Protocol Title: EA8134: International Penile Advanced Cancer Trial (International Rare Cancers Initiative Study) - InPACT

Target Population: Squamous Cell Carcinoma of the Penis

Summary: This is an international phase III trial, with a Bayesian design, incorporating two sequential randomizations. It efficiently examines a series of questions that routinely arise in the sequencing of treatment. The study design has evolved from lengthy international consultation that has enabled us to build consensus over which questions arise from current knowledge and practice. It will enable potential randomization for the majority of patients with inguinal lymph node metastases and will provide data to inform future clinical decisions. InPACT-neoadjuvant patients are stratified by disease burden as assessed by radiological criteria. Treatment options are then defined according to the disease burden strata. Treatment is allocated by randomization.

Key Inclusion Criteria:
- Measurable disease as determined by RECIST (version 1.1) Criteria
- Histologically-proven Squamous Cell Carcinoma of the Penis
- Stage:
  - Any T, N1 (i.e. a palpable mobile unilateral inguinal lymph node), M0 or
  - Any T, N2 (i.e. palpable mobile multiple or bilateral inguinal lymph nodes), M0 or
  - Any T, N3 (i.e. fixed inguinal nodal mass or any pelvic lymphadenopathy), M0
- Performance Status ECOG 0, 1 or 2

Key Exclusion Criteria:
- Pure Verrucous Carcinoma of the Penis
- Non-Squamous Malignancy of the Penis
- Squamous Carcinoma of the Urethra
- Stage M1
- Previous chemotherapy or chemoradiotherapy
- Concurrent Malignancy (other than SCC or Basal Cell Carcinoma of non-penile skin) that has required surgical or non-surgical treatment in the last 3 Years

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For additional information: https://clinicaltrials.gov/ct2/show/NCT02305654