SKIPPirr: Evaluating Prophylactic Strategies to Reduce the Incidence of IRRs With Amivantamab

Rationale

- In CHRYSALIS, a phase 1 study, **IV amivantamab** has an IRR incidence of ~67% at first infusion[1,a]
- Standard mitigation approaches in clinical trials include a **split first dose of amivantamab over 2 days in the first cycle** and premedication with oral or IV antihistamines, oral or IV antipyretics, and IV glucocorticoids[2]

SKIPPirr Study Design

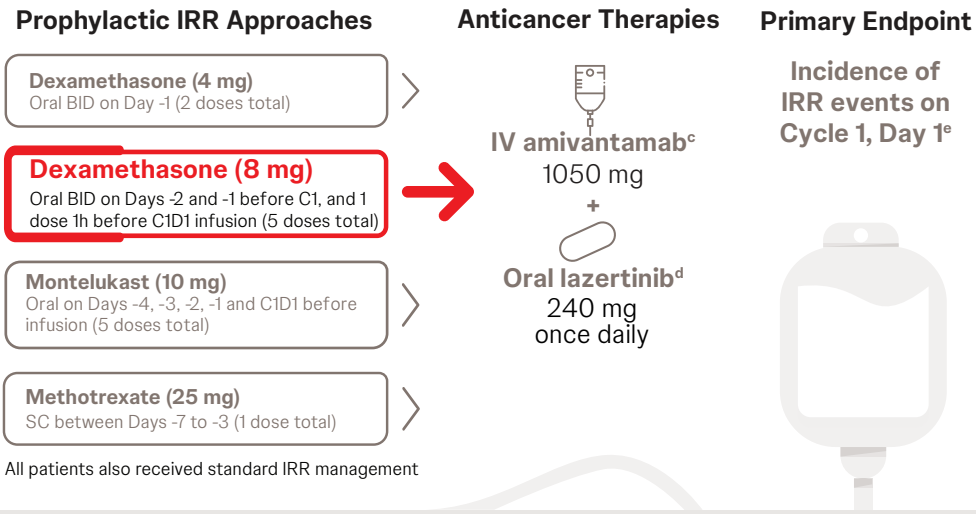
SKIPPirr is a phase 2 prospective study (NCT05663866) that assesses prophylactic strategies administered prior to amivantamab infusion in order to reduce the incidence and/or severity of first-dose IRRs. This Simon's 2-stage study design evaluates prophylactic approaches in 4 cohorts, with the dexamethasone 8 mg oral cohort reaching the expansion stage.[b]

Limitation:

- The dexamethasone 8 mg oral cohort sample size is n=40. Further studies are needed to determine prophylactic regimens

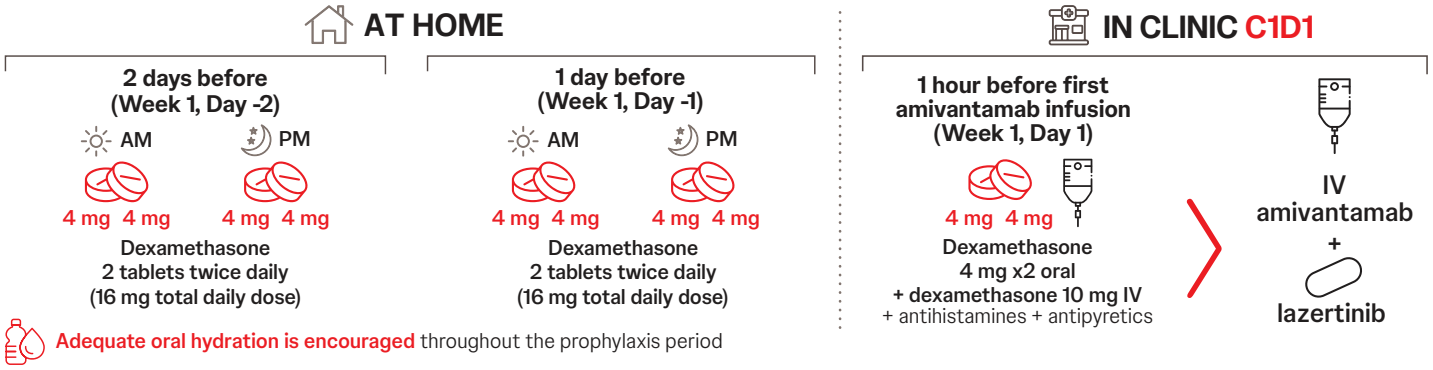
Key Eligibility Criteria

- *EGFR* Ex19del or L858R advanced/ metastatic NSCLC
- Progression after prior osimertinib and prior platinum-based chemotherapy
- ECOG PS 0–1



One cohort tested in SKIPPirr reached the expansion stage: dexamethasone 8 mg oral cohort[3]

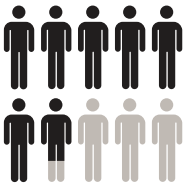
Prophylactic schedule



Adequate oral hydration is encouraged throughout the prophylaxis period

In SKIPPirr, the Week 1, Day 1 dexamethasone dose is 10 mg IV. In the amivantamab Prescribing Information, the Week 1, Day 1 dexamethasone dose is 20 mg IV.[2,3]

Rate of IRRs on C1D1



67.4%
Standard IRR management[1]
(historic; 256/380)

22.5% (95% CI, 10.8–38.5)
Dexamethasone 8 mg IRR prophylaxis
(9/40)

SKIPPirr is not a comparative study. Please refer to the limitation section for additional information.

No grade ≥3 IRRs with dexamethasone 8 mg prophylaxis vs **2%** with standard IRR management

- The most common IRR-related symptoms were nausea (8%), dyspnea (5%), and hypotension (5%). All symptoms were grade 1–2 (no grade ≥3)

[a]Based on an analysis of the CHRYSALIS study.
[b]Stage 1 n=6. Stage 2 n=16. Expansion stage n=40. See full presentation for more details.
[c]IV amivantamab: 1050 mg (1400 if ≥80 kg) once weekly for 4 weeks and then every 2 weeks thereafter.
[d]Administer lazertinib any time prior to amivantamab when given on the same day.
[e]Defined as IRR events with onset within 24 hours of the start of the C1D1 amivantamab infusion and prior to the start of the C1D2 infusion.

1. Park K, et al. *Lung Cancer*. 2023;178:166–171. **2.** RYBREVANT® (amivantamab-vmjw) [prescribing information]. Horsham, PA: Janssen Biotech, Inc. **3.** Lopes G, et al. Presented at the World Conference on Lung Cancer (WCLC); September 7-10, 2024; San Diego, CA, USA.

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