Background and methods

ARROW study design

Efficacy interim analysis

Efficacy summary (blinded independent central review)

Duration of response in treatment-naïve patients

Tumor shrinkage in patients with platinum-based chemotherapy

Tumor shrinkage in patients with prior platinum-based chemotherapy

Treatment-related adverse events

Conclusions

Patient disposition/analyses populations

Results

Protocol amendment July 2019; this amendment expanded inclusion criteria to allow recruitment of treatment-naïve patients eligible for standard platinum-based therapy who had previously not been permitted.

Poster Number 5089

Surgical specimens were available from 122 patients in the platinum-based therapy group, of whom 115 patients (95%) had evaluable specimens. Among the 115 patients with evaluable specimens, 104 (91%) had RET fusion–positive NSCLC, 9 (8%) had RET fusion–positive non-small cell lung cancer (NSCLC), and 2 patients (2%) had RET fusion–positive small cell lung cancer.

Notably, ORR was 88% in the post eligibility revision subset, which illustrates the clinical relevance of these findings. The median objective response duration for those in the post eligibility revision subset with complete response (CR) was 16.5 (10.5–24.1) months.

A total of 26 of 471 patients (5%) in the overall safety population (all tumor types) discontinued due to treatment-related AEs.

Pralsetinib is currently approved for the treatment of metastatic RET fusion–positive NSCLC, with a safety profile consistent with previous reports and no new safety signals.

With a longer overall follow-up (17.1 months vs 9.8 months in previous analysis), pralsetinib showed robust, durable responses across all RET fusion–positive NSCLC treatment groups.

Notably, ORR was 88% in the post-eligibility revision subset, which included treatment-naive patients who were otherwise eligible for standard platinum-based therapy, providing support for RET inhibitors as first-line standard of care.

These data highlight the importance of early biomarker testing for all patients with metastatic NSCLC prior to treatment initiation to inform optimal healthcare decisions.

Pralsetinib is currently approved for the treatment of metastatic RET fusion–positive NSCLC and advanced or metastatic RET–fused thyroid cancers in the USA, and is locally advanced or metastatic NSCLC after platinum-based chemotherapy in China.

References


Protocol amendment July 2019; this amendment expanded inclusion criteria to allow recruitment of treatment-naïve patients eligible for standard platinum-based therapy who had previously not been permitted.

A total of 26 of 471 patients (5%) in the overall safety population (all tumor types) discontinued due to treatment-related AEs.

Pralsetinib is currently approved for the treatment of metastatic RET fusion–positive NSCLC, with a safety profile consistent with previous reports and no new safety signals.

With a longer overall follow-up (17.1 months vs 9.8 months in previous analysis), pralsetinib showed robust, durable responses across all RET fusion–positive NSCLC treatment groups.

Notably, ORR was 88% in the post-eligibility revision subset, which included treatment-naive patients who were otherwise eligible for standard platinum-based therapy, providing support for RET inhibitors as first-line standard of care.

These data highlight the importance of early biomarker testing for all patients with metastatic NSCLC prior to treatment initiation to inform optimal healthcare decisions.

Pralsetinib is currently approved for the treatment of metastatic RET fusion–positive NSCLC and advanced or metastatic RET–fused thyroid cancers in the USA, and is locally advanced or metastatic NSCLC after platinum-based chemotherapy in China.

References


Protocol amendment July 2019; this amendment expanded inclusion criteria to allow recruitment of treatment-naïve patients eligible for standard platinum-based therapy who had previously not been permitted.

A total of 26 of 471 patients (5%) in the overall safety population (all tumor types) discontinued due to treatment-related AEs.

Pralsetinib is currently approved for the treatment of metastatic RET fusion–positive NSCLC, with a safety profile consistent with previous reports and no new safety signals.

With a longer overall follow-up (17.1 months vs 9.8 months in previous analysis), pralsetinib showed robust, durable responses across all RET fusion–positive NSCLC treatment groups.

Notably, ORR was 88% in the post-eligibility revision subset, which included treatment-naive patients who were otherwise eligible for standard platinum-based therapy, providing support for RET inhibitors as first-line standard of care.

These data highlight the importance of early biomarker testing for all patients with metastatic NSCLC prior to treatment initiation to inform optimal healthcare decisions.

Pralsetinib is currently approved for the treatment of metastatic RET fusion–positive NSCLC and advanced or metastatic RET–fused thyroid cancers in the USA, and is locally advanced or metastatic NSCLC after platinum-based chemotherapy in China.