# Idecabtagene vicleucel chimeric antigen receptor T-cell therapy for relapsed/refractory multiple myeloma with renal impairment

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**Received:** July 16, 2023.
**Accepted:** September 8, 2023.
**Early view:** September 21, 2023.

**https://doi.org/10.3324/haematol.2023.283940**

**Supplementary Data**

**Supplementary Methods**

**Table S1: Institutional protocols for fludarabine dose reduction based on creatinine clearance from 11 centers participating in this study. Conventional dose is 30 mg/m$^2$**

| | | |
|---|---|---|
| 1. | Stanford University | CrCl 50-69mL/min: 24mg/m$^2$ (20% reduction)<br>CrCl 30-49mL/min: 18mg/m$^2$ (40% reduction)<br>CrCl <30mL/min, not on dialysis: 15mg/m2 (50% reduction)<br>Dialysis: Dosing and schedule to be coordinated with BMT pharmacist and nephrology |
| 2. | Moffitt Cancer Center | CrCl 50-69mL/min: 24mg/m$^2$ (20% reduction)<br>CrCl 30-49mL/min: 18mg/m$^2$ (40% reduction)<br>CrCl <30mL/min, not on dialysis: 15mg/m$^2$ (50% reduction)<br>Hemodialysis: 24 mg/m$^2$ (20% dose reduction) and 12-hour separation from dialysis. See footnote* |
| 3. | Cleveland Clinic | CrCl 50-70mL/min: 24mg/m$^2$ (20% reduction)<br>CrCl 30-49mL/min: 18mg/m$^2$ (40% reduction)<br>CrCl <30mL/min, not on dialysis: 15mg/m$^2$ (50% reduction)<br>Hemodialysis: 15 mg/m$^2$ (50% dose reduction) and dialysis 12 hours after fludarabine on days -4, -2 and day 0 before cell infusion |
| 4 | Medical University of South Carolina | CrCl 30-59 mL/min: 24 mg/m$^2$ (20% dose reduction)<br>CrCl < 30 mL/min: 18 mg/m$^2$ (50% dose reduction)<br>Hemodialysis: 20% dose reduction AND dialysis 12 hours after fludarabine administration |
| 5. | University of Texas, Southwestern | CrCl 50-70 ml/min: 24 mg/m$^2$ (20% reduction)<br>CrCl 30-49 ml/min: 18 mg/m$^2$ (40% dose reduction<br>CrCl < 30 ml/min: Contract provider.<br>No patients in this dataset from this center had CrCl< 30 ml/min |
| 6. | Virginia Commonwealth University | CrCl 10-50 ml/min: 22.5 mg/m$^2$ (25% dose reduction)<br>CrCl < 10 ml/min: 15 mg/m2 (50% dose reduction) |
| 7. | MD Anderson Cancer Center | CrCl 30-49 ml/min: 22.5 mg/m$^2$ (25% reduction)<br>CrCl < 30 ml/min: 15 mg/m$^2$ (50% reduction) |
| 8. | University of Utah | CrCl 10-50 ml/min: 22.5 mg/m2 (25% dose reduction<br>CrCl < 10 ml/min: 15 mg/m$^2$ (50% dose reduction)<br>Dialysis: Consult BMT pharmacist |
| 9. | Kansas University Medical Center | CrCl 30 to 70 mL/min: 24 mg/m$^2$ (20% dose reduction)<br>CrCl < 30 ml/min: fludarabine is not recommended per package insert |
| 10. | Levine Cancer Center | No fixed protocol and varies from physician to physician. Typically<br>CrCl < 70 ml/min, not on dialysis: 24 mg/m$^2$ (20% reduction)<br>Hemodialysis: 15 mg/m2 (50% dose reduction) |
| 11. | University of Maryland | CrCl 50-79 ml/min: 24 mg/m2 (20% dose reduction<br>CrCl 30-49 mL/min: 18 mg/m$^2$ (50% dose reduction)<br>CrCl < 30 mL/min: Case by case basis |

*Administration of FluCy LD in patients who have severe RI and are dialysis-dependent are dosed based upon hemodialysis schedule. A single patient included in this analysis received daily hemodialysis (iHD) on days -5 and -4 in the morning followed by full dose cyclophosphamide and reduced dose fludarabine at 24mg/$m^2$ in the evening. At least a 12-hour separation was given from dialysis to each FluCy administration. A 20% dose reduction of fludarabine was utilized (24 mg/$m^2$) whereas full dose cyclophosphamide was administered due to its limited renal excretion (10-20%).

