In the phase 3 open-label CLEAR study, we compared the efficacy and safety of lenvatinib + pembrolizumab versus sunitinib in adult patients with advanced RCC.

At the primary analysis (median survival follow-up duration: 26.6 months), a statistically significant improvement in median OS (95% CI) was observed in the lenvatinib + pembrolizumab arm versus the sunitinib arm (Figure 4).

The HR for OS favored lenvatinib + pembrolizumab versus sunitinib across all subgroups of interest (Figure 5).

In the lenvatinib + pembrolizumab arm versus the sunitinib arm (Figure 6A).

For patients with a near-complete response (ie, partial response with a tumor reduction of ≥ 90%), the adjusted HR was 0.39 (95% CI, 0.26–0.59).

In the lenvatinib + pembrolizumab arm versus the sunitinib arm (Figure 6B).

The estimated median OS (95% CI) was 37.2 months (22.4–NE) for patients with a complete response (ie, partial response with a tumor reduction of ≥ 75%)

In the lenvatinib + pembrolizumab arm versus the sunitinib arm (Figure 6C).

In the lenvatinib + pembrolizumab arm versus the sunitinib arm (Figure 6D).

In the lenvatinib + pembrolizumab arm versus the sunitinib arm (Figure 6E).

PFS benefit was observed irrespective of risk subgroups (Figure 7).

Safety

The safety profile of lenvatinib + pembrolizumab was consistent with that of the primary analysis and of the known profile of each monotherapy.

Adverse events were managed with dose modifications as necessary.

In the lenvatinib + pembrolizumab arm versus the sunitinib arm (Figure 8).

In the lenvatinib + pembrolizumab arm versus the sunitinib arm (Figure 9).

CONCLUSIONS

Lenvatinib + pembrolizumab continued to demonstrate clinically meaningful and durable benefit in OS, PFS, and ORR versus sunitinib in the first-line treatment of patients with advanced RCC at the final analysis (with a median follow-up of 4 years).

No new safety signals were identified adverse events were managed with dose modifications as necessary.

REFERENCES


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