Patients with anti-PD-(L)1-naïve, previously-treated MSS mCRC tumors were enrolled. Pre- and on-treatment tumor biopsies were available from 37 patients and paired blood samples for biomarker analyses were collected; additional methods are available via QR code.

Methods

- Patients with anti-PD-(L)1-naïve, previously-treated MSS mCRC tumors were enrolled. Pre- and on-treatment tumor biopsies and blood samples for biomarker analyses were collected; additional methods are available via QR code.

- 40 patients received BI 754111 600 mg plus BI 754091 240 mg Q3W.
- To date (April 2020), 5 (12.5%) patients achieved a PR (3 (7.5%) confirmed) and 11 (27.5%) had SD as best response.
- In some patients, BI 754111 in combination with BI 754091 produced deep and durable responses (Figure 1).

Results

- A similar effect was seen for CD4 T cells (data not shown).
- Activated (but not parental) CD8 T cells showed increased IFN-γ gene signature score (Figure 2).
- Dual blockade of the checkpoint receptors, PD-1 and LAG-3, may reactivate the anti-tumor T-cell response better (Figure 3).
- In some patients, BI 754111 in combination with BI 754091 showed preliminary anti-tumor activity in patients with microsatellite stable metastatic colorectal cancer (Figure 4).
- Biomarker analyses showed treatment led to activation of the immune system.
- Gene expression analysis demonstrated that high expression of PD-L1 at baseline was associated with clinical benefit.
- Immunohistochemical analysis did not show an association between baseline PD-L1 protein expression and clinical benefit.

Discussion

- BI 754111 in combination with BI 754091 showed preliminary anti-tumor activity in patients with microsatellite stable metastatic colorectal cancer.
- Biomarker analyses showed treatment led to activation of the immune system.
- Gene expression analysis demonstrated that high expression of PD-L1 at baseline was associated with clinical benefit.
- Immunohistochemical analysis did not show an association between baseline PD-L1 protein expression and clinical benefit.

Conclusions

- BI 754111 in combination with BI 754091 showed preliminary anti-tumor activity in patients with microsatellite stable metastatic colorectal cancer.
- Biomarker analyses showed treatment led to activation of the immune system.
- Gene expression analysis demonstrated that high expression of PD-L1 at baseline was associated with clinical benefit.
- Immunohistochemical analysis did not show an association between baseline PD-L1 protein expression and clinical benefit.

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References