADA, anti-drug antibody; ASCT, autologous stem cell transplant; BCMA, B-cell maturation antigen; CBR, clinical benefit rate; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; IRC, Independent review committee; MM, multiple myeloma. ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PI, proteasome inhibitor; PK, pharmacokinetics; POEMS, polyneuropathy, organomegaly, endocrinopathy, myeloma protein and skin changes; Q3W, every 3 weeks. TTP, time to progression. TTR, time to response.

1. Lonial S, Lee HC, Badros A, et al. Belantamab mafodotin for relapsed or refractory multiple myeloma (DREAMM-2): a two-arm, randomised, open-label, phase 2 study. *Lancet Oncol.* 2020;21(2):207-221. doi:10.1016/S1470-2045(19)30788-0; 2. Lonial S, Lee HC, Badros A, et al. Pivotal DREAMM-2 study: single-agent belantamab mafodotin (GSK2857916) in patients with relapsed/refractory multiple myeloma (RRMM) refractory to proteasome inhibitors (PIs), immunomodulatory agents, and refractory and/or intolerant to anti-CD38 monoclonal antibodies (mAbs). Poster presented at: American Society of Clinical Oncology Annual Meeting; May 29-June 2, 2020; Virtual.

Belantamab mafodotin (BLENREP) is approved in the EU as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least 4 prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. In Spain, belantamab mafodotin is now under price and reimbursement process and its not commercialised yet. Any other intended use of belantamab mafodotin reviewed in this display is investigational. All clinical study information updated as of July 22, 2020.

# DREAMM-3 (NCT04162210)

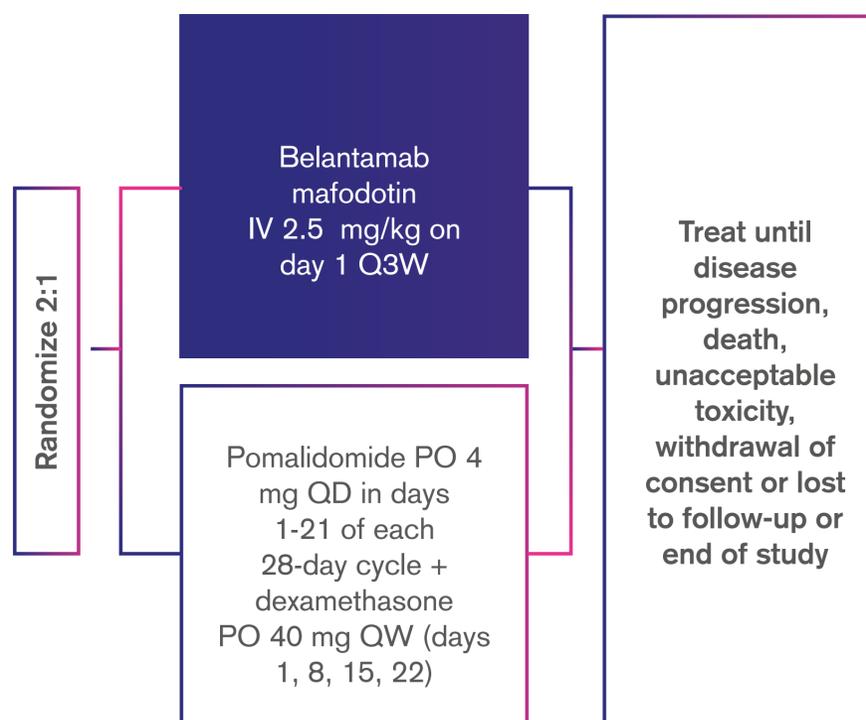
Belantamab mafodotin monotherapy compared with pomalidomide and dexamethasone in patients with relapsed/refractory multiple myeloma

Phase III, randomized, open-label, multicenter study (N=380)

|   |
|---|
| <b>Study Status</b><br>Active, recruiting |
| <b>Spain Status</b><br>Active, recruiting |

| KEY INCLUSION CRITERIA  |
|---|
| <ul style="list-style-type: none"> <li>• Measurable disease</li> <li>• Histologically or cytologically confirmed diagnosis of MM</li> <li>• Prior ASCT or considered transplant ineligible</li> <li>• ≥2 prior lines of MM therapy, including ≥2 consecutive cycles of both lenalidomide and a PI (separately or in combination)</li> <li>• ECOG PS 0-2; adequate organ function</li> </ul> |

| KEY EXCLUSION CRITERIA  |
|---|
| <ul style="list-style-type: none"> <li>• Prior anti-BCMA or pomalidomide therapy</li> <li>• Prior anti-MM mAb treatment within 30 days, or other systemic anti-MM therapy or investigational drug within 14 days or 5 half-lives prior to study drug first dose</li> <li>• Prior allogeneic stem cell transplant</li> <li>• Symptomatic amyloidosis, active POEMS syndrome, or plasma cell leukemia</li> <li>• Concurrent renal condition, mucosal or internal bleeding, unstable liver or biliary disease, or other malignancies</li> <li>• Unable to tolerate thromboembolic prophylaxis</li> </ul> |



**Tumor type:**  
Relapsed/refractory multiple myeloma (RRMM)

**Study population:**  
Patients with RRMM who have been treated with at least 2 prior lines of therapy, including at least 2 consecutive cycles of both lenalidomide and a PI (separately or in combination)

## Endpoints

| PRIMARY   |
|---|
| <ul style="list-style-type: none"> <li>• PFS</li> </ul> |

| SECONDARY   |
|---|
| <ul style="list-style-type: none"> <li>• OS</li> <li>• ORR</li> <li>• CBR</li> <li>• DoR</li> <li>• TTR</li> <li>• TTP</li> <li>• Safety and tolerability</li> <li>• Ocular findings</li> <li>• PK</li> <li>• ADA incidence and titers</li> <li>• Health-related quality of life</li> <li>• MRD rate</li> </ul> |

ADA, anti-drug antibody; ASCT, autologous stem cell transplant; BCMA, B-cell maturation antigen; CBR, clinical benefit rate; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; IV, intravenous; mAb, monoclonal antibody; MM, multiple myeloma; MOA, mechanism of action; MRD, minimal residual disease; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PI, proteasome inhibitor; PK, pharmacokinetics; PO, by mouth; POEMS, polyneuropathy, organomegaly, endocrinopathy, myeloma protein, and skin changes; Q3W, every 3 weeks; QD, once daily; QW, once weekly; TTP, time to progression; TTR, time to response.

