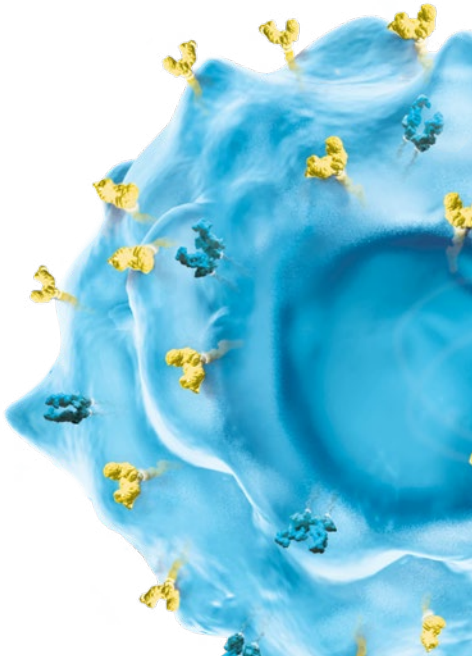
HIRSLANDEN
KLINIK HIRSLANDEN

CAR T CELL THERAPY

for the treatment of multiple myeloma

BROCHURE FOR REFERRING PHYSICIANS

INFORMATION ON THE THERAPY WITH ABECMA®
AND PATIENT CARE



IS YOUR PATIENT ELIGIBLE FOR CAR T THERAPY?

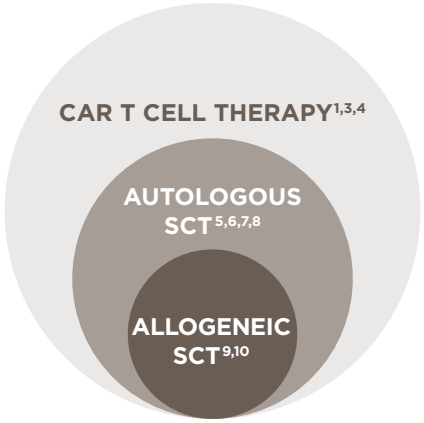
TREATMENT OF MULTIPLE MYELOMA WITH ABECMA® (IDECABTAGENE VICLEUCEL)

A genetically modified autologous T cell immunotherapy consisting of T cells transduced with a lentiviral vector (LVV) encoding a chimeric antigen receptor (CAR) that recognises the B cell maturation antigen.[1]

ABECMA® (idecabtagene vicleucel; ide-cel) is indicated for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody, and have demonstrated disease progression on the last therapy.[1]

FIRST APPROVED CAR T CELL THERAPY IN RRMM[1,2]

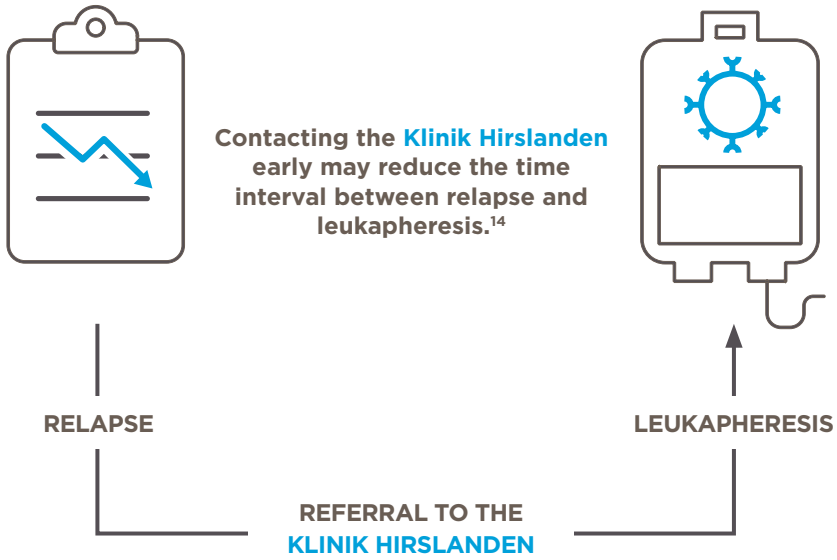
ELIGIBILITY AND DECISION IN FAVOUR OF CAR T THERAPY



Although certain eligibility criteria for CAR T overlap with those for SCT*, a broader patient population may benefit from CAR T therapy:[11,12,13]

- ☑ No upper age limit
- ☑ Chemosensitive or chemorefractory
- ☑ Eligible or ineligible for SCT

CAR T therapy may also be considered for patients who are not eligible for SCT* or who relapse after SCT.[11,12,13]



INDICATION[1]

- Adult patients (>18 years) with rrMM
- Received at least three prior therapies with the 3 main drug groups IMiD®, PI and anti-CD38 antibodies
- With progression under last therapy

- ☑ Discuss the option of CAR T therapy prior to a possible relapse.
- ☑ Contact the **Klinik Hirslanden** early.
- ☑ Choose therapies that do not prejudice possible later CAR T therapy.*
- ☑ Evaluate whether myeloma therapy is needed until leukapheresis.

