# 5043: Phase II study of the efficacy of retifanlimab (INCMGA00012) in penile squamous cell carcinoma (PSCC): ORPHEUS final analysis

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PSCC is a rare tumor, with a prevalence of 0.1-0.5 per 100,000 men in developed countries, although its incidence increases in low-income regions. Risk factors include HPV status (>50% of cases), immunosuppression, phimosis, or smoking [7,9]. Surgery can be an effective option for localized disease, but PSCC is characterized by poor early control for cancer stage and prognosis significantly decreases once metastasis has occurred [12]. The mainstay of treatment for advanced disease is platinum- based chemotherapy, but outcomes remain poor [1]. There is an unmet need for more effective and less toxic therapies for these patients. Most of PSCC patients present high levels of PD-L1 [13]. Promising results have been reported with anti-PD-L1/PD-1 agents in different SCC, but evidence with immunotherapy is very limited in penile cancer. According to NCCN guidelines, only pembrolizumab is recommended for advanced PSCC as second line [2,4].

Retifanlimab (INCMGA00012), a PD-1 inhibitor that has demonstrated tolerability and preliminary efficacy in different solid tumors in clinical trials [5-7], ORPHEUS evaluates the efficacy and safety of retifanlimab in patients with unresectable locally advanced or metastatic PSCC previously treated or not with chemotherapy.

**STUDY DESIGN**

**Objectives:**
- To evaluate the safety and efficacy of retifanlimab in patients with advanced PSCC.
- To assess safety and tolerability of retifanlimab in advanced PSCC.
- To identify potential predictive biomarkers for clinical responses to retifanlimab.

**Patient selection:**
- Male patients aged ≥ 18 years.
- Histological evidence of locally advanced or metastatic stage T1b-T4 N0-1 M0 (as per AJCC). No prior or ongoing chemotherapy.
- Pretreated patients should have received their last line of chemotherapy ≥ 6 months before study entry.
- Patients had to be evaluable for efficacy
- Provided informed consent.

**Study population:**
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