SAFETY AND EFFICACY OF VANDETANIB AS SYSTEMIC TREATMENT FOR PATIENTS WITH ADVANCED AND PROGRESSIVE MEDULLARY THYROID CANCER (MTC)


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Aim: Vandetanib has demonstrated efficacy in advanced MTC in a large phase III trial (NCT00410761). However, little evidence is available on safety and efficacy of vandetanib in daily-practice patients. This is a retrospective multicenter analysis of the safety and activity of vandetanib in the community setting.

Methods: Pts with advanced, unresectable MTC and documented radiological disease progression were included in a compassionate use program in Spain. Pts received vandetanib 300 mg qd as the initial dose, allowing dose reductions as per toxicity. Primary endpoint was response rate (RR) by RECIST and secondary endpoints were safety, progression-free survival (PFS) and correlation between RR and biomarkers. The program was validated by regulatory authorities and all patients signed an informed consent form.

Results: 27 pts were enrolled (med age: 48 yo; male: 52%). Vandetanib was given as first-line MKI in 59%, second-line in 22% and third-line in 19% of pts. Dose reductions were needed in 44% of pts to manage toxicity. Most common grade 1-2 adverse events were rash (33%), fatigue (33%), diarrhea (33%), hand-foot syndrome (19%), AST/ALT elevation (19%), mucositis (15%), nausea and vomiting (15%), anorexia (15%) and hypertension (11%). The most frequent grade 3-4 side effects were rash (22%), hypertension (4%), mucositis (4%) and cardiac toxicity (<3%). 25 pts were evaluable for efficacy. Overall RR was 24% (including one complete response), disease stabilization was 60% (44% for more than 6 months) and 16% had progressive disease. Median percentage of tumor shrinkage was 30% (range, 4-100%). No significant differences were found regarding treatment lines and previous exposure to MKIs. Median PFS was 17.6 months (95%CI, 8.3-26.9 months) with 66% of events at the time of analysis. No correlation was found between calcitonin and/or CEA reduction and disease control rate (RR + SD).

Conclusions: Vandetanib showed meaningful activity with an acceptable safety profile in advanced and progressive MTC in a cohort of patients with a worse prognosis than previously reported. Activity is seen regardless of treatment line.

Disclosure: All authors have declared no conflicts of interest.

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