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Protocol Title: A phase I/III, randomised, double blind, multicentre, parallel arm, clinical study comparing the efficacy, safety, immunogenicity and pharmacokinetics of proposed biosimilar nivolumab with nivolumab reference medicinal product (OPDIVO®) administered by the intravenous route in patients previously treated for locally advanced or metastatic squamous cell non-small cell lung cancer (NSCLC)

Key Inclusion criteria

Patients affected by histologically or cytologically documented solid tumor malignancies as described below:

Cohort 1: Unresectable Locally Advanced/Metastatic Non- Small Cell Lung Cancer

- **Locally advanced or recurrent NSCLC ALK / EGFR Mutations Negative that is not eligible for curative surgery and/or definitive radiotherapy with or without chemoradiotherapy, or metastatic non squamous or squamous NSCLC.**
- **No prior systemic treatment for metastatic NSCLC. Patients who have received prior neoadjuvant, adjuvant chemotherapy, radiotherapy, or chemoradiotherapy with curative intent for nonmetastatic disease must have experienced a disease-free interval of ≥ 6 months from the last dose of chemotherapy and/or radiotherapy prior to signing informed consent.**

Cohort 2: Recurrent/Metastatic Squamous Cell Head and Neck Cancer

- **Recurrent or metastatic HNSCC that is not amenable to by local curative therapies with surgery or radiation.**
- **Primary tumor site of oral cavity, oropharynx, hypopharynx, or larynx.**
  Patients with a primary tumor site of nasopharynx are excluded. (Note: human papillomavirus (HPV) status will not be required prior to entering the study)
- **No prior systemic therapy administered in recurrent or metastatic setting. Systemic therapy which is given as part of multimodal treatment for locally advanced disease is allowed.**

For further more information please contact

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