**References**:

1. Rebecca Fahrenbruch, Polly Kintzel, Anne Marie Bott, Steven Gilmore, and Ryan Markham. Journal of Oncology Practice 2018 14:3, e130-e136
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**Supplementary results**

**Table S2:** Subgroup Analysis: Safety and Efficacy in patients with severe renal impairment CrCl < 30 ml/min compared to other categories of renal function

| | **CrCl < 30 ml/min N=11** | **CrCl 30-49 ml/min N=17** | **CrCl ≥ 50 ml/min N=186** | **P-value** |
|---|---|---|---|---|
| | **Median (range) or N (%)** | **Median (range) or N (%)** | **Median (range) or N (%)** | |
| **Cytokine release syndrome** | | | | |
| Any | 11 (100%) | 14 (82%) | 157 (84%) | 0.4 |
| Grade ≥ 3 | 1 (9.1%) | 1 (5.9%) | 4 (2.2%) | 0.2 |
| | | | | |
| **ICANS** | | | | |
| Any | 4 (40%) | 2 (12%) | 35 (20%) | 0.2 |
| Grade ≥ 3 | 2 (20%) | 1 (6.2%) | 10 (5.6%) | 0.2 |
| | | | | |
| **Resource Utilization** | | | | |
| Median hospital stay, days | 7.0 (6.0, 69.0) | 13.0 (7.0, 29.0) | 9.0 (5.0, 68.0) | 0.1 |
| Intensive care unit stay, yes | 3 (27%) | 2 (12%) | 14 (7.5%) | 0.08 |
| Tocilizumab use | 9 (82%) | 13 (76%) | 127 (68%) | 0.6 |
| Corticosteroid use | 5 (45%) | 7 (41%) | 49 (26%) | 0.2 |
| Anakinra | 0 (0%) | 1 (5.9%) | 9 (4.8%) | 0.8 |
| | | | | |
| **Infection** | 2 (18%) | 10 (59%) | 57 (31%) | **0.046** |
| | | | | |
| **Hematologic toxicity in first 90 days** | | | | |
| **Grade ≥ 3 cytopenia at Day 7, N=213** | | | | |
| Grade ≥ 3 anemia | 4 (36%) | 8 (47%) | 46 (25%) | 0.12 |
| Grade ≥ 3 neutropenia | 8 (73%) | 14 (82%) | 121 (68%) | 0.6 |
| Grade ≥ 3 thrombocytopenia | 10 (91%) | 11 (65%) | 84 (45%) | **0.006** |
| **Grade ≥ 3 cytopenia at Day 30, N=208** | | | | |
| Grade ≥ 3 anemia | 4 (36%) | 4 (24%) | 31 (17%) | 0.2 |
| Grade ≥ 3 neutropenia | 4 (36%) | 11 (65%) | 61 (34%) | **0.046** |
| Grade ≥ 3 thrombocytopenia | 8 (73%) | 13 (76%) | 73 (41%) | **0.003** |
| **Grade ≥ 3 cytopenia at Day 60, N=168** | | | | |
| Grade ≥ 3 anemia | 2 (22%) | 7 (50%) | 23 (16%) | **0.008** |
| Grade ≥ 3 neutropenia | 1 (11%) | 6 (43%) | 37 (26%) | 0.2 |
| Grade ≥ 3 thrombocytopenia | 5 (56%) | 5 (36%) | 48 (33%) | 0.4 |
| **Grade ≥ 3 cytopenia at Day 90, N=181** | | | | |