Belantamab mafodotin (BLENREP) is approved in the EU as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least 4 prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. In Spain, belantamab mafodotin is now under price and reimbursement process and its not commercialised yet. Any other intended use of belantamab mafodotin reviewed in this display is investigational. All clinical study information updated as of July 22, 2020.

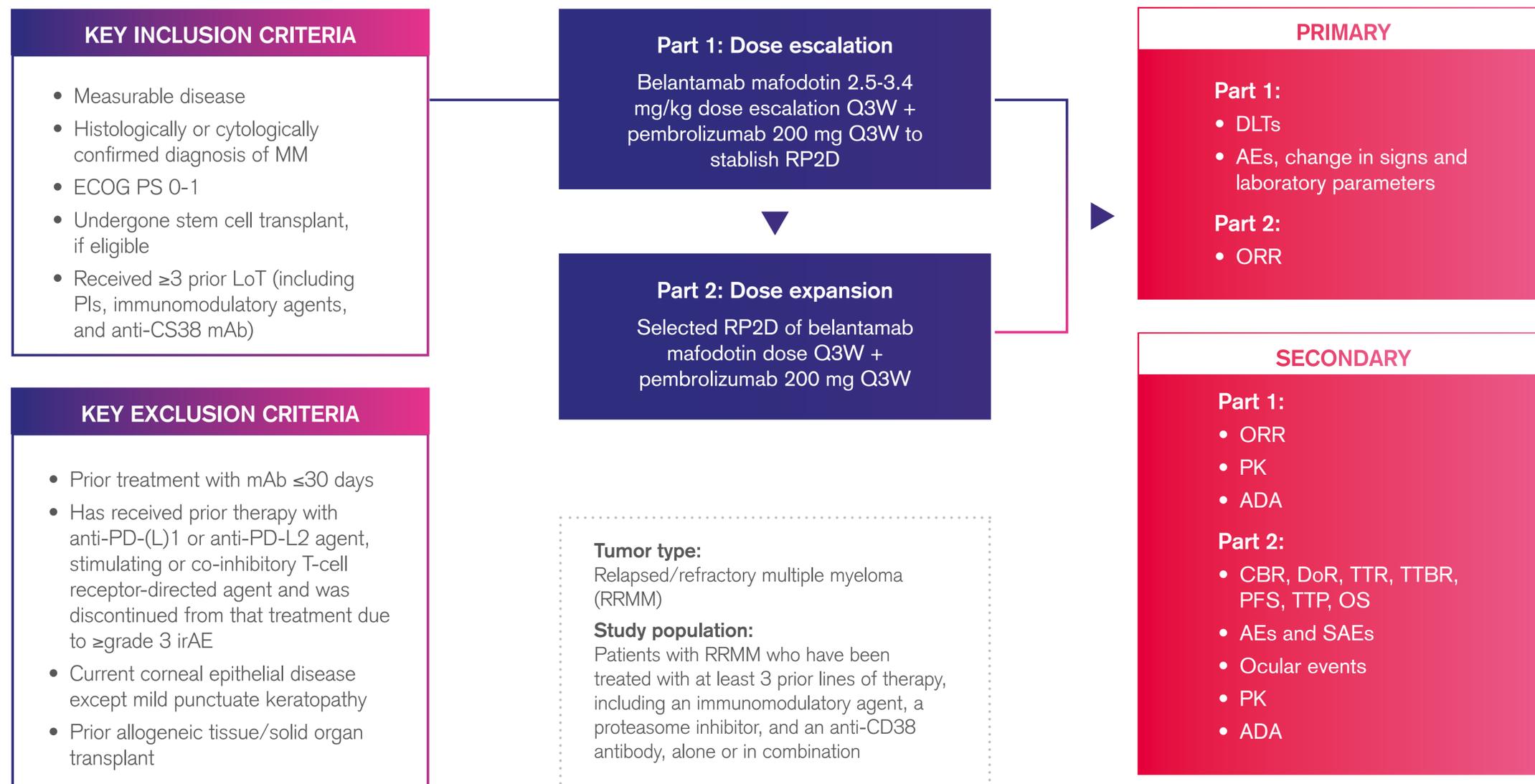
# DREAMM-4 (NCT03848845)

Study of belantamab mafodotin in combination with pembrolizumab in patients with relapse/refractory multiple myeloma

Phase I/ II, non-randomized, single arm, open-label, two-part study (N=40)

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| <b>Study Status</b><br>Active, recruiting |
| <b>Spain Status</b><br>Closed             |

## Endpoints



ADA, anti-drug antibody; AE, adverse events; BCMA, B-cell maturation antigen; CBR, clinical benefit rate; DLT, dose-limiting toxicity; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; irAE, immune-related adverse event; LoT, lines of therapy; mAb, monoclonal antibody; MM, multiple myeloma; MOA, mechanism of action; ORR, objective response rate; OS, overall survival; PD-(L)1, programmed cell death (ligand) 1; PDL-2, programmed cell death ligand 2; PFS, progression-free survival; PI, proteasome inhibitor; PK, pharmacokinetics; PO, by mouth; Q3W, every 3 weeks; QD, once daily; QW, once weekly; TTP, time to progression; TTR, time to response.

Belantamab mafodotin (BLENREP) is approved in the EU as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least 4 prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. In Spain, belantamab mafodotin is now under price and reimbursement process and its not commercialised yet. Any other intended use of belantamab mafodotin reviewed in this display is investigational. All clinical study information updated as of July 22, 2020.

