PYRAMID-1 (Jiangsu)

A Phase 3, Randomized, Open-label, Multicenter Study of the Efficacy and Safety of Pyrotinib Versus Docetaxel in Patients With Advanced Non-squamous Non-small Cell Lung Cancer (NSCLC) Harboring a HER2 Exon 20 Mutation Who Progressed on or After Treatment With Platinum Based Chemotherapy.

This is the trial summary as assessed on clinicaltrials.gov on 27/05/2021.

Minor changes in the protocol may occur. You can check this on this direct link: https://clinicaltrials.gov/ct2/show/NCT04447118

Trial Design:

Arm	Intervention
Experimental	Pyrotinib 400 mg, once daily (QD), will be administered with water within 30 minutes after completion of a meal, at approximately the same time each day on a continuous daily dosing schedule, with 21 days as a cycle.
Control	Docetaxel 75 mg/m2, once every 3 weeks (Q3W), will be administered by intravenous infusion over 1 hour, with 21 days as a cycle.

Inclusion criteria:

- Signed and dated written informed consent which is approved by IRB/EC, willing and able to comply with scheduled treatment, all examinations at study visits, and other study procedures.
- ECOG PS 0-1.
- Have histologically or cytologically confirmed locally advanced or metastatic non-squamous NSCLC disease.
- Before enrollment, a documented confirmed presence of activating mutations in exon 20 of the HER2 gene must be provided. Sufficient tumor tissue samples should be provided to retrospectively confirm the mutation status of the HER2 gene.
- Must have measureable disease per RECIST v1.1.
- For advanced NSCLC, patients must have had progressive disease on or after a platinum based chemotherapy, with or without immune checkpoint inhibitors (PD-1/PD-L1 inhibitors) and/or anti-angiogenic drugs. No more than 2 prior lines of systemic therapy are allowed.
- The laboratory test values must meet the following standards to manifest that the functional level of important organs/systems meets the requirements.
- Female patient of childbearing potential (WOCBP) and male patient whose - partner is WOCBP must agree to use effective contraception method during the study period.

Exclusion criteria:

- Malignant tumors with other pathological types.
- Medical history of other active malignancies within last 5 years.
- Subjects with active CNS metastases.
- Previously treated with targeted drugs for HER2 gene mutations,or previously treated with docetaxel.
- Prior to the first dose of study treatment, patients with severe effusions with clinical symptoms, severe cardiac disease, or severe infection.
- Prior to the first dose of study treatment, patients with diseases or special conditions that affect drug administration and absorption.
- Congenital or acquired immunodeficiency.
- History of allergy to the study drugs or components.
- Prior to the first dose of study treatment, or during the study period, patients receive or are anticipated to receive continuous strong CYP3A4 inducers or inhibitors, P-gp inhibitors, or medications that are known to cause QT/QTc prolongation.