# Society for Immunotherapy of Cancer (SITC) clinical practice guideline on immunotherapy for the treatment of nonmelanoma skin cancer

***Update v1.1**: Table 2 was updated from the original publication to include the POD1UM-201 trial data that led to the retifanlimab approval. For the full guideline text and other updates included in v1.1, please see https://doi.org/10.1136/jitc-2021-004434.*

## Table 2: Landmark clinical trial data for FDA-approved Immunotherapies for MCC

| Trial characteristics | | | | Outcomes for FDA approval | |
|---|---|---|---|---|---|
| **Trial** | **Study design** | **Study population for SBLA** | **Intervention(s)** | **ORR** | **DOR** |
| JAVELIN Merkel 200 (NCT02155647) [6, 57] | Phase II open-label, non-randomized | Part A – metastatic, chemotherapy R/R MCC (88 patients) | Avelumab | 33.0% (95% CI 23.3% to 43.8%)† | **Median DOR**: Median not reached (range 2.8–23.3+ months)† |
| | | Part B* – metastatic, systemic therapy naïve MCC (116 patients) | | 39.7% (95% CI 30.7% to 49.2%) | **Median DOR**: 18.2 months (95% CI 11.3 to NE) |
| KEYNOTE-017 (NCT02267603) [8] | Phase II open-label, non-randomized | Recurrent locally advanced or metastatic MCC (50 patients) | Pembrolizumab | 56% (95% CI 41% to 70.0%)† | **Median DOR**: Median not reached (range 5.9–34.5+ months)† |
| POD1UM-201 (NCT03599713) [178] | Phase II open label, non-randomized | Metastatic or recurrent locally advanced systemic therapy naïve MCC (65 patients) | Retifanlimab | 52% (95% CI 40% to 65%) | **DOR rate ≥6 months**: 76% (n = 26)<br><br>**DOR rate ≥12 months**: 62% (n = 21) |

**Data from this cohort were not evaluated for the FDA approval of avelumab*
*†Since approval, updated follow-up results have become available, which are discussed in the **Approved anti-PD-(L)1 agents for MCC** section.*

*Abbreviations used: CI, confidence interval; DOR, duration of response; FDA, US Food and Drug Administration; ICI, immune checkpoint inhibitor; MCC, Merkel cell carcinoma; NE, not estimable; PFS, progression-free survival; ORR, objective response rate; OS, overall survival; SBLA, Supplemental Biologics License Application; R/R, relapsed/refractory*

**Source:** Society for Immunotherapy of Cancer (SITC) clinical practice guideline on immunotherapy for the treatment of nonmelanoma skin cancer v1.1. SITC NMSC CPG informational website – Updates since publication

**References**

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