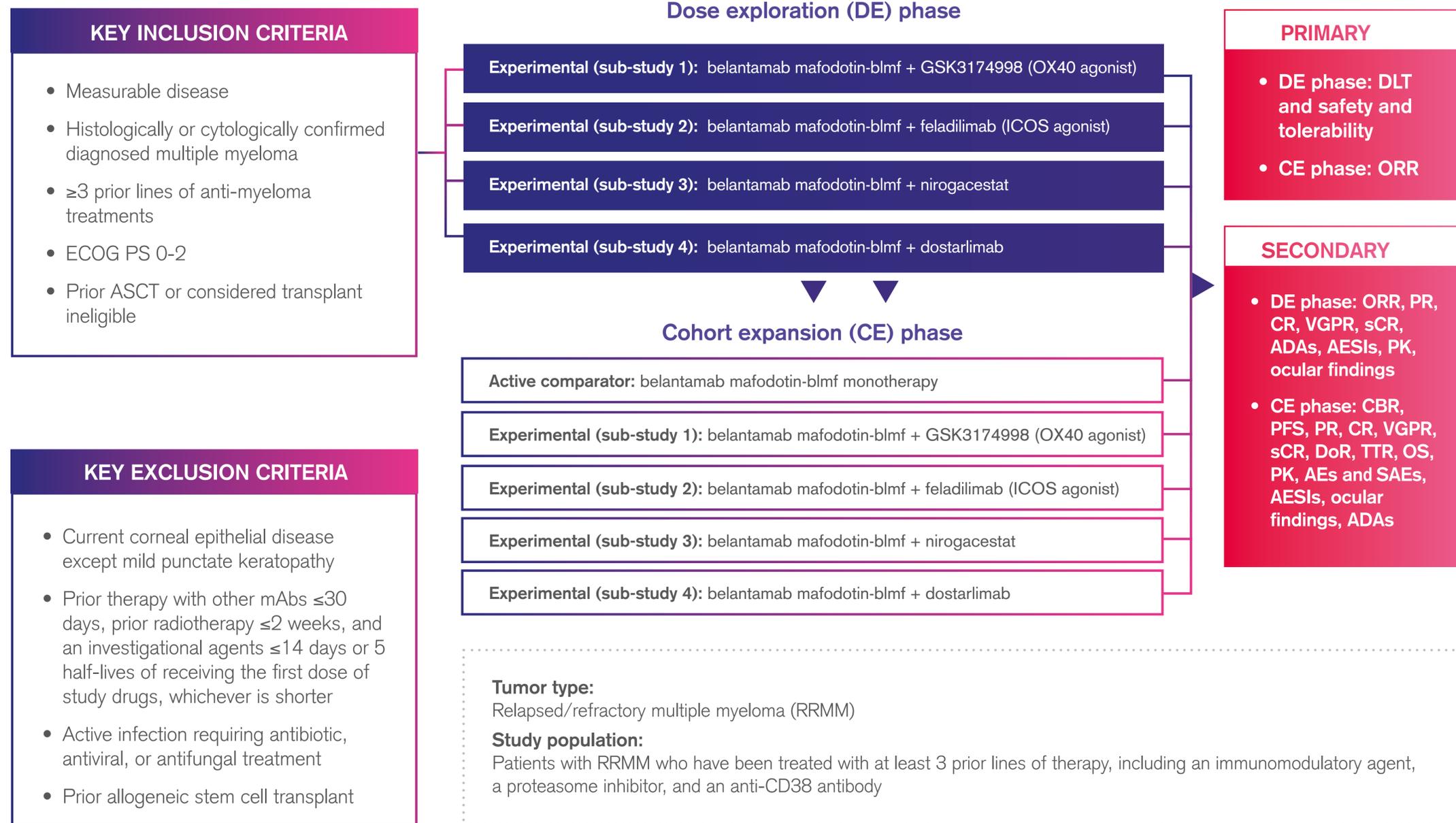
# DREAMM-5 (NCT04126200)

Belantamab mafodotin alone and in combination with GSK3174998 (OX40 agonist antibody), feladilimab (ICOS agonist IgG4 antibody), nirogacestat or dostarlimab in patients with relapse/refractory multiple myeloma

**Phase I/II,  
randomized, open-  
label study (N=464)**

|   |
|---|
| <b>Study Status</b><br>Active, recruiting |
| <b>Spain Status</b><br>Active, recruiting |

## Endpoints



ADA, anti-drug antibody; AE, adverse event; AESI, adverse event of special interest; ASCT, autologous stem cell transplant; BCMA, B-cell maturation antigen; CBR, clinical benefit rate; CR, complete response; DLT, dose-limiting toxicity; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; ICOS, inducible T-cell costimulator; IgG4, immunoglobulin G4; mAb, monoclonal antibody; ORR, objective response rate; OS, overall survival; OX40, tumor necrosis factor receptor superfamily, member 4; PFS, progression-free survival; PK, pharmacokinetics; PR, partial response; SAE, serious adverse event; sCR, stringent complete response; TTR, time to response; VGPR, very good partial response. Belantamab mafodotin (BLENREP) is approved in the EU as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least 4 prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. In Spain, belantamab mafodotin is now under price and reimbursement process and its not commercialised yet. Any other intended use of belantamab mafodotin reviewed in this display is investigational. All clinical study information updated as of October 29, 2020.

