MMCI metrics

Sponsor summary on site performance in FIH trial

- FIH clinical trial of novel ADC, as monotherapy as well as in combination of established SoC
- Selected GI indication of high unmet medical need
- 6 sites in CZ + WE EU countries, 2 sites in US
- APR 2024

FIH trial

- Operational
 - European CTA submission (regulatory + ECs) on 13 Jan 2022
 - 1st patient enrolled 31 Mar 2022 (i.e. in approx. 2.5 month of submission)
 - 100% PI attendance on dose escalation meetings
- Patient enrollment
 - Top recruiter with enrolled 9 patients out of 33 in total (at 8 sites in EU + US)
- Data performance
 - Data entry on average in 1 day of the visit date
 - Overall query rate / page = 1.65 (TOP site in trial)
 - TAT for query response = 1.14 day (TOP site in trial)
- Compliance
 - Successful GCP inspection by local regulatory authority without any critical observation