* Stem cell transplant

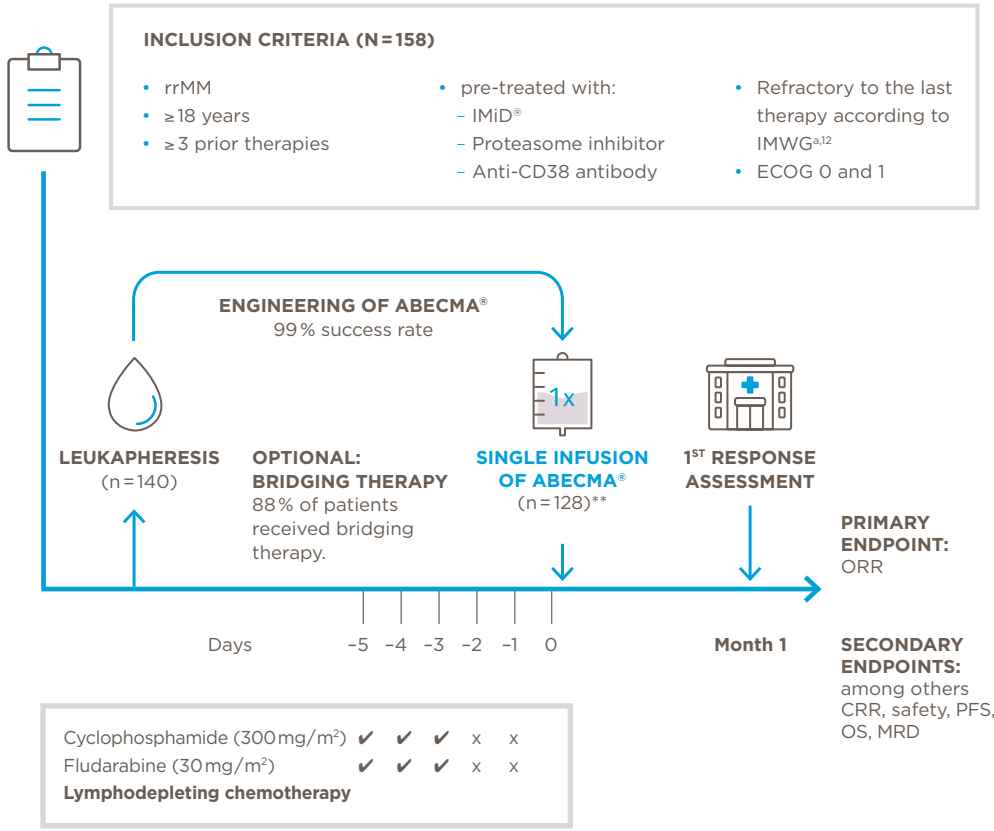
* Certain therapies (e.g. alkylators) can interfere with the engineering success of CAR T therapy as they inhibit the production of healthy T cells.[15]

WHY CAR T CELL THERAPY IN RRMM?

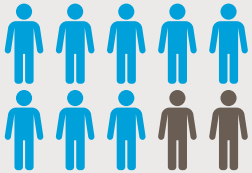
KARMMA: MULTICENTRE PHASE II STUDY WITH ABECMA®

STUDY DESIGN[12]

Single-arm, multicentre Phase II study on the efficacy and safety of CAR T cell therapy with ABECMA® (idecabtagene vicleucel) in triple-class-exposed adult patients with rrMM.



LONG-LASTING EFFECTIVENESS AFTER A SINGLE INFUSION OF ABECMA®



8 OF 10 PATIENTS RESPONDED*

OVER 1 YEAR MEDIAN PROGRESSION-FREE SURVIVAL (MPFS)[16]

mPFS

AT MAXIMUM TARGET DOSE:
450×10⁶ CAR-positive T cells
(n=54)

MORE THAN 2 YEARS MEDIAN OVERALL SURVIVAL (MOS)[17]

mOS

AT MAXIMUM TARGET DOSE:
450×10⁶ CAR-positive T cells
(n=54)

150**–450×10⁶ CAR-positive T cells (n=128)[#9]	
mPFS	8.6 months (95% CI: 5.6–11.6)

150**–450×10⁶ CAR-positive T cells (n=128)[#9]	
mOS	24.8 months (95% CI: 19.9–31.2)

* In the pivotal KarMMa Study at a target dose of 450×10⁶ CAR T cells (n=54).[2]

** The dose of 150×10⁶ CAR-positive T cells (n=4/128) is not part of the approved dosage range. The approved target dose of ABECMA® is 420×10⁶ CAR-positive viable T cells in a range of 260–500×10⁶ CAR-positive viable cells.[1]

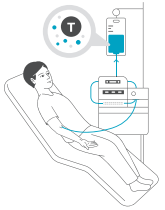
Data cut-off Oriol A et al: Dec 21, 2020.