# DREAMM-6 (NCT03544281)

Study of belantamab mafodotin in combination with lenalidomide and dexamethasone or with bortezomib and dexamethasone in patients with relapsed/refractory multiple myeloma

Phase I/II, open-label, non-randomized, two-arm, two-part study (N=152)

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| <b>Study Status</b><br>Active, recruiting |
| <b>Spain Status</b><br>Active, recruiting |

## Endpoints

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| <b>PRIMARY</b>   |
| <ul style="list-style-type: none"> <li>• Safety and tolerability</li> <li>• ORR</li> </ul> |

|   |
|---|
| <b>SECONDARY</b>  |
| <ul style="list-style-type: none"> <li>• PK</li> <li>• ADAs</li> <li>• AESI (including corneal events)</li> <li>• Health-related quality of life</li> </ul> |

|   |
|---|
| <b>KEY INCLUSION CRITERIA</b>   |
| <ul style="list-style-type: none"> <li>• Prior ASCT or considered transplant ineligible</li> <li>• Progressed on ≥1 prior line of MM therapy</li> <li>• Measurable disease with ≥1 of following:             <ul style="list-style-type: none"> <li>- Urine M-protein excretion ≥200 mg/day</li> <li>- Serum M-protein concentration ≥0.5 g/dl</li> <li>- FLC level ≥10mg/dl and sFLC ratio (&lt;0.26 or &gt;1.65)</li> </ul> </li> <li>• ECOG PS 0-1 for arm A; ECOG PS 0-2 for arm B</li> </ul> |

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| <b>KEY EXCLUSION CRITERIA</b>   |
| <ul style="list-style-type: none"> <li>• Prior treatment with a mAb ≤30 days</li> <li>• Prior allogeneic stem cell transplant</li> <li>• Active liver or biliary disease</li> <li>• Current corneal disease except for mild punctate keratopathy</li> </ul> |

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| <b>Experimental: Arm A</b>   |
| <ul style="list-style-type: none"> <li>• Belantamab mafodotin-blmf 2.5 mg/kg or 1.9 mg/kg on day 1 of every 28-day cycle + lenalidomide + dexamethasone</li> <li>• <b>SPLIT:</b> belantamab mafodotin-blmf 2.5 mg/kg; Split dose of 1.25 mg/kg dose on day 1 and 1.25 mg/kg dose on day 8 of each 28-day cycle</li> <li>• <b>STRETCH:</b> belantamab mafodotin-blmf 1.9 mg/kg dose on day 1 of every alternate 28-day cycle + lenalidomide 25 mg or 10 mg daily on days 1-21 of each 28-day cycle + dexamethasone 40 mg weekly on days 1, 8, 15, and 22 of each cycle</li> </ul> |

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| <b>Experimental: Arm B</b>   |
| <ul style="list-style-type: none"> <li>• Belantamab mafodotin-blmf 3.4 mg/kg, 2.5 mg/kg or 1.9 mg/kg on day 1 of each 21-day cycle</li> <li>• <b>SPLIT:</b> belantamab mafodotin-blmf in two equally divided doses; Split dose of 3.4 mg/kg and 2.5 mg/kg on days 1 and 8 of each 21-day cycle</li> <li>• <b>STRETCH:</b> belantamab mafodotin-blmf 2.5 mg/kg on day 1 of every alternate 21-day cycle, 1.9 mg/kg on day 1 of every alternate 21-day cycle + bortezomib 1.3 mg/m<sup>2</sup> on days 1, 4, 8 and 11 of every 21-day cycle + dexamethasone 20 mg on days 1, 2, 4, 5, 8, 9, 11 and 12 of every 21-day cycle</li> </ul> |

|   |
|---|
| <b>Tumor type:</b><br>Relapsed/refractory multiple myeloma (RRMM) |
| <b>Study population:</b><br>Patients with RRMM                    |

ADA, anti-drug antibody; AESI, adverse event of special interest; ASCT, autologous stem cell transplant; BCMA, B-cell maturation antigen; CR, complete response; ECOG PS, Eastern Cooperative Oncology Group performance status; FLC, free light chain; mAb, monoclonal antibody; MM, multiple myeloma; MOA, mechanism of action; ORR, objective response rate; PK, pharmacokinetics; sFLC, serum free light chain.

Belantamab mafodotin (BLENREP) is approved in the EU as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least 4 prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. In Spain, belantamab mafodotin is now under price and reimbursement process and its not commercialised yet. Any other intended use of belantamab mafodotin reviewed in this display is investigational. All clinical study information updated as of October 29, 2020.

# DREAMM-7 (NCT04246047)

Belantamab mafodotin in combination with bortezomib and dexamethasone compared with daratumumab, bortezomib, and dexamethasone in patients with relapsed/refractory multiple myeloma

Phase III, open-label, randomized, multicenter study (N=478)

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|---|
| <b>Study Status</b><br>Active, recruiting |
| <b>Spain Status</b><br>Active, recruiting |

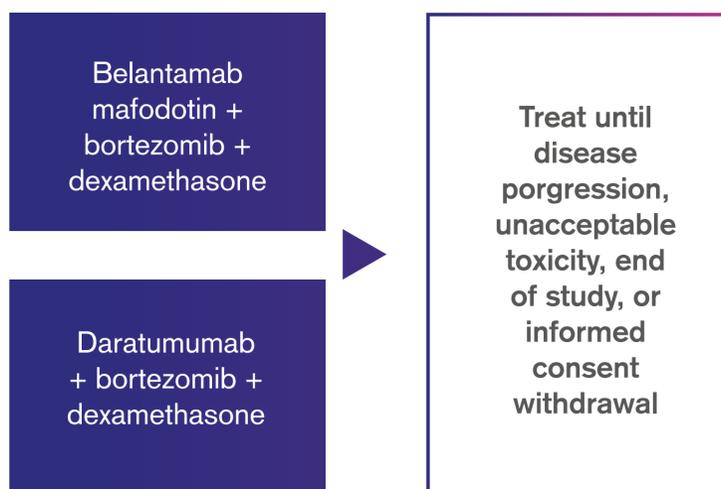
## Endpoints

**KEY INCLUSION CRITERIA**

- Measurable disease with  $\geq 1$  of following:
  - Urine M-protein  $\geq 200$ mg/day
  - Serum M-protein  $\geq 0.5$ g/dl
  - FLC level  $\geq 10$ mg/dl and sFLC ratio ( $< 0.26$  or  $> 1.65$ )
- ECOG PS 0-2
- Previously treated with  $\geq 1$  prior line of MM therapy with documented disease progression during or after most recent therapy

