Dacomitinib

is an investigational agent and has not been approved by any regulatory agency at this time.

ABOUT DACOMITINIB

Dacomitinib is an investigational, oral, once-daily, irreversible pan-human epidermal growth factor receptor (HER) tyrosine kinase inhibitor. It has not received regulatory approval in any country.

EGFR IN NON-SMALL CELL LUNG CANCER (NSCLC)

Worldwide, lung cancer is the leading cause of cancer death in both men and women.[1] NSCLC accounts for about 85 percent of lung cancer cases and remains difficult to treat, particularly in the metastatic setting.[2]

EGFR is a protein that helps cells grow and divide. When the EGFR protein is mutated it can cause cancer cells to form. EGFR mutations occur in 10 to 20 percent of non-squamous NSCLC tumors overall, and 35 to 55 percent of non-squamous NSCLC tumors in Asian populations.[3,4]

CLINICAL STUDIES

ARCHER 1050

Pfizer is exploring dacomitinib as a treatment for patients with locally advanced or metastatic EGFR-mutant NSCLC through the global Phase 3 ARCHER 1050 trial.

- ARCHER 1050 is the first global, randomized, Phase 3 trial to evaluate two EGFR inhibitors (dacomitinib vs. gefitinib) head-to-head for the first-line treatment of EGFR-activating mutation-positive NSCLC patients.
- ARCHER 1050 recruited patients with the two most common EGFR activating mutations (exon 19 deletion or mutation in exon 21, with or without T790M).
- ARCHER 1050 was conducted in Asia and Europe; specifically, in China, Hong Kong, Italy, Japan, Poland, South Korea, and Spain.

May 2017

Pooled Analysis of ARCHER 1009 and Study A7471028

The ARCHER 1009 and A7471028 studies randomized patients with locally advanced/metastatic NSCLC following progression with one or two prior chemotherapy regimens to dacomitinib or erlotinib. The studies did not demonstrate improvement in Progression Free Survival (PFS) among the overall study population. Patients with EGFR mutations from both studies were pooled in a retrospective subset analysis to compare the efficacy of dacomitinib to erlotinib. Additionally, this analysis compared dacomitinib and erlotinib in patients with EGFR exon 19 and 21 mutations.

For patients with exon 19/21 mutations, median PFS was 14.6 months (95% CI, 9.0, 18.2) with dacomitinib (n=53) and 9.6 months (95% CI, 7.4, 12.7) with erlotinib (n=48) (HR=0.717 [95% CI, 0.458, 1.124], p=0.146). This is the same mutational subset of patients being analyzed in ARCHER 1050.

Dacomitinib was associated with a higher incidence of diarrhea and mucositis in both studies compared with erlotinib.

For a complete listing of dacomitinib clinical trials, please visit www.clinicaltrials.gov.

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REFERENCES

1. The International Agency for Research on Cancer, the World Health Organization, GLOBOCAN 2012, Available at: http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx. Accessed October 15, 2015.
2. Reade CA, Ganti AK. EGFR targeted therapy in non-small cell lung cancer: potential role of cetuximab. *Biologics*. 2009; 3: 215 224.
3. Pao W, Miller VA. Epidermal growth factor receptor mutations, small-molecule kinase inhibitors, and non-small cell lung cancer: current knowledge and future directions. *J Clin Onc*. 2005; 23:25562568.
4. Mok TS, We YL, Thongprasert S, et al. Gefitinib or carboplatin-paclitaxel in pulmonary adenocarcinoma. *N Engl J Med*. 2009; 361: 947-57.
5. S. S. Ramalingam, et. al. Dacomitinib versus erlotinib in patients with EGFR-mutated advanced nonsmall-cell lung cancer (NSCLC): pooled subset analyses from two randomized trial *Ann Oncol* (2016) 27 (3): 423 429 first published online January 13, 2016 doi:10.1093/annonc/mdv593