PROCEDURE AND CARE DURING CAR T THERAPY IN THE KLINIK HIRSLANDEN[1,3,18]

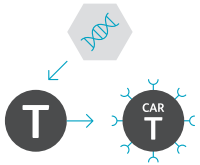
Diagnosis of relapse and referral
by referring physician

Preliminary discussion

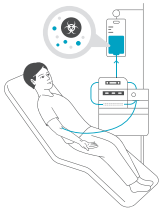
Leuka-pheresis



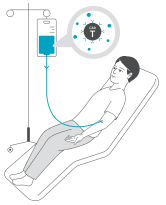
Transport of the cells and engineering of the CAR T cells



Lympho-depletion



Infusion of CAR T cells



Monitoring

Long-term follow-up
by referring physician and the Klinik Hirslanden

outpatient inpatient

COMMON ADVERSE REACTIONS AND SYMPTOMS OF CAR T THERAPY

CYTOKINE RELEASE SYNDROME (CRS)[19,20*]

Tachycardia, arrhythmia

Hypoxia

Hypotension

Chills

Fever

NEUROTOXICITY (NT)[19,20*]

Encephalopathy

Dizziness, delirium, headache

Aphasia

Fatigue

* Not an exhaustive list of CRS and NT symptoms.

REFERENCES, SUCCINT STATEMENT

1. Product Information of ABECMA®, version March 2023, www.swissmedicinfo.ch. **2.** Munshi NC et al. Idecabtagene Vicleucel in Relapsed and Refractory Multiple Myeloma. N Engl J Med. 2021 Feb 25;384(8):705-716. **3.** Product Information of BREYANZI®, version March 2022, www.swissmedicinfo.ch. **4.** Hayden PJ, Sirait T, Koster L, et al. An international survey on the management of patients receiving CAR T-cell therapy for haematological malignancies on behalf of the Chronic Malignancies Working Party of EBMT. Curr Res Transl Med. 2019 Jun;67:79-88. **5.** Gisselbrecht C, Glass B, Mounier N, et al. Salvage regimens with autologous transplantation for relapsed large B-cell lymphoma in the rituximab era. J Clin Oncol. 2010 Sep;28(27):4184-4190. **6.** Gisselbrecht C, Van Den Neste E. How I manage patients with relapsed/refractory diffuse large B cell lymphoma. Br J Haematol. 2018 Sep;182(5):633-643. **7.** Al Hamed R, Bazarbachi AH, Malard F, et al. Current status of autologous stem cell transplantation for multiple myeloma. Blood Cancer J. 2019 Apr;9(4):44. **8.** Belotti A, Ribolla R, Cancelli V, et al. Transplant eligibility in elderly multiple myeloma patients: prospective external validation of the international myeloma working group frailty score and comparison with clinical judgment and other comorbidity scores in unselected patients aged 65–75 years. Am J Hematol. 2020 Jul;95(7):759-765. **9.** Fenske TS, Hamadani M, Cohen JB, et al. Allogeneic hematopoietic cell transplantation as curative therapy for patients with non-Hodgkin lymphoma: increasingly successful application to older patients. Biol Blood Marrow Transplant. 2016 Sep;22(9):1543-1551. **10.** Luoma S, Silvennoinen R, Rauhala A, et al. Long-term outcome after allogeneic stem cell transplantation in multiple myeloma. Annals of Hematology. 2021 Apr;100:1553-1567. **11.** Chavez JC, Bachmeier C, Kharfan-Dabaja MA. CAR T-cell therapy for B-cell lymphomas: clinical trial results of available products. Ther Adv Hematol. 2019 Apr;10:1-20. **12.** Munshi NC, Anderson LD, Shah N, et al. Idecabtagene vicleucel in relapsed and refractory multiple myeloma. N Engl J Med. 2021 Feb;25;384(8):705-716. **13.** Abramson JS, Palomba ML, Gordon LI, et al. Lisocabtagene maraleucel for patients with relapsed or refractory large B-cell lymphomas (TRANSCEND NHL 001): a multicentre seamless design study. Lancet. 2020 Sep;396:839-852. **14.** Gagelmann N et al. Access to and affordability of CAR T-cell therapy in mulQple myeloma: an EBMT posiQon paper. Lancet Haematol. 2022 Oct;9(10):e786-e795. **15.** Rytlewski J, Fuller J, Mertz DR, et al. Correlative analysis to define patient profiles associated with manufacturing and clinical endpoints in relapsed/refractory multiple myeloma (RRMM) patients treated with idecabtagene vicleucel (ide-cel; bb2121), an anti-BCMA CAR T cell therapy. J Clin Oncol 40. 2022 Jun; suppl 16; abstr 8021. **16.** Anderson LD et al. Idecabtagene vicleucel (ide-cel, bb2121), a BCMA-directed CAR T cell therapy, in relapsed and refractory multiple myeloma: Updated KarMMa results. Clin Oncol.2021;39:15(suppl):8016-8016. **17.** Oriol A et al. Idecabtagene vicleucel (ide-cel, bb2121), a BCMA-directed CAR T cell therapy, in patients with relapsed and refractory multiple myeloma: updated KarMMa results. EHA Library. Oriol A. 06/09/21; 324732; EP1009. **18.** Maus MV, Levine BL. Chimeric antigen receptor T-cell therapy for the community oncologist. Oncologist. 2016 May;21:608-617. **19.** Shimabukuro-Vornhagen A, Gödel P, Subklewe M, et al. Cytokine release syndrome. J Immunother Cancer. 2018 Jun;6(1):56. **20.** Lee DW, Santomasso BD, Locke FL, et al. ASTCT consensus grading for cytokine release syndrome and neurologic toxicity associated with immune effector cells. Biol Blood Marrow Transplant. 2019 Apr;25(4):625-638. **Literature on request.**