**KEY EXCLUSION CRITERIA**

- Intolerant of daratumumab or refractory to daratumumab or any other anti-CD38 therapy
- Intolerant or refractory to bortezomib
- Prior treatment with anti-BCMA therapy
- Ongoing Grade 2 or higher peripheral neuropathy or neuropathic pain
- Prior allogeneic stem cell transplant
- Corneal epithelial disease



**Tumor type:**  
Relapsed/refractory multiple myeloma (RRMM)

**Study population:**  
Patients with RRMM who have been treated with at least 1 prior line of MM therapy

**PRIMARY**

- PFS

**SECONDARY**

- CRR
- ORR
- DoR
- TTR
- TTP
- OS
- PFS2
- MRD
- Safety and tolerability
- Ocular findings
- PK
- Health-related quality of life, PROs
- ADA

ADA, anti-drug antibody; BCMA, B-cell maturation antigen; CD, cluster of differentiation; CRR, complete response rate; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; FLC, free light chain; MM, multiple myeloma; MRD, minimal residual disease; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PFS2, progression-free survival on subsequent line of therapy; PK, pharmacokinetics; PRO, patient-reported outcome; sFLC, serum free light chain; TTP, time to progression; TTR, time to response

Belantamab mafodotin (BLENREP) is approved in the EU as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least 4 prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. In Spain, belantamab mafodotin is now under price and reimbursement process and its not commercialised yet. Any other intended use of belantamab mafodotin reviewed in this display is investigational. All clinical study information updated as of July 22, 2020.

# DREAMM-8 (NCT04484623)

Belantamab mafodotin in combination with pomalidomide and dexamethasone vs pomalidomide, bortezomib, and dexamethasone in relapsed/refractory multiple myeloma

**Phase III, multicenter,  
open-label, randomized study  
(N=450)**

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| <b>Study Status</b><br>Active, recruiting |
| <b>Spain Status</b><br>Active, recruiting |

## Endpoints

| KEY INCLUSION CRITERIA   |
|--|
| <ul style="list-style-type: none"> <li>Confirmed diagnosis of MM</li> <li>Previously treated with ≥1 prior line of MM therapy, including a lenalidomide-containing regimen</li> <li>Measurable disease with ≥1 of the following:                             <ul style="list-style-type: none"> <li>Urine M-protein excretion ≥200mg/day</li> <li>Serum M-protein concentration ≥0.5 g/dl</li> <li>FLC level ≥10mg/dl and sFLC ratio &lt;0.26 or &gt;1.65</li> </ul> </li> <li>Disease progression during or alter most recent therapy</li> <li>Undergone ASCT or considered transplant ineligible</li> <li>ECOG PS 0-2</li> </ul> |



|  |
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| <b>Experimental (Arm A):</b><br>Belantamab mafodotin +<br>pomalidomide + dexamethasone |
|--|



| PRIMARY   |
|---|
| <ul style="list-style-type: none"> <li>PFS</li> </ul> |

|  |
|--|
| <b>Experimental (Arm B):</b><br>pomalidomide + bortezomib +<br>dexamethasone |
|--|

| SECONDARY        |
|------------------|
| • MRD            |
| • ORR            |
| • CRR            |
| • VGPR           |
| • DoR            |
| • TTBR, TTR, TTP |
| • OS             |
| • PFS2           |
| • AEs and SAEs   |
| • PK             |
| • ADAs           |
| • PROs           |

| KEY EXCLUSION CRITERIA  |
|---|
| <ul style="list-style-type: none"> <li>Active plasma cell leukemia</li> <li>Symptomatic amyloidosis, active POEMS syndrome</li> <li>Prior treatment with systemic anti-myeloma therapy within 14 days or 5 half-lives, whichever is shorter</li> <li>Received prior treatment with or intolerant to pomalidomide</li> <li>Received prior BCMA targeted therapy</li> <li>Intolerant or refractory to bortezomib</li> <li>Active infection requiring treatment</li> <li>Any major surgery within 4 weeks</li> <li>Current corneal disease except for mild punctate keratopathy</li> </ul> |

|   |
|---|
| <b>Tumor type(s)</b><br>Relapsed/refractory multiple myeloma (RRMM)                                       |
| <b>Study population</b><br>Patients with RRMM who have been treated with at least 1 prior line of therapy |

ADA, antidrug antibody; AE, adverse event; ASCT, autologous stem cell transplant; BCMA, B-cell maturation antigen; CRR, complete response rate; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; FLC, free light chain; MM, multiple myeloma; MRD, minimal residual disease; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PFS2, progression-free survival on subsequent line of therapy; PK, pharmacokinetics; POEMS, polyneuropathy, organomegaly, endocrinopathy, myeloma protein and skin changes; PRO, patient-reported outcome; SAE, serious adverse event; sFLC, serum free light chain; TTBR, time to best response; TTP, time to progression; TTR, time to response; VGPR, very good partial response.

Belantamab mafodotin (BLENREP) is approved in the EU as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least 4 prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. In Spain, belantamab mafodotin is now under price and reimbursement process and its not commercialised yet. Any other intended use of belantamab mafodotin reviewed in this display is investigational. All clinical study information updated as of July 22, 2020.

# DREAMM-9 (NCT04091126)

Belantamab Mafodotin in combination with the Standard of Care in participants with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplantation.