| | | | | |
|---|---|---|---|---|
| Grade ≥ 3 anemia | 1 (10%) | 1 (6.7%) | 14 (9.0% | >0.9 |
| Grade ≥ 3 neutropenia | 0 (0%) | 3 (20%) | 21 (14%) | 0.4 |
| Grade ≥ 3 thrombocytopenia | 3 (30%) | 2 (13%) | 36 (23%) | 0.6 |
| | | | | |
| **Supportive care for cytopenias** | | | | |
| G-CSF | 10 (91%) | 15 (88%) | 137 (74%) | 0.3 |
| TPO agonist | 4 (36%) | 6 (35%) | 25 (14%) | **0.01** |
| Stem cell boost | 0 (0%) | 1 (8.3%) | 7 (4.0%) | 0.6 |
| | | | | |
| Day 30, N=206 | | | | |
| ORR | 10 (91%) | 14 (93%) | 136 (76%) | 0.2 |
| CR | 5 (45%) | 5 (33%) | 50 (28%) | 0.4 |
| | | | | |
| Day 90, N=204 | | | | |
| ORR | 8 (73%) | 11 (69%) | 127 (72% | >0.9 |
| CR | 5 (45%) | 6 (38%) | 65 (37%) | 0.8 |
| | | | | |
| Best response, N=211 | | | | |
| ORR | 1 (100%) | 15 (88%) | 150 (82%) | 0.4 |
| CR | 9 (82%) | 8 (47%) | 89 (49%) | 0.1 |

**Table Abbreviations**
CR: complete response. G-CSF: granulocyte colony stimulating factor. ICANS: Immune Effector Cell Associated Neurotoxicity. ORR: overall response rate. TPO: Thrombopoietin.

**Table S3: Renal Function Evolution in Patients with Paired Data Available at CAR-T and Day 30**

| | **Day 30 CrCL < 30 ml/min** | **Day 30 CrCl 30-49 ml/min** | **D30 CrCl ≥ 50 ml/min** |
|---|---|---|---|
| **Baseline** | | | |
| CrCL < 30 ml/min, N=10 | 7 | 3 | 0 |
| CrCL 30-49 ml/min, N=16 | 0 | 12 | 4 |
| CrCL ≥50 ml/min, N=167 | 5 | 6 | 156 |
| | | | |

**Table S4: Efficacy of idecabtagene vicleucel in patients with relapsed/refractory multiple myeloma with and without renal impairment (creatinine clearance of < 50 ml/min)**

| | CrCl < 50 ml/min N=28 | CrCl ≥ 50 ml/min N=186 | P-value |
|---|---|---|---|
| | Median (range) or N (%) | Median (range) or N (%) | |
| **Day 30, N=206** | | | |
| ORR | 24 (92%) | 136 (76%) | 0.06 |
| ≥ CR rate | 10 (38%) | 50 (28%) | 0.3 |
| | | | |
| **Month 3, N=204** | | | |
| ORR | 19 (70%) | 127 (72%) | 0.9 |
| ≥ CR rate | 11 (41%) | 65 (37%) | 0.7 |
| | | | |
| **Best response, N=211** | | | |
| ORR | 26 (93%) | 150 (82%) | 0.2 |
| ≥ CR rate | 17 (61%) | 89 (49%) | 0.2 |
| VGPR | 7 (25%) | 34 (19%) | |
| PR | 2 (7.1%) | 27 (15%) | |
| SD | 0 (0%) | 15 (8.2%) | |
| PD | 2 (7.1%) | 18 (9.8%) | |
| Unknown | 0 | 3 | |

Abbreviations: CR: Complete response, ORR: overall response rate

Patients who died or progressed before the timepoint of interest were considered non-responders. Patients who were not evaluable by IMWG response criteria, or when data was not provided or timepoint not reached were excluded from the denominator.