ABECMA® (idecabtagene vicleucel) ▼ This medicinal product is subject to additional monitoring. For more information, please refer to the Summary of Product Characteristics for ABECMA® at www.swissmedicinfo.ch. I: In adults with relapsed and refractory multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody, and who have progressed since the most recent therapy. **D:** as a single infusion with a target dose of 420×10^6 CAR-positive viable T cells (range 260 to 500×10^6 CAR-positive viable T cells) under the direction and supervision of a trained physician at a qualified treatment centre. **CI:** hypersensitivity to active substances/excipients. Also note contraindications for lymphodepleting chemotherapy. **W&P:** cytokine release syndrome (CRS) and neurological toxicities with life-threatening reactions have occurred after treatment with ABECMA®. Patients must be monitored daily in a qualified facility for 10 days after infusion. Two doses of tocilizumab and access to another dose within 8 h need to be available. Parkinsonism with reported symptoms such as tremor, dysphasia, bradykinesia and parkinsonian-like reflexes occurred. Allergic reactions and virus reactivations (CMV and HBV) may occur. Severe infections and febrile neutropenia have been observed. Risk of prolonged cytopenia and hypogammaglobulinemia. Patients may develop secondary malignancies. No administration to patients with active infections or inflammatory diseases. Vaccination with live viral vaccines should be avoided 6 weeks before treatment. Patients should not be treated with ABECMA® within 4 months after allogeneic stem cell transplantation either (risk of increased GvHD). The donation of blood, organs, tissues and cells is prohibited. **IA:** no interaction studies have been conducted. **AE:** infections, decreased blood cell count, disseminated intravascular coagulation, hypogammaglobulinemia, CRS, haemophagocytic lymphohistiocytosis, electrolyte disorders, decreased appetite, insomnia, delirium, headache, encephalopathy, dizziness, tremor, motor dysfunction, aphasia, ataxia, hemiparesis, seizure, tachycardia, atrial fibrillation, hypotension, hypertension, cough, dyspnoea, hypoxia, pulmonary oedema, diarrhoea, nausea, constipation, vomiting, gastrointestinal bleeding, arthralgia, myalgia, fatigue, pyrexia, oedema, chills, asthenia, AP increased, AST increased, ALT increased, CRP increased. **PF:** one or more infusion bags containing a total cell dispersion of 260 to 500×10^6 CAR-positive viable T cells. **Detailed information:** Information for Healthcare Professionals at www.swissmedicinfo.ch. **MAH:** Bristol-Myers Squibb SA, CH-Steinhausen. Version 05/2023.

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CONTACT

Find out more about CAR T cell therapy using the QR code. For questions and referrals regarding cell therapy at the Klinik Hirslanden, the team of physicians involved in the medical programme for cell therapy would be pleased to help you by phone at +41 (0)44 387 37 80 or by email.

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