A Phase 1 Clinical Study of NXP800 in Subjects with Advanced Cancers and Expansion in Subjects with Ovarian Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Part A

Inclusion Criteria:

* Provide written informed consent. * 18 years old or older. * Life expectancy of at least 12 weeks. * Histologically- or cytologically-confirmed, advanced, metastatic, and/or progressive solid tumors for whom there is no authorized or effective therapy available, or for whom such therapies are considered inappropriate by the Investigator (in Part B, subjects with specific cancer types will be enrolled; Specific criteria will be introduced in a protocol amendment). * Measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1. * Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 2. Part A

Exclusion Criteria:

* Radiotherapy (except for palliative reasons), endocrine therapy, chemotherapy, or investigational agent within 28 days, (42 days for nitrosoureas, mitomycin-C) of first dose of NXP800. Subjects can continue to receive bisphosphonates due to metastatic bone disease or GnRH agonists if they have prostate cancer. * Ongoing toxic manifestations of previous treatments \> Grade 2. * Subjects with treated brain metastases are eligible if there is no evidence of progression for at least 28 days after central nervous system (CNS) directed treatment, as ascertained by clinical examination and brain imaging (magnetic resonance imaging \[MRI\] or computed tomography \[CT\] scan) during the Screening period. * Female subjects who can become pregnant (or are already pregnant or lactating). * Male subjects with partners of childbearing potential (unless they agree to take measures not to father children by using a barrier method of contraception (condom plus spermicide) or to sexual abstinence). Part B

Inclusion Criteria:

* Provide written informed consent. * 18 years old or older. * Subjects with the following ARID1a mutated, ovarian/fallopian tube/primary peritoneal cancer histologies (ARID1a mutation status determined by a DNA-based Next Generation Sequencing test): * Clear cell ovarian carcinoma (≥ 50% clear cell carcinoma with no serous differentiation) * Endometrioid ovarian carcinoma * Subjects must have disease progression within 6 months (182 days) from completion of platinum-based therapy (6 months should be calculated from the date of the last administered dose of platinum therapy to the date of radiographic imaging showing progression) * Measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1. * Subjects with a BRCA mutation must have received prior treatment with a PARP inhibitor. * Subjects must have received at least 1 but not more than 3 prior systemic lines of anticancer therapy, including at least 1 line of therapy containing bevacizumab. * Adjuvant + neoadjuvant are considered one line of therapy * Maintenance therapy (i.e., bevacizumab, PARP inhibitors) will be considered as part of the preceeding line of therapy and are not counted independently. * Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. * Subjects must have a sufficient archival Formalin-Fixed Paraffin-Embedded (FFPE) tissue specimen, or be willing to consent to a fresh tissue biopsy during the study. Part B

Exclusion Criteria:

* Subjects with disease that did not respond to, or has progressed during or within 4 weeks of the last dose of first-line platinum containing chemotherapy. * Radiotherapy (except for palliative reasons), endocrine therapy, chemotherapy, or investigational agent within 28 days, (42 days for nitrosoureas, mitomycin-C) of first dose of NXP800. * Ongoing toxic manifestations of previous treatments \> Grade 2, with the exception of alopecia. * Subjects with treated brain metastases are eligible if there is no evidence of progression for at least 12 weeks while off corticosteroids after central nervous system (CNS) directed treatment, as ascertained by clinical examination and brain imaging (magnetic resonance imaging \[MRI\] or computed tomography \[CT\] scan) during the Screening period. * Female subjects who can become pregnant (or are already pregnant or lactating).

Conditions & Interventions

Interventions:
DRUG: NXP800
Conditions:
Advanced Solid Tumor, Ovarian Cancer, Ovarian Clear Cell Carcinoma, Ovarian Clear Cell Tumor, Ovarian Clear Cell Adenocarcinoma, Ovarian Endometrioid Adenocarcinoma, Ovarian Endometrioid Tumor, ARID1A Gene Mutation
Keywords:
Solid Tumor, Carcinoma, Neoplasms, Adenocarcinoma, ARID1a

More Information

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