Phase I/II, Single-Arm, Open-Label, Multi-Centre Study Evaluating the Safety and Clinical Activity of [IP], a CAR T Cell Treatment in Patients with Relapsed or Refractory Diffuse Large B Cell Lymphoma

Cmed
An Aixial Group Company

Trial Summary

Design:

- 3+3 escalation to expansion
- Escalation: up to 30 patients
- Expansion: up to 101 patients

Product: Autologus T Cell product transduced to express [x] CAR

Sites: 4 UK (2 further to be opened Nov 19 and Jan 20) and 7 US (3 open, 4 to be opened by end of Nov 2019)

Dates: 2017 to present

Successes

- Strong LCRA and CRAs better suited to manage sites via data/performance/risk metric visibility in encapsia
- Bespoke site support via tailored site visits frequency, knowledge on IP and study as well as CRA availability to site
- The site and patient engagement have been good. Rare screen fails
- Minimal time to dose-escalation review and decisions supported by encapsia exports and insights

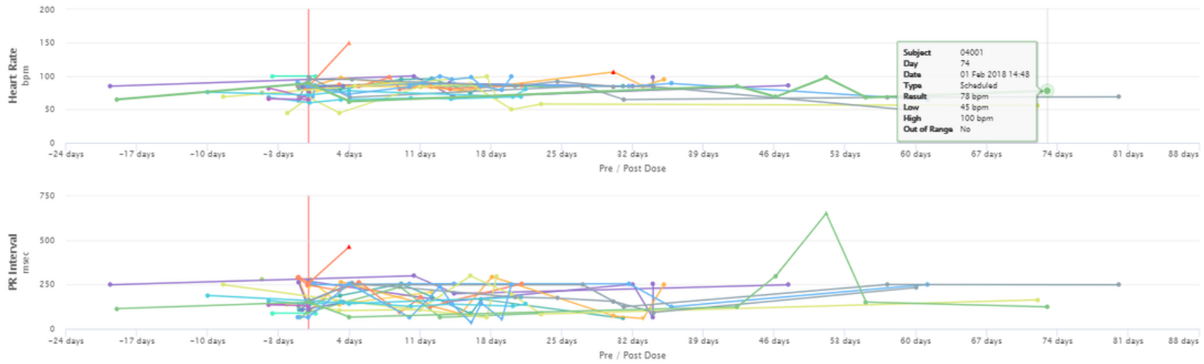

Fig 1 Real time, customizable results over time insights facilitate ongoing safety oversight

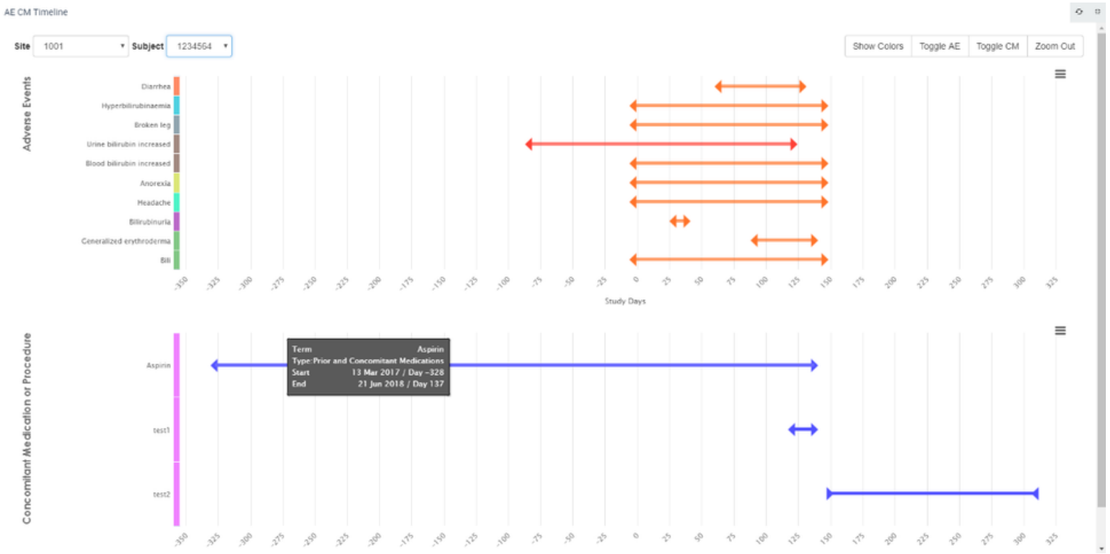

Fig 2. Real time AE/CM activity vs dosing visibility to support dosing level decisions

Challenges with Mitigations

- IP distribution by couriers mitigated by ID of new courier with clear expectations
- Manufacturing slots are prime, even within Sponsor facilities. Slot management is addressed at every team meeting and managed proactively. Transparency with site from beginning of the study
- Challenges with keeping site support high mitigated by an increase in logistics management for samples