MOR202 in combination with pomalidomide or lenalidomide in relapsed or refractory multiple myeloma: Data from a clinically relevant cohorts from a phase I/IIa study

Study design
- Standard 3+3 dose-escalation study starting with MOR202 monotherapy of 31 mg/kg every 2 weeks (q1w) and 62 mg/kg every 2 weeks (q2w) each for 2 cycles.
- In combination with Dexamethasone (Dex) at 4 mg/kg and 8 mg/kg q1w, respectively.
- In combination with pomalidomide (POM) at 4 mg/kg q1w and 8 mg/kg q2w, respectively.

Results
- The study is ongoing; this is a report of interim safety, and preliminary efficacy data in the MOR202 monotherapy cohorts.
- As of April 26, 2016, a total of 32 patients had been treated with MOR202 monotherapy initially including 24 patients treated in combination with Dex only or an IMiD + Dex (Table 1).

Preliminary efficacy analysis
- Efficacy data for patients with a scheduled response assessment after treatment cycle 2 to 5 patients.
- Time to study and best response (Figure 2).
- Best response in M-protein (Figure 3).
- 7 out of 9 responses are ongoing.

Safety
- Adverse events (AEs) of any grade and grade ≥3 are shown in Table 2.
- Only one patient in the combination cohorts discontinued due to AEs with suspected causal relationship to MOR202. This AE (pancreatic necrosis/reacting tissue) had not a suspected causal relationship to POM and Dex.
- Few adverse events have been noted in the MOR202 + Dex cohorts and no responses in cohorts of MOR202 with an IMiD.

Biomarkers
- Figure 5 shows the evaluation of CD38 expression on 94 patients bone marrow plasma cells at baseline and during MOR202 therapy.
- Data suggest increased CD38 expression is preserved during MOR202 therapy (Figure 1).

Conclusions
- The MTD of MOR202 alone and in combination has not yet been reached.
- MOR202 in doses ≥10 mg/kg can be safely administered as a weekly IMiD or a weekly and or a biweekly IMiD.
- MOR202 was well tolerated with a low incidence of IRRs, mainly limited to the first infusion.
- Current data suggest CD38 expression on MPM patient bone marrow plasma cells is preserved during MOR202 therapy.

References

Acknowledgments
This study was sponsored by MorphoSys AG. Medical writing support was provided by Paul Hoban, Cancer Communications and Consultancy Ltd (Knutsford, UK) and was funded by MorphoSys AG.