Day 30 responses known in 206 of 214 patients. Out of remaining 8 patients, responses not known in 2 patients (1 patient reach in both groups), day 30 not reached in 2 patients (both in CrCl < 50 ml/min) and response not evaluable by IMWG response criteria in 4 patients 1 in CrCl < 50 ml/min and 3 in CrCL ≥ 50 ml/min group. Month 3 response known in 204 patients. Out of remaining 8 patients, 3 month timepoint not reached in 2 patients (both in CrCL ≥ 50 ml/min group), response not evaluable by IMWG response criteria in 4 patients (1 in CrCl < 50 ml/min and 3 in CrCL ≥ 50 ml/min group) and response not known in 4 patients (all in CrCL ≥ 50 ml/min group). Best response known in 211 patients not known in 3 patients, all in the CrCL ≥ 50 ml/min group.

**Table S5: Multivariable models of the association of selected patient characteristics with PFS and OS in patients treated with idecabtagene vicleucel based on varying degrees of renal impairment**

| | PFS | | OS | |
|---|---|---|---|---|
| **Characteristic** | **HR (95% CI)** | **P** | **HR (95% CI)** | **P** |
| Renal function | | | | |
| CrCl ≥ 50 ml/min | 1.00 (Referent) | | 1.00 (Referent) | |
| CrCl 30-49 ml/min | 0.94 (0.46, 1.90) | 0.9 | 0.44 (0.13, 1.42) | 0.2 |
| CrCl < 30 ml/min | 0.64 (0.23, 1.75) | 0.4 | 1.01 (0.31, 3.28) | >0.9 |
| Prior BCMA-TT | | | | |
| No | 1.00 (Referent) | | 1.00 (Referent) | |
| Yes | 1.82 (1.23, 2.69) | **0.003** | 1.66 (1.00, 2.75) | **0.05** |
| High-risk cytogenetics | | | | |
| No | 1.00 (Referent) | | 1.00 (Referent) | |
| Yes | 1.61 (1.10, 2.36) | **0.02** | 1.44 (0.87, 2.37) | 0.2 |
| Patient age | 0.98 (0.96, 1.00) | 0.08 | 0.98 (0.95, 1.00) | 0.07 |

Full data on all variables available in 187 patients. Missing data in 27 patients is due to missing cytogenetic data.

**Abbreviations:** CI: Confidence interval. CrCl: Creatinine Clearance. HR: Hazard ratio. BCMA-TT: B cell maturation antigen-targeted therapy. High-risk cytogenetics: includes del(17p), t(4;14) and t(14;16). P-values < 0.05 are shown in bold.

**Supplementary Table S6: Baseline and treatment characteristics in patients with relapsed/refractory multiple myeloma with and without renal impairment (<45 vs. ≥ 45 ml/min) receiving idecabtagene vicleucel**

