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# CLINICAL TRIAL ANNOUNCEMENT

## PHASE 2 TRIAL OF TESEVATINIB IN SUBJECTS WITH NSCLC and BRAIN or LEPTOMENINGEAL METASTASIS

This study will enroll subjects with brain metastases (BM) or leptomeningeal metastases (LM) occurring while being treated with erlotinib or afatinib or gefitinib.

The objective of this trial is to evaluate the clinical activity of tesevatinib in subjects with non-small cell lung cancer (NSCLC), activating EGFR mutations, and BM or LM.

**Tesevatinib** (formerly known as KD019) is an orally administered tyrosine kinase inhibitor that has been documented to inhibit multiple molecular drivers of tumor growth, including EGFR, HER2, Src, and VEGFR2.

**Tesevatinib** effectively penetrates into the brain and has levels in the choroid plexus and meninges that are 10 times the plasma levels and may be an effective treatment for leptomeningeal metastases.

#### KEY Inclusion Criteria

##### Cohort A: Brain Metastases

- History of NSCLC with EGFR mutation (either exon 19 deletion or L858R mutation).
- Occurrence or progression of BM while receiving either erlotinib or afatinib or gefitinib.
- At least one measurable BM by RECIST 1.1 criteria ( $\geq 10\text{mm}$  in longest diameter).
- No clinically significant progression outside of the CNS on most recent EGFR inhibitor therapy.

##### Cohort B: Leptomeningeal Metastases

- History of NSCLC with EGFR mutation (either exon 19 deletion or L858R mutation).
- Occurrence or progression of LM while receiving either erlotinib or afatinib or gefitinib.
- Presence of at least one CTCAE 4.03 symptom/sign of at least Grade 1 attributed by the investigator to LM
- Diagnosis of LM by:
  - ◊ Cytological evidence in CSF sample of LM due to NSCLC, and/or
  - ◊ Findings on gadolinium-enhanced MRI
- No clinically significant progression outside of the CNS on most recent EGFR inhibitor therapy.