ZENITH20 Poziotinib (Spectrum)

A Phase 2 Study of Poziotinib in Patients with Non-small cell Lung Cancer (NSCLC), Locally Advanced or Metastatic, with EGFR or HER2 Exon 20 Insertion Mutation.

This is the trial summary as assessed on clinicaltrials.gov on 02/012020.

Minor changes in the protocol may occur. You can check this on this direct link:

https://clinicaltrials.gov/ct2/show/NCT03318939?term=spi-poz-202&draw=1&rank=1

Trial Design:

This is a Phase 2, open-label, multicenter study to evaluate the efficacy and the safety/tolerability of poziotinib

- Cohort 1: Previously treated patients with EGFR exon 20 insertion mutation positive NSCLC (closed to enrollment)
- Cohort 2: Previously treated patients with HER2 exon 20 insertion mutation positive NSCLC (closed to enrollment)
- Cohort 3: Treatment naïve patients with EGFR exon 20 insertion mutation positive NSCLC
- Cohort 4: Treatment naïve patients with HER2 exon 20 insertion mutation positive NSCLC
- Cohort 5: Patients who meet the criteria for enrollment in Cohort 1 to 4, but the enrollment in the respective cohort has been closed
- Cohort 6: Patients with acquired EGFR mutation who progressed while on treatment with first-line osimertinib
- Cohort 7: Patients with EGFR or HER2 activating mutations

Key Inclusion Criteria:

Patient must be willing and capable of giving written Informed Consent, adhering to dosing and visit schedules, and meeting all study requirements

Patient has histologically or cytologically confirmed locally advanced or metastatic non-small cell lung cancer (NSCLC) that is not amenable to treatment with curative intent

Prior treatment status:

- Cohorts 1 and 2: Patient has had at least one prior systemic treatment for locally advanced or metastatic NSCLC
- Cohorts 3 and 4: Patient is treatment-naïve for locally advanced or metastatic NSCLC and eligible to receive first-line treatment with poziotinib as determined by the Investigator. Adjuvant/neo-adjuvant therapies (chemotherapy, radiotherapy, or investigational agents) are permissible as long as they end at least 15 days prior to study entry.
- Cohort 5: Patients who meet the criteria for enrollment in Cohort 1 to 4, but the enrollment in the respective cohort has been closed
- Cohort 6: Patients with EGFR mutation-positive NSCLC who progressed while on treatment with first-line osimertinib
- Cohort 7: Patient has had at least one prior systemic treatment for locally advanced or metastatic NSCLC

Specific mutations:

- Cohort 1 and 3: Documented EGFR exon 20 insertion mutation
- Cohort 2 and 4: Documented HER2 exon 20 insertion mutation
- Cohort 5: Documented EGFR or HER2 exon 20 insertion mutations
- Cohort 6: Documented acquired EGFR mutation
- Cohort 7: Documented EGFR or HER2 activating mutations

Patient has adequate organ function at Baseline

Key Exclusion Criteria:

Patient has had previous treatment with poziotinib or any other EGFR or HER2 exon 20 insertion mutation-selective tyrosine kinase inhibitor (TKI) prior to study participation. The currently approved TKIs (ie, erlotinib, gefitinib, afatinib, osimertinib) are not considered to be exon 20 insertion-selective and are permissible (Cohorts 1 to 4).

Patient is concurrently receiving chemotherapy, biologics, immunotherapy for cancer treatment; systemic anti-cancer treatment or investigational treatment should not be used within 2 weeks; local radiation therapy for bone pain may be allowed

Patient has had other malignancies within the past 3 years, except for stable non-melanoma skin cancer, fully treated and stable early stage prostate cancer or carcinoma in situ of the cervix or breast without need of treatment

Patient is pregnant or breast-feeding