| | **CrCl < 45 ml/min N=24** | **CrCl ≥ 45 ml/min N=190** | **P-value** |
|---|---|---|---|
| | **Median (range) or N (%)** | **Median (range) or N (%)** | |
| **Age** | 69 years (52, 83) | 63 years (36, 83) | **<0.001** |
| **Age, ≥ 65 years** | 18 (75%) | 85 (45%) | **0.005** |
| **Sex, Female** | 16 (67%) | 70 (37%) | **0.005** |
| **Race and ethnicity** | | | 0.08 |
| Hispanic | 0 (0%) | 22 (12%) | |
| Non-Hispanic Black | 6 (25%) | 30 (16%) | |
| Non-Hispanic White | 16 (67%) | 132 (69%) | |
| Other | 2 (8%) | 6 (3%) | |
| **Extramedullary disease** | 11 (46%) | 85 (45%) | >0.9 |
| **BMPCs (≥ 50%), N=196** | 8 (33%) | 50 (29%) | 0.7 |
| **ECOG PS 2-4, N=206** | 5 (23%) | 30 (16%) | 0.5 |
| **R-ISS at CAR-T infusion, N=163** | | | 0.06 |
| I | 1 (5.0%) | 35 (24%) | |
| II | 10 (50%) | 73 (51%) | |
| III | 9 (45%) | 35 (24%) | |
| **High-risk cytogenetics, N=187** | 9 (43%) | 53 (32%) | 0.3 |
| **Laboratory Data** | | | |
| ANC < 1000/uL | 1 (4.2%) | 25 (13%) | 0.3 |
| Hemoglobin < 8 g/dL | 4 (17%) | 29 (15%) | 0.8 |
| Platelets < 50,000/uL | 7 (29%) | 34 (18%) | 0.3 |
| Beta-2-microglobulin, mg/L | 4.2 (2.4, 13.5) | 2.9 (0.7, 15.3) | **0.005** |
| Albumin, g/dL | 3.3 (2.4, 4.2) | 3.7 (1.7, 4.8) | **0.002** |
| **Prior Therapy** | | | |
| Prior lines of therapy | 8 (5, 12) | 6 (3, 19) | **0.03** |
| Prior autologous SCT | 19 (79%) | 161 (85%) | 0.6 |
| Prior allogeneic SCT | 1 (4.2%) | 9 (4.7%) | >0.9 |
| Prior anti-BCMA therapy | 6 (25%) | 47 (25%) | >0.9 |
| Triple Refractory | 22 (92%) | 156 (82%) | 0.4 |
| Penta Refractory | 9 (38%) | 84 (44%) | 0.5 |
| **Bridging Therapy** | 22 (92%) | 144 (76%) | 0.08 |
| **CAR-T cell dose, median (range)*** | 418 (318, 455) | 406 (154, 459) | 0.2 |
| **Cell dose ≥ 400 million CAR-T cells** | 17 (71%) | 103 (54%) | 0.1 |
| **Fludarabine dose reduction, yes** | 19 (79%) | 42 (22%) | **<0.001** |
| **Fludarabine dose reduction %** | | | **0.006** |
| ≤ 20% | 2 (11%) | 20 (48%) | |
| 21-40% | 5 (26%) | 11 (26%) | |
| >40% | 12 (63%) | 11 (26%) | |

**Abbreviations and other definitions**: ECOG PS: Eastern Cooperative Oncology Group performance status. R-ISS: Revised International Staging System. High-risk cytogenetics: Includes del(17p), t(4;14) and t(14;16). SCT: Stem cell transplantation. ANC: Absolute neutrophil count. BCMA: B cell maturation antigen. Triple-refractory disease: refractory to an IMiD, PI, and an anti-CD38 monoclonal antibody. Penta-refractory disease: refractory to lenalidomide, pomalidomide, bortezomib, carfilzomib, and daratumumab or isatuximab.
* CAR-T cell dose was not known in one patient with CrCl ≥ 50 ml/min.

**Supplemental Table S7: Toxicities in patients with relapsed/refractory multiple myeloma with and without renal impairment (creatinine clearance of < 45 ml/min) receiving idecabtagene vicleucel**

