JOHN WAYNE CANCER INSTITUTE
at Providence Saint John's Health Center

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 (≥ 10mm 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.

For more information, please contact the Neuro-Oncology Clinical Trial Team at:
neuro.oncology@jwci.org
310-829-8265

Clinical Trial Investigators

Garni Barkhoudarian, MD

Daniel Kelly, MD

Santosh Kesari
MD, PhD, FANA, FAAN

Steven O'Day, MD

Clinical Trial Team

Najee Boucher, CRA
najee.boucher@providence.org
310-582-7460

Annie Heng, RN, BSN
HengA@jwci.org
310-582-7457

Marlon Garzo Saria,
MSN, RN, AOCNS, FAAN
SariaM@jwci.org
310-582-7340

Sponsor

Kadmon Corporation, LLC

Please feel free to contact the clinical trial team to learn more about this study.