Latest findings from the breast cancer cohort in SUMMIT – a phase 2 ‘basket’ trial of neratinib + trastuzumab + fulvestrant for HER2-mutant, hormone receptor-positive, metastatic breast cancer

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Methods

Figure 1. Current SUMMIT study design

Table 1. Baseline demographics

Table 2. Prior therapies in the locally advanced/metastatic setting

Table 3. Subject disposition

Table 4. Efficacy summary (RECIST evaluable patients, n=37)

Figure 2. Distribution of HER2 mutations (RECIST evaluable patients, n=30)

Figure 3. Change in tumor size and characteristics (%)

Figure 4. Duration of treatment and best response (RECIST evaluable patients, n=27)

Figure 5. Change in tumor size and characteristics (%)

Figure 6. Duration of treatment and best response (RECIST evaluable patients, n=27)

Table 5. Most common treatment-emergent adverse events

Table 6. Characteristics of diarrhea

Conclusions

HER2 mutations are oncogenic in a subset of MBC and are clinically actionable with HER2-directed therapies.

The combination of neratinib + fulvestrant + trastuzumab demonstrated encouraging clinical activity in heavily pre-treated HER2-mutant, HER2-monosomy MBC, including patients who had previously received either fulvestrant and/or CDK4/6-inhibitor-based therapies.

While the rate of grade 3 diarrhea was higher than that observed with single-agent neratinib in SUMMIT, this was manageable in terms of tolerability and diarrhea did not lead to discontinuation.

SUMMIT has recently been amended to evaluate neratinib + fulvestrant + trastuzumab, which is a treatment option for patients with HER2-mutant MBC.

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References


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