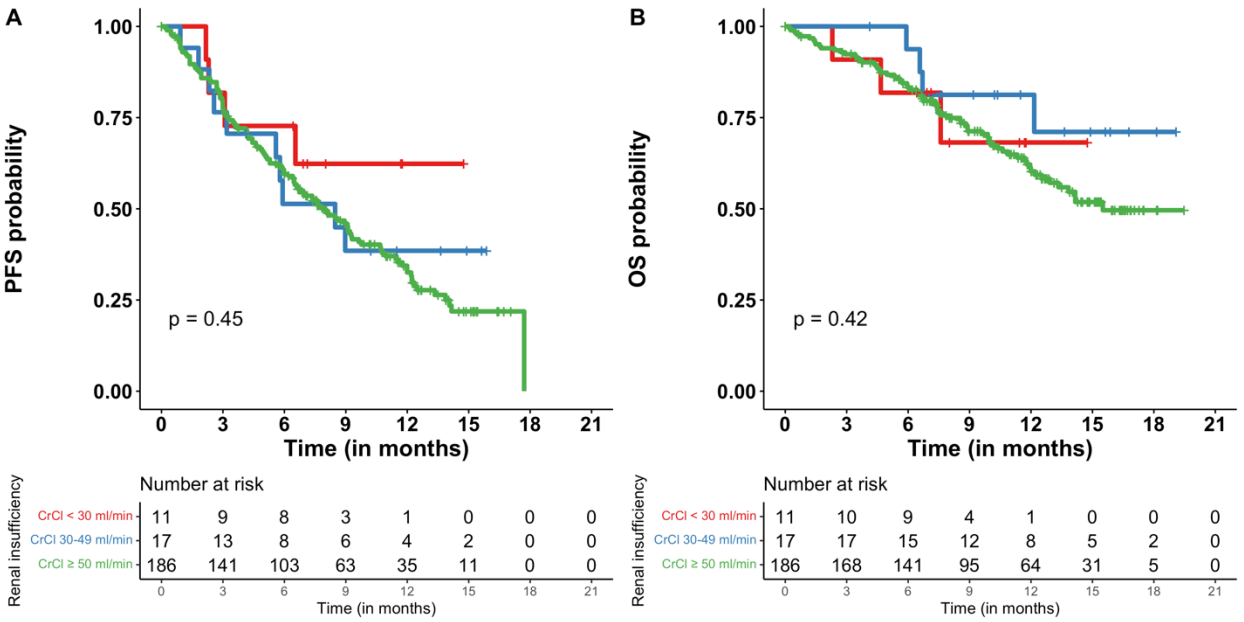
| | CrCl < 45 ml/min N=24 | CrCl ≥ 45 ml/min N=190 | P-value |
|---|---|---|---|
| | Median (range) or N (%) | Median (range) or N (%) | |
| **Cytokine release syndrome** | | | |
| Any | 22 (92%) | 160 (84%) | 0.5 |
| Grade ≥ 3 | 2 (8%) | 4 (2%) | 0.1 |
| **ICANS**[a] | | | |
| Any | 6 (26%) | 35 (19%) | 0.4 |
| Grade ≥ 3 | 3 (13%) | 10 (6%) | 0.2 |
| **Resource Utilization** | | | |
| Median hospital stay, days | 14 (6, 69) | 9 (5, 68) | 0.08 |
| Intensive care unit stay, yes | 4 (17%) | 15 (8%) | 0.2 |
| Tocilizumab use | 19 (79%) | 130 (68%) | 0.3 |
| Corticosteroid use | 10 (42%) | 51 (27%) | 0.1 |
| Anakinra use | 0 (0%) | 10 (5.3%) | 0.6 |
| **Infection** | 10 (42%) | 59 (31%) | 0.3 |
| **Hematologic toxicity in 90 days**[b] | | | |
| **Day 7, Grade ≥ 3 cytopenia** | | | |
| Grade ≥ 3 anemia | 9 (38%) | 49 (26%) | 0.2 |
| Grade ≥ 3 neutropenia | 20 (83%) | 123 (68%) | 0.12 |
| Grade ≥ 3 thrombocytopenia | 18 (75%) | 87 (46%) | **0.007** |
| **Day 30, Grade ≥ 3 cytopenia** | | | |
| Grade ≥ 3 anemia | 7 (29%) | 32 (17%) | 0.2 |
| Grade ≥ 3 neutropenia | 12 (50%) | 64 (35%) | 0.2 |
| Grade ≥ 3 thrombocytopenia | 17 (71%) | 77 (42%) | **0.007** |
| **Day 60, Grade ≥ 3 cytopenia** | | | |
| Grade ≥ 3 anemia | 7 (37%) | 25 (17%) | 0.06 |
| Grade ≥ 3 neutropenia | 6 (32%) | 38 (26%) | 0.6 |
| Grade ≥ 3 thrombocytopenia | 8 (42%) | 50 (34%) | 0.5 |
| **Day 90, Grade ≥ 3 cytopenia** | | | |
| Grade ≥ 3 anemia | 2 (9.5%) | 14 (8.8%) | >0.9 |
| Grade ≥ 3 neutropenia | 1 (4.8%) | 23 (14%) | 0.3 |
| Grade ≥ 3 thrombocytopenia | 5 (24%) | 36 (23%) | >0.9 |
| **Supportive care for cytopenias** | | | |
| G-CSF | 21 (88%) | 141 (75%) | 0.2 |
| TPO agonist | 9 (38%) | 26 (14%) | **0.007** |
| Stem cell boost | 0 (0%) | 8 (4.5%) | >0.9 |

Abbreviations: G-CSF: Granulocyte colony stimulating factor. ICANS: Immune Effector Cell Associated Neurotoxicity. TPO: Thrombopoietin.

