GEM-MeziDAL

Multicenter, open label, phase II clinical trial evaluating the combination of alnuctamab with mezigdomide and dexamethasone in patients with relapsed/refractory multiple myeloma

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Background

- CELMoDs are **good partners for combination** with TCE
- TCE are moving towards **limited duration treatment** (infections & convenience)
- **MRD adapted therapy** is an attractive possibility
- **ERI** with reintroduction of the TCE is also attractive
- We do not know the potential **influence of dexamethasone on TCE** efficacy
- We can evaluate the **immune profile** of these agents and its combination

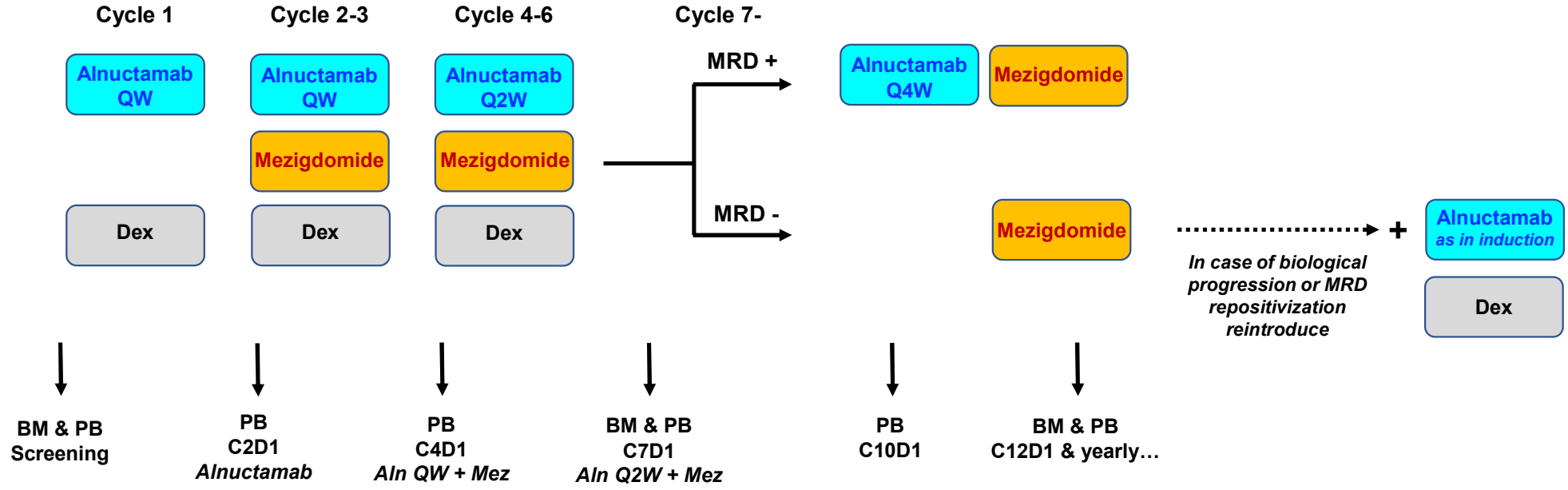
GEM-MeziDAI: Mezigdomide (CC-92480) + Dex + Alnuctamab (CC-93269)

n=60 RRMM pts Len refractory

Primary endpoint: Achievement of MRD (-) with Mezigdomide + Dex + Alnuctamab

Secondary:

- ORR (CR, VGPR, PR) with Mezigdomide + Dex + Alnuctamab
- Sustained MRD rate at 12 months according to a MRD based maintenance.
- PFS with Mezigdomide + Dex + Alnuctamab + ERI
- Safety of the combination
- Immune profiling induced by Alnuctamab, Mezigdomide & the combination



Alnuctamab 3-6-30 sq
- QW x 3 cycles
- Q2W x 3 cycles
- Q4W subsequently

Mezigdomide po at the RD 21/28

Dexamethasone 20 (10) mg weekly

Study Milestones

Milestone	BMS Proposed Finish Date	BMS revised proposed finish date	Actual Finish Date
Full Concept Submission			06-Oct-2022 (part of 2022 RFP2cycle-ISR conversion)
Full concept Endorsement			08-Sep-2023
Preliminary agreement ~CDA (draft sent on 02-Oct-2023)	31-Dec-2023	31 Oct 2023	
Protocol Endorsement*	01-Mar-2024	31 Jan 2024	
ICF Endorsement	01-Mar-2024	31 Jan 2024	
Full Contract Execution *	15-Feb-2024	31 Jan 2024	
HA (EMA) approval	31-May-2024	31-May-2024	
EC approval	28-Jun-2024	28-Jun-2024	
First Patient First Visit (FPFV)	31-Jul-2024	31-Jul-2024	
Last Patient First Visit (LPFV) (2 years enrollment)	30-Jun-2026	30-Jun-2026	
Last Patient Last Visit (LPLV) (Treatment duration 20 months + FU duration :12 months => LPLV = June 2026 + 32months = Feb 2029)	28-Feb-2029	28-Feb-2029	
Clinical Study Report (LPLV + 6months)	28-Sep-2029	28-Sep-2029	
Study operationally Closed (CSR receipt date + 3	31-Dec-2029	31-Dec-2029	