**Phase I, open label, randomized study (N=144)**

**Study Status**  
Active, recruiting

**Spain Status**  
Active, recruiting

## Dose and Schedule evaluation study

## Endpoints

| KEY INCLUSION CRITERIA  | Cohort 1   | Cohort 2-5  | Cohort 6-8   | PRIMARY   |
|---|--|---|--|---|
| <ul style="list-style-type: none"> <li>Measurable disease with <math>\geq 1</math> of following:                             <ul style="list-style-type: none"> <li>Urine M-protein excretion <math>\geq 200</math>mg/day</li> <li>Serum M-protein concentration <math>\geq 0.5</math>g/dl</li> <li>FLC level <math>\geq 10</math>mg/dl and sFLC ratio (<math>&lt; 0.26</math> or <math>&gt; 1.65</math>)</li> </ul> </li> <li>ECOG PS 0-2</li> <li>Not a candidate for high-dose chemotherapy with ASCT due to frailty and/or significant comorbid condition(s)</li> </ul> | <p><b>Belantamab mafodotin</b></p> <p>1.9 mg/kg Q3/4W*</p> <p>+<br/><b>SoC</b></p> <p>Bortezomib + lenalidomide + dexamethasone (VRd/Rd<sup>†</sup>)</p> | <p><b>Belantamab mafodotin</b></p> <p>1.4 mg/kg Q6/8W<br/>1.9 mg/kg Q6/8W<br/>1 mg/kg Q3/4W<br/>1.4 mg/kg Q3/4W</p> <p>+<br/><b>SoC</b></p> <p>Bortezomib + lenalidomide + dexamethasone (VRd/Rd<sup>†</sup>)</p> | <p><b>Belantamab mafodotin</b></p> <p>1.9 or 2.5 mg/kg Q9/12W<br/>1.9 or 2.5 mg/kg Q6/8W SPLIT<sup>^</sup><br/>2.5 mg/kg Q6/8W</p> <p>+<br/><b>SoC</b></p> <p>Bortezomib + lenalidomide + dexamethasone (VRd/Rd<sup>†</sup>)</p> | <ul style="list-style-type: none"> <li>DLTs</li> <li>AEs</li> </ul>   |
| KEY EXCLUSION CRITERIA  |  |   |  | SECONDARY   |
| <ul style="list-style-type: none"> <li>Prior systemic therapy for MM or SMM</li> <li>Patient eligible for HDT with ASCT</li> <li>Active liver or biliary disease</li> <li>Current corneal epithelial disease except for mild punctate keratopathy</li> </ul>  |  |   |  | <ul style="list-style-type: none"> <li>RDI</li> <li>Cumulative dose</li> <li>PK</li> <li>ADAs</li> <li>ORR, CRR, VGPR</li> </ul>                          |
|   |  |   |  | <p><b>Tumor type(s)</b><br/>Newly diagnosed multiple myeloma (NDMM)</p> <p><b>Study population</b><br/>Patients with NDMM who are ineligible for ASCT</p> |

\*Q3W for the first 8 cycles and Q4W from cycle 9 onwards. †Belantamab mafodotin will be administered for the first 8 cycles with VRd every Q3W, Q6W, or Q9W in induction, and then from cycle 9 onwards with Rd every Q4W, Q8W, or Q12W in maintenance. ^Participants will receive a total dose of either 1.9 mg/kg or 2.5 mg/kg of belantamab mafodotin (split in to two equal doses of 0.95 mg/kg or 1.25 mg/kg to be given on Day 1 and Day 8)

AE, adverse event; ASCT, autologous stem cell transplant; CRR, complete response rate; DLT, dose-limiting toxicity; ECOG PS, Eastern Cooperative Oncology Group performance status; FLC, free light chain; HDT, high-dose therapy; MM, multiple myeloma; ORR, objective response rate; PK, pharmacokinetics; RDI, relative dose intensity; sFLC, serum free light chain; SMM, smoldering multiple myeloma; SoC, standard of care; VGPR, very good partial response; VRd, bortezomib + lenalidomide+ dexamethasone; Rd, lenalidomide + dexamethasone. Belantamab mafodotin (BLENREP) is approved in the EU as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least 4 prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. In Spain, belantamab mafodotin is now under price and reimbursement process and its not commercialised yet. Any other intended use of belantamab mafodotin reviewed in this display is investigational. All clinical study information updated as of September 2020.

# DREAMM-12 (NCT04398745)

A pharmacokinetics and safety study of belantamab mafodotin in patients with relapsed/refractory multiple myeloma with normal or varying degrees of impaired renal function

Phase I, open-label, parallel assignment study (N=40)