[a]Data on ICANS was missing in 10 patients (1 in CrCl < 45 ml/min cohort and 9 in CrCL ≥ 45 ml/min cohort.

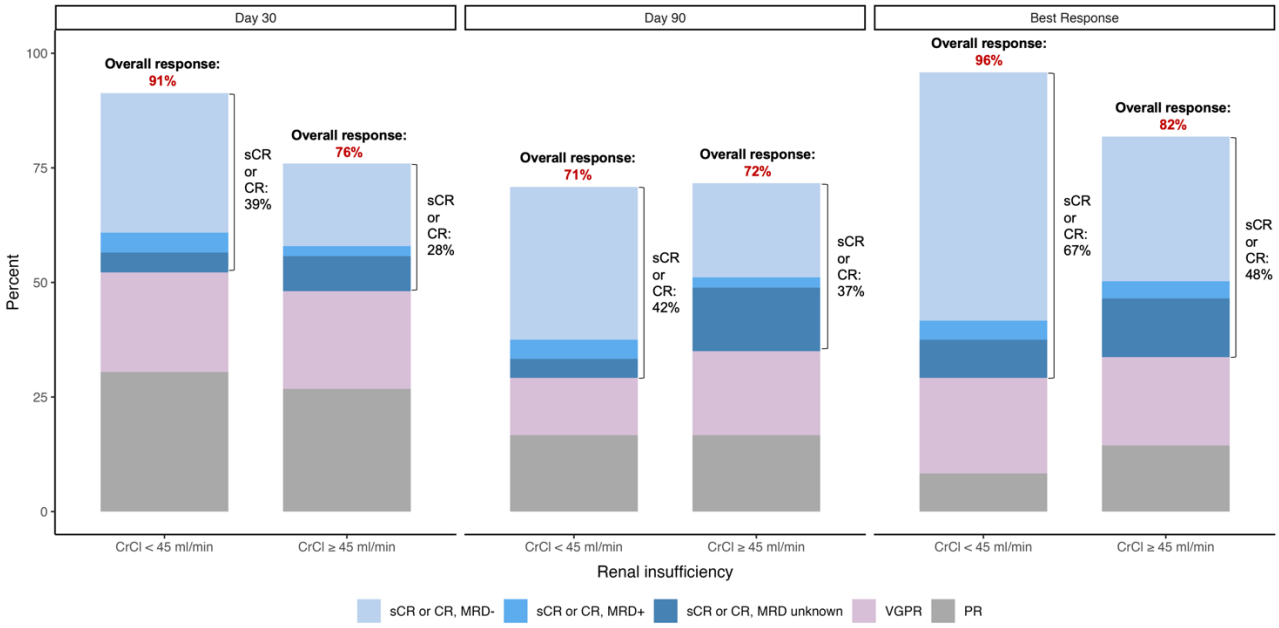
[b]For hematology labs, at day 7, 1 patient missing anemia and thrombocytopenia data and 9 patients missing neutropenia data; Day 30: 6 patients missing anemia and thrombocytopenia data and 7 missing neutropenia data; Day 60: 46 missing anemia and thrombocytopenia data and 47 missing neutropenia data. Day 90: 33 patients missing anemia and thrombocytopenia data and 34 missing neutropenia

**Figure S1:** Survival outcomes in patients treated with idecabtagene vicleucel based on varying degrees of renal impairment (a) progression free survival and (b) overall survival



