

**Inclusion**

1. Written informed consent
2. Adults (as defined by local regulations)
3. EGFR activating mutation (exon 19 deletion or the L858R mutation in exon 21)
4. Newly diagnosed stage IIIB/IIIC/IV or recurrent NSCLC of adenocarcinoma histo and/or cytopathology or its pathologically accepted variants using tumor specimen (recurrent= minimum of 12 months disease free interval between completion of systemic therapy and recurrence of NSCLC required)
5. ECOG PS of 0 or 1
6. No prior treatment with systemic therapy for locally advanced or metastatic NSCLC. Completed neoadjuvant /adjuvant chemotherapy/immunotherapy and/or combined modality chemotherapy/radiation therapy permitted only when there is minimum 12 months disease free interval between completion of systemic therapy and NSCLC recurrence.
7. Radiologically measurable disease by RECIST v1.1 criteria
8. Adequate organ function, including:
  - Estimated creatinine clearance  $\geq 30$  mL/min
  - Absolute neutrophil count (ANC) $\geq 1500$  cells/mm<sup>3</sup>
  - Platelets  $\geq 100,000$  cells/mm<sup>3</sup>
  - Hemoglobin  $\geq 10.0$  g/dL
  - Bilirubin  $\leq 1.5$  x upper limit of normal (ULN)
  - Aspartate aminotransferase (AST) and Alanine aminotransferase (ALT)  $\leq 2.5$  x ULN ( $\leq 5.0$  x ULN if hepatic metastases)
9. Female subjects must be postmenopausal, or they or their partners must be surgically sterile, or must agree to use effective contraception while receiving study treatment & for at least 3 months thereafter
10. All female subjects with reproductive potential must have a negative pregnancy test
11. Male subjects or their female partners must be surgically sterile or must agree to use effective contraception while receiving study treatment & for at least 3 months thereafter

**Exclusion:**

1. Any evidence of mixed histo-and/or cytopathology that includes elements of small cell or carcinoid lung cancer. No squamous element can be present
2. EGFR exon 20 T790M or exon 20 insertion mutation
3. Symptomatic brain or leptomeningeal metastases, who are neurologically unstable or require increasing doses of steroids and/or anti-seizure medications to manage CNS symptoms within two weeks prior to starting dacomitinib

**Note:** Patients with controlled CNS metastases may participate in this trial

4. Any previous anti-cancer systemic treatment of locally advanced, or metastatic NSCLC
5. Any surgery (not including minor procedures such as lymph node biopsy), palliative radiotherapy or pleurodesis within 2 weeks of 1stdose of study treatment
6. Any clinically significant gastrointestinal abnormalities that may impair intake, transit or absorption of the study drug
7. Current enrolment in another therapeutic clinical study
8. Any psychiatric or cognitive disorder that would limit the understanding or rendering of informed consent and/or compromise compliance with the requirements of this study or known drug abuse/alcohol abuse
9. History of, or currently suspected, diffuse non infectious pneumonitis or interstitial lung disease
10. Any history of rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption
11. Clinically important abnormalities in cardiac rhythm, conduction or morphology of resting ECG
12. Severely impaired (defined as Child Pugh Class C) hepatic dysfunction
13. Prior malignancy: Subjects will not be eligible if they have history of, or evidence of active disease of another concurrent malignancy within the previous five years
14. Other severe acute or chronic medical condition that may increase the risk associated with study participation or study drug administration or may interfere with the interpretation of study results and, in the judgment of the investigator, would make the subject inappropriate for entry into this study
15. Use of CYP2D6 substrates where minimal increases in concentration may lead to serious or life threatening toxicities from screening to enrolment (procainamide, pimozide , thioridazine , etc.)