**Study Status**  
Active, recruiting

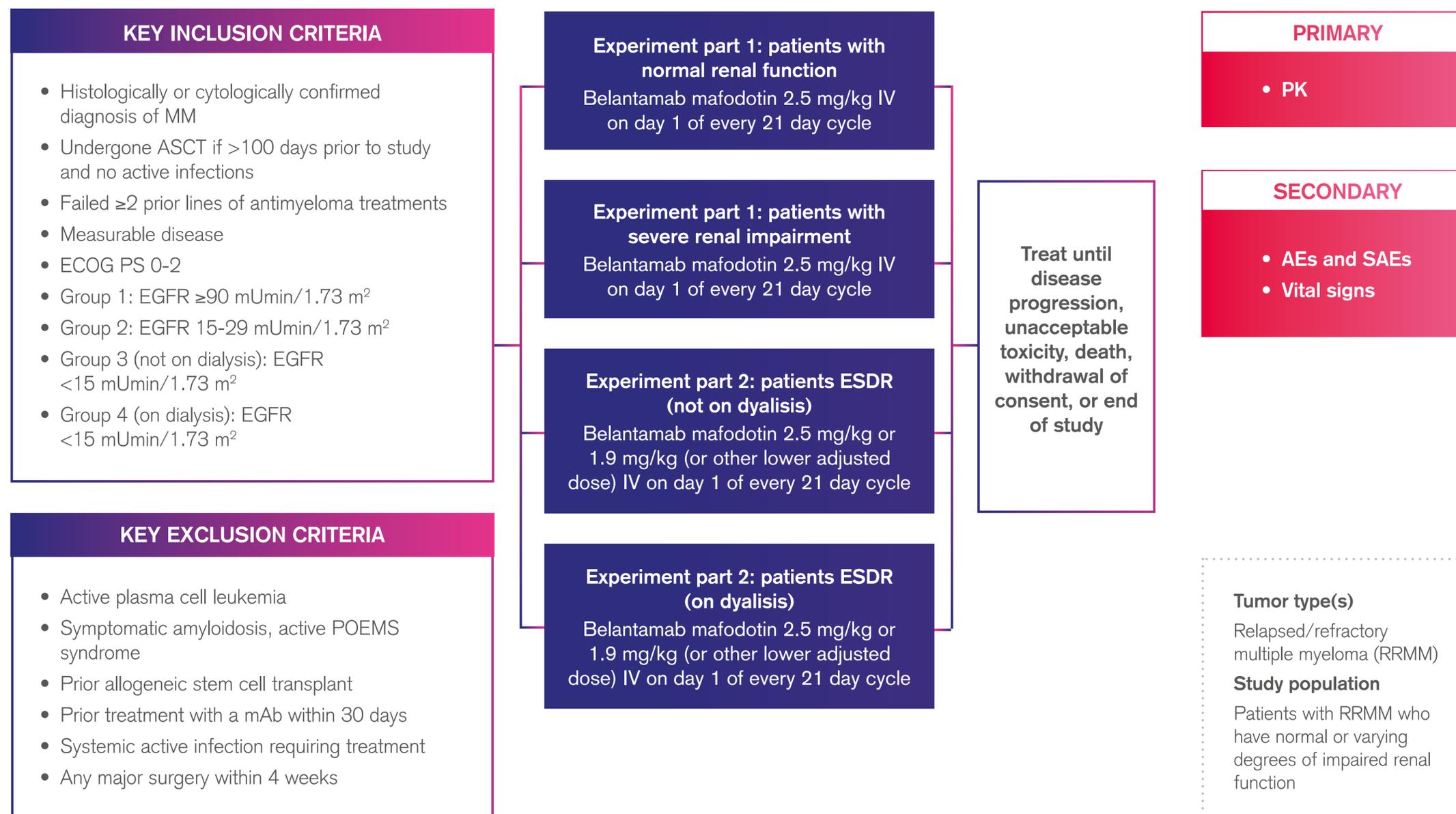
## Endpoints

### PRIMARY

- PK

### SECONDARY

- AEs and SAEs
- Vital signs



AE, adverse event; ASCT, autologous stem cell transplant; BCMA, B-cell maturation antigen; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, estimated glomerular filtration rate; ESRD, end-stage renal disease; IV, intravenous; mAb, monoclonal antibody; MM, multiple myeloma; PK, pharmacokinetics; POEMS, polyneuropathy, organomegaly, endocrinopathy, myeloma protein, and skin changes; SAE, serious adverse event.

Belantamab mafodotin (BLENREP) is approved in the EU as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least 4 prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. In Spain, belantamab mafodotin is now under price and reimbursement process and its not commercialised yet. Any other intended use of belantamab mafodotin reviewed in this display is investigational. All clinical study information updated as of July 22, 2020.

# DREAMM-13 (NCT04398680)

A pharmacokinetics and safety study of belantamab mafodotin in patients with relapsed/refractory multiple myeloma with normal or varying degrees of impaired hepatic function

Phase I, open-label,  
parallel assignment study  
(N=40)

