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Pfizer Unveils Positive Results for VIZIMPRO® as first-line monotherapy in NSCLC patients

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Efficacy and tolerability results from Asian subgroup analysis of ARCHER 1050 study showed significant improvement in Progression-Free and overall survival in EGFR-mutated Non-Small Cell Lung Cancer Patients who received First-Line Dacomitinib

Pfizer Inc. on 25th Nov 2019, announced the efficacy and tolerability results from the subgroup analysis of Asian patients enrolled in the ARCHER 1050, a randomized, multicenter, multinational, open-label Phase 3 study evaluating the efficacy of VIZIMPRO® (dacomitinib) – an epidermal growth factor inhibitor (EGFR) tyrosine kinase inhibitor (TKI) – as first-line monotherapy in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR-activating mutations. The results, which were announced at ESMO Asia Congress 2019, show significant prolongation of progression-free survival (PFS); and an extended follow-up demonstrated significant improvement in overall survival (OS) with the first-line dacomitinib versus gefitinib in Asian patients with EGFR-positive advanced NSCLC.

The subgroup analysis involved a subset of 346 Asian patients who were enrolled in China, Hong Kong SAR, Japan and Korea. Data cutoff dates were July 29, 2016, for the PFS analysis and May 13, 2019, for the extended OS analysis.

When treated with first-line VIZIMPRO®, the subgroup of Asian patients achieved significant prolongation of PFS (as determined by blinded Independent Radiologic Central (IRC) review) compared with gefitinib (HR = 0.509 [95% CI: 0.391, 0.662], 2-sided p<0.0001). Patients who were randomized to receive once-daily VIZIMPRO® achieved a median PFS of 16.5 months (95% CI: 12.9, 18.4) compared with 9.3 months (95% CI: 9.2, 11.0) in the gefitinib arm.

In 2017, the analysis of the intent-to-treat population of ARCHER 1050 reported that the median PFS was 14.7 months in the VIZIMPRO® group (95% CI: 11.1, 16.6) versus 9.2 months (95% CI: 9.1, 11.0) in the gefitinib group. The Asian subgroup analysis presented today demonstrates that treatment with the first-line dacomitinib results in a significant prolongation of PFS compared with gefitinib in Asian patients. “The results from the current subgroup analysis provide us with a more robust confirmation of the efficacy of dacomitinib as a first-line treatment option for Asian patients with EGFR-positive advanced NSCLC,” said Professor Tony Shu Kam Mok, Chairman of the Department of Clinical Oncology and Li Shu Fan Medical Foundation Professor of Clinical Oncology of the Faculty of Medicine at The Chinese University of Hong Kong, who presented the results.

An extended follow-up of the Asian subgroup (median of 47.9 months for both treatment arms) demonstrated that dacomitinib resulted in significant improvements in the secondary efficacy endpoints of OS and duration of response (DoR) versus gefitinib. Median OS was 37.7 months (95% CI: 30.2, 44.7) for dacomitinib patients versus 29.1 months for gefitinib (95% CI: 25.6, 36.0) (HR for OS = 0.759 [95% CI: 0.578, 0.996] favoring VIZIMPRO®). Median DoR in the VIZIMPRO® group was double that of the gefitinib group (16.6 months [95% CI: 13.8, 30.4] versus 8.3 months [95% CI: 8.1, 10.2], respectively).

Significantly, this OS benefit was maintained in patients who had a dose reduction. “We reported, in both the intent-to-treat population as well as the Asian subgroup, that OS benefit was maintained in patients who had a dose modification with dacomitinib at 30mg or 15mg QD. This is important as dose modification is the most effective way to manage toxicity, thereby enabling therapy to be better tolerated without compromising on the efficacy of treatment,” said Professor Mok.

The Asian subgroup analysis also showed that VIZIMPRO® had a longer duration of treatment (DoT) compared with gefitinib (77.9 weeks vs. 52.7 weeks). Similar to the as-treated population of ARCHER 1050, the most commonly observed adverse events (AEs) in VIZIMPRO®-treated patients of this Asian subgroup were diarrhoea (90.6%), paronychia (64.7%) and dermatitis acneiform (56.5%). No clinically relevant differences in the overall frequency of all-cause AEs were observed between the Asian subgroup and the as-treated patient population. Overall, the rates of dose reductions or dosing interruptions were similar in both the Asian subgroup and the astreated population.