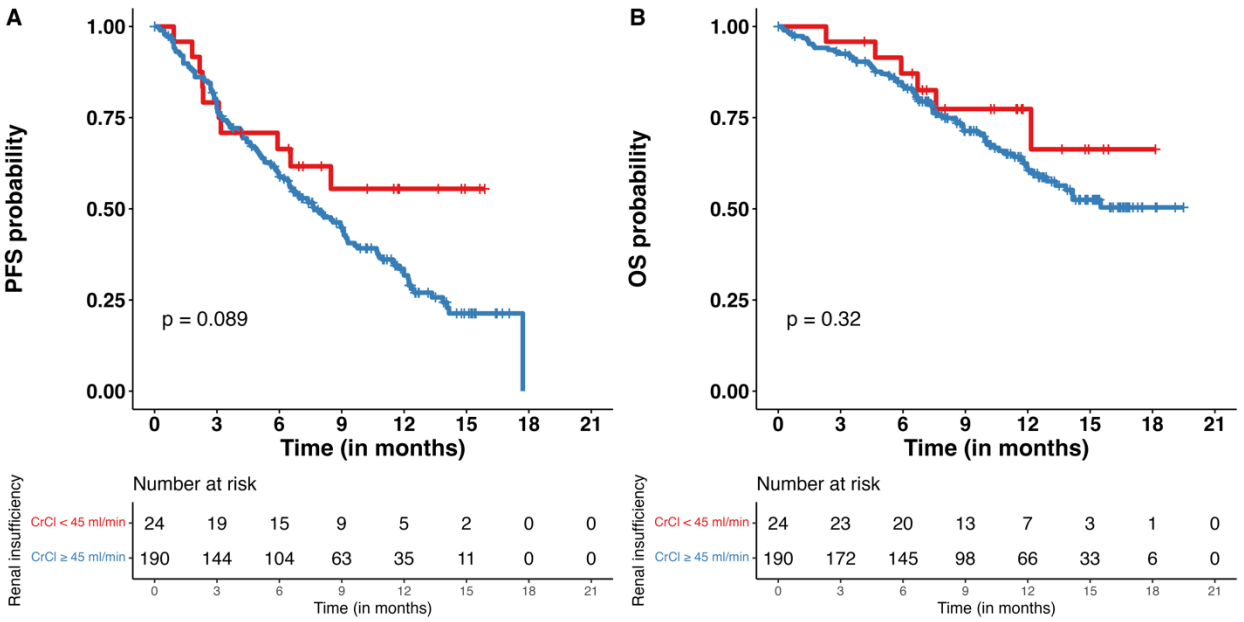

| | Median PFS | 95% CI (PFS) | Median OS | 95% CI (OS) |
|---|---|---|---|---|
| CrCl < 30 ml/min | Not reached | 6.5 months- NR | NR | 7.6 months-NR |
| CrCl 30-49 ml/min | 8.5 months | 5.6 months- NR | NR | 12.2 months- NR |
| CrCl ≥ 50 ml/min | 8 months | 6.5 months -9.3 | 15.5 months | 12.9 months - NR |

**Figure S2: Efficacy of idecabtagene vicleucel in patients with relapsed/refractory multiple myeloma with and without renal impairment based on creatine clearance cut-off of 45 ml/min**




Patients who died or progressed before the timepoint of interest were considered non-responders. Patients who were not evaluable by IMWG response criteria, or when data was not provided or timepoint not reached were excluded from the denominator.

**Figure S3: Survival outcomes with idecabtagene vicleucel in patients with relapsed/refractory multiple myeloma with and without renal impairment based on creatine clearance cut-off of 45 ml/min**




| | Median PFS | 95% CI (PFS) | Median OS | 95% CI (OS) |
|---|---|---|---|---|
| CrCl < 45 ml/min | Not reached | 5.9 months -NR | NR | 12.2 months – NR |
| CrCl ≥ **45** ml/min | 7.7 months | 6-5- 9.3 months | NR | 12.9 months - NR |
| Median follow-up: 9.6 months | | | | |

Abbreviations: NR: not reached, OS: overall survival, PFS: progression free survival