**Study Status**  
Not yet recruiting

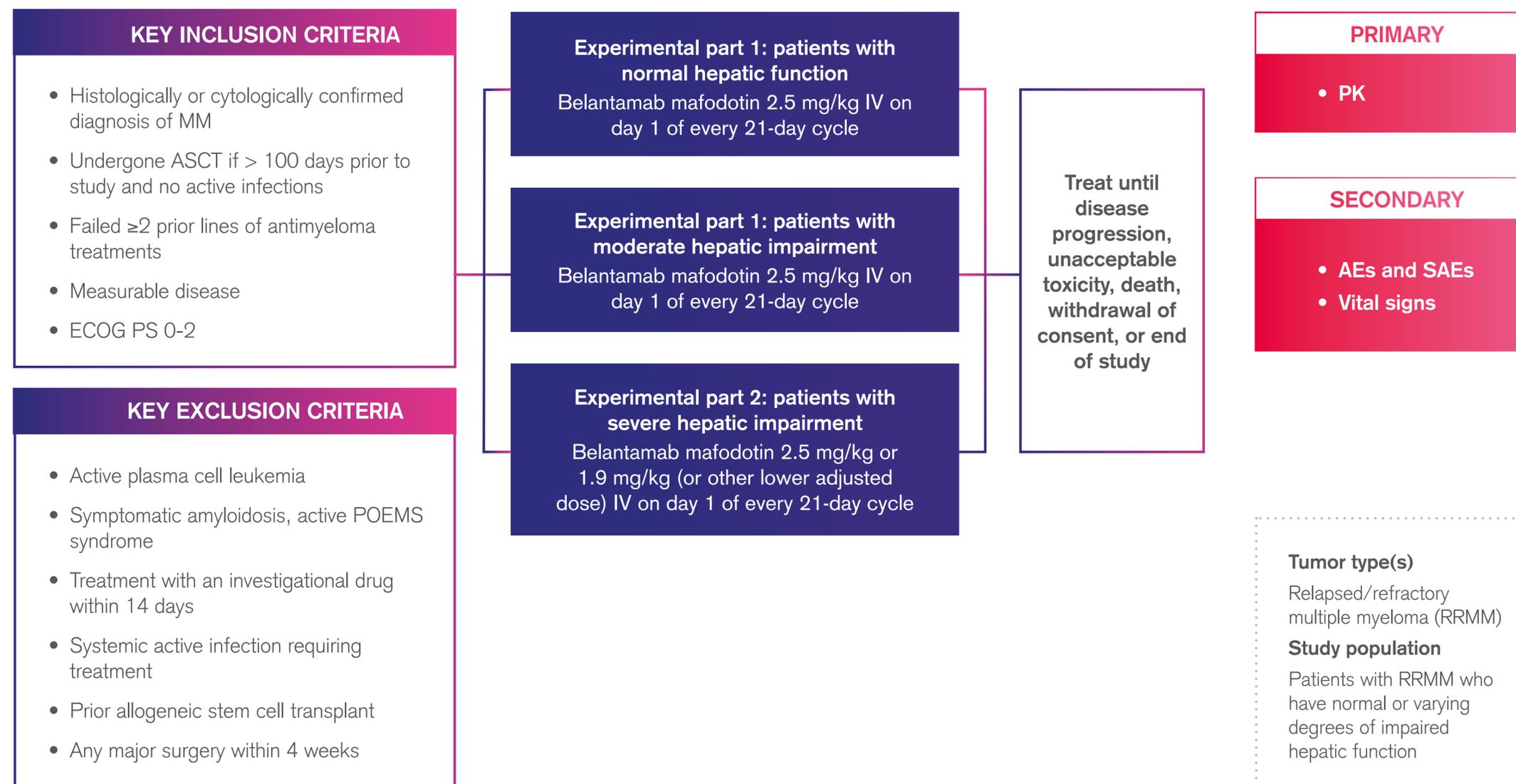
## Endpoints

### PRIMARY

- PK

### SECONDARY

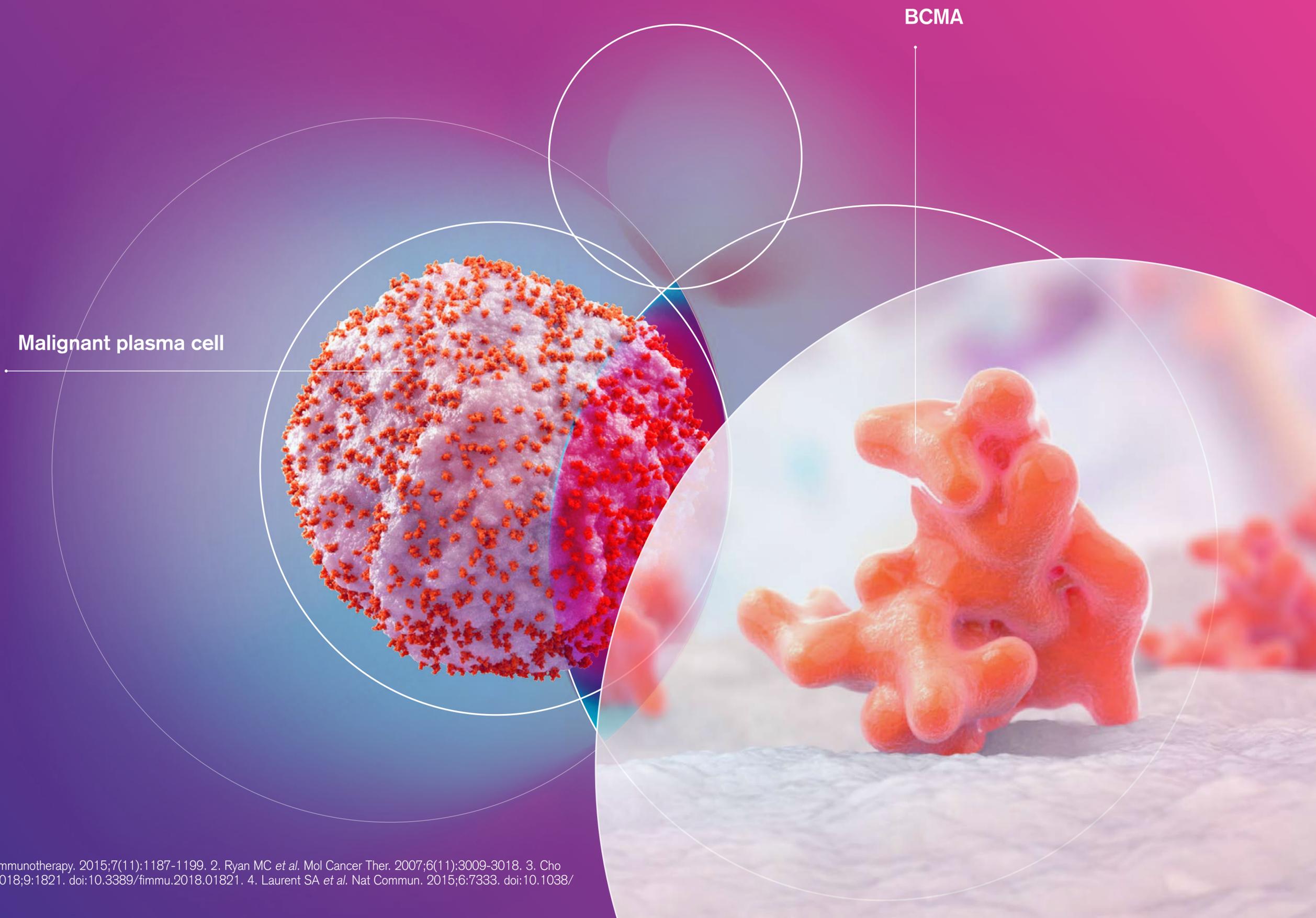
- AEs and SAEs
- Vital signs



AE, adverse event; ASCT, autologous stem cell transplant; BCMA, B-cell maturation antigen; ECOG PS, Eastern Cooperative Oncology Group performance status; IV, intravenous; PK, pharmacokinetics; POEMS, polyneuropathy, organomegaly, endocrinopathy, myeloma protein, and skin changes; SAE, serious adverse event.

Belantamab mafodotin (BLENREP) is approved in the EU as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least 4 prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. In Spain, belantamab mafodotin is now under price and reimbursement process and its not commercialised yet. Any other intended use of belantamab mafodotin reviewed in this display is investigational. All clinical study information updated as of July 22, 2020.

BCMA is a cell surface protein expressed predominantly on late-stage B cells and plasma cells<sup>1-3</sup>. BCMA is required for optimal survival of long-lived plasma cells in the bone marrow<sup>1,2</sup>. BCMA is highly expressed on malignant plasma cells in all patients with MM<sup>2,4</sup>.



# Nos tomamos la hematología como algo personal



No sabemos el origen de todas las amenazas



**pero sí cómo ayudar al organismo a combatir las**

La inmunooncología es hoy caldo de cultivo para un nuevo concepto de medicina. Y el tiempo invertido en crear soluciones biológicas es apostar por la vida a cualquier escala.

