Description of study design

- A sub-study of our basket trial under the nationwide large registry for rare cancers in Japan (MASTER KEY Project)
- Phase 2, open-label, 2-part clinical study (JMACCT ID: JMA-II A00402)
- Study period: December 2018 – November 2022

Key inclusion criteria

- *MDM2* amplification is confirmed by NGS or FISH or IHC
- Wild-type *TP53* is confirmed by NGS or FISH or IHC
- Age ≥ 18 years old at informed consent
- PS=0-2
- Has measurable target lesion at baseline

Part 1
Safety lead-in cohort
N = 3

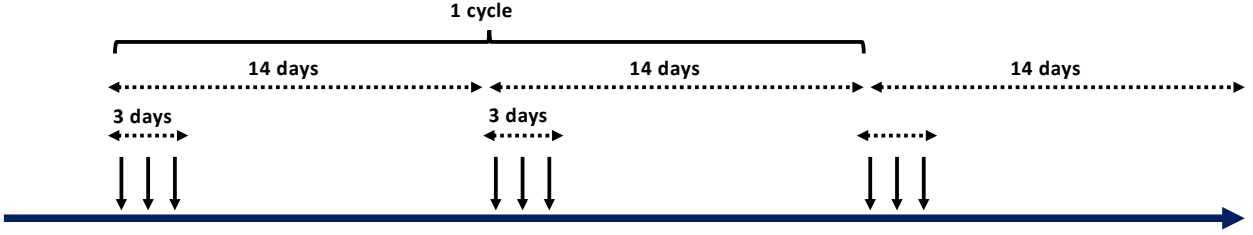
→ **Safety evaluation** →

Part 2
Expansion cohort
N = 2-7

To evaluate the safety, tolerability, and pharmacokinetics of milademetan

Dose and schedule

- Milademetan 260 mg qdx3 every 14 days twice in a 28 days cycle



Supplementary Fig. S6. Study design.
Key inclusion criteria, dose, and schedule.

Abbreviations: NGS, next-generation sequencing; PS, performance status; qd, once daily