ABOUT DACOMITINIB
Dacomitinib is an investigational, second-generation, oral, once-daily, irreversible pan-human epidermal growth factor receptor (HER) tyrosine kinase inhibitor. Dacomitinib is an investigational agent and has not received regulatory approval for any indication anywhere in the world.

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 35 percent of non-squamous NSCLC tumors globally, and 35 to 55 percent of non-squamous NSCLC tumors in Asian populations yet the disease is associated with low survival rates and disease progression remains a challenge.\(^3\)\(^-\)\(^5\)

CLINICAL STUDIES
ARCHER 1050
Pfizer is exploring dacomitinib as a treatment for patients with locally advanced or metastatic EGFR-mutated NSCLC through the global Phase 3 ARCHER 1050 trial. Findings from this study were published in *Lancet Oncology*, shared as an oral late-breaker presentation at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting and featured in the ASCO press program.

- ARCHER 1050 is a global head-to-head trial investigating dacomitinib (n=227) compared to gefitinib (n=225) that showed dacomitinib demonstrated a clinically meaningful improvement over gefitinib.
- 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.
ARCHER 1050 (cont.)

The Phase 3 ARCHER 1050 study found a statistically significant and clinically meaningful improvement in progression-free survival (PFS) with dacomitinib compared with gefitinib as a first-line treatment for patients with locally advanced or metastatic NSCLC with EGFR-activating mutations.

- Patients that received dacomitinib in the study experienced a median progression-free survival of 14.7 months compared with 9.2 months in patients treated with gefitinib, as measured by Blinded Independent Central Review (BICR). This difference represented a 41% reduction in the risk of disease progression or death for patients treated with dacomitinib compared with gefitinib (HR = 0.59 [95% CI: 0.47,0.74], P <0.0001) as a first-line treatment in locally advanced or metastatic NSCLC with EGFR-activating mutations. PFS was also analyzed by investigator review, and median PFS in the dacomitinib group was 16.6 months (95% CI: 12.9, 18.4) compared with 11.0 months (95% CI: 9.4, 12.1) in the gefitinib arm.

- The adverse events observed with dacomitinib in the study were consistent with findings from previous trials. The most common adverse events were diarrhea (87%), nail changes (62%), rash/dermatitis acniform (49%), and mouth sores (46%). The most common Grade 3 AEs with dacomitinib were rash (14%) and diarrhea (8%). Grade 4 AEs occurred in 2% of dacomitinib-treated patients. There was one case of Grade 5 diarrhea and one case of Grade 5 liver disease. The discontinuation rate due to treatment-related AEs for dacomitinib was 10% compared to 7% for gefitinib.

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

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REFERENCES