KD025-213: Pivotal Trial of KD025 in cGVHD

Interim Analysis Topline Results

November 11, 2019

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CEO Opening Remarks

Harlan W. Waksal, M.D., President and CEO

KD025-213: Interim Analysis Outcomes

- **KD025 met the primary endpoint at the interim analysis of the pivotal trial in cGVHD (KD025-213)**
- **KD025 achieved statistically significant and clinically meaningful Overall Response Rates (ORRs):**
  - 64% ORR with KD025 200 mg QD (95% CI: 51%, 75%)
  - 67% ORR with KD025 200 mg BID (95% CI: 54%, 78%)
- **KD025 has been well tolerated**
  - AEs have been consistent with those expected in this patient population
- **Results from primary analysis expected Q1 2020**
- **Data will be submitted for presentation at an upcoming scientific meeting**

KD025-208: Updated Results

Phase 2 Clinical Trial of KD025 in cGVHD

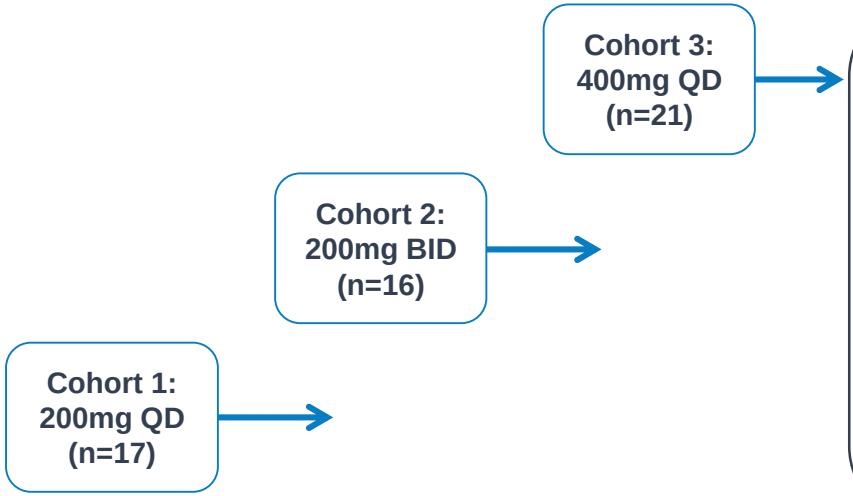
Sanjay Aggarwal, M.D., SVP, Clinical Development

KD025-208: Phase 2a Study of KD025 for Patients with cGVHD

Study initiated September 2016; Conducted at 7 U.S. Sites

Key Eligibility Criteria:

- Adults who have had allogeneic hematopoietic cell transplantation (HCT) with steroid-dependent or steroid-refractory cGVHD
- Have persistent active cGVHD after at least 2 months of steroid therapy
- Receiving glucocorticoid therapy +/- calcineurin inhibitor therapy for cGVHD
- 1-3 prior lines of treatment for cGVHD



Three cohorts enrolled sequentially, following safety assessment of previous cohort

Key Endpoints:

- ORR, per 2014 NIH criteria
- Safety and tolerability
- Duration of response
- Response by organ system
- Changes in corticosteroid and calcineurin inhibitor dose

KD025-208: Updated Data With Additional 6 Months of Follow-up

KD025-208 ORR				
	KD025 200 mg QD (n=17)	KD025 200 mg BID (n=16)	KD025 400 mg QD (n=21)	mITT (n=54)
ORR 95% CI	65% (38, 85)	69% (41, 89)	62% (38, 82)	**65%** (51, 77)

Data as of March 8, 2019

Clinically Meaningful and Durable Responses

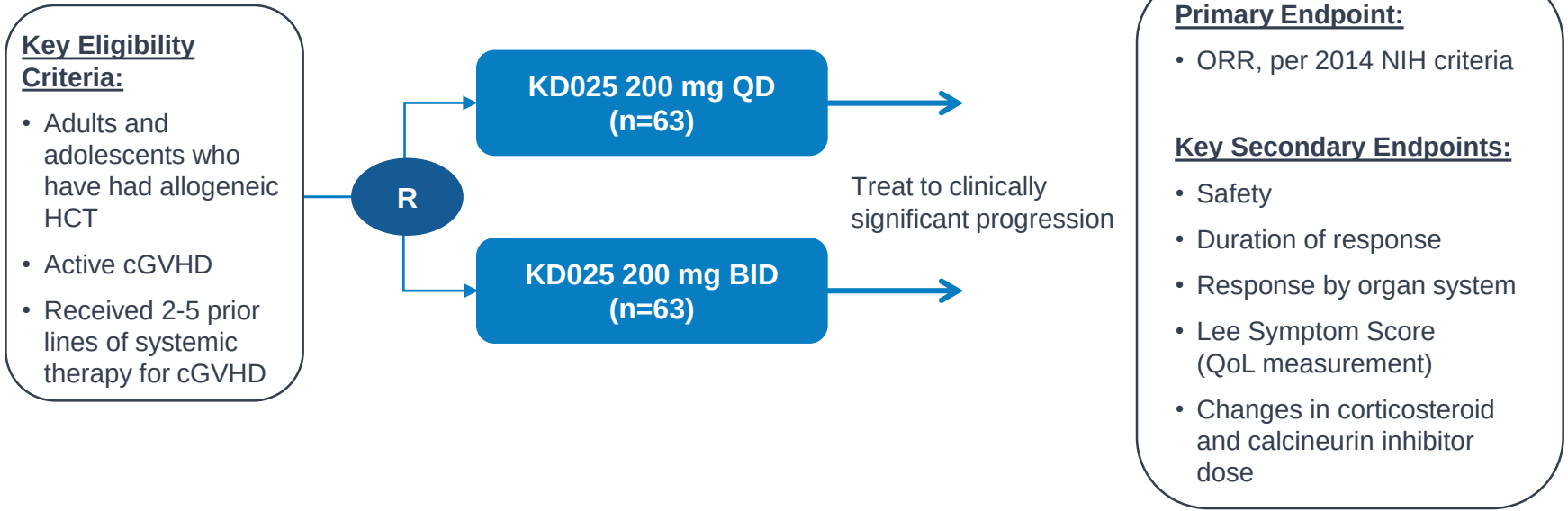
- **ORR of 65% across all 3 cohorts**
  - Responses observed in all organ systems, including in organs with fibrotic disease
  - Median of duration of response: 34 weeks
- **Well tolerated**
  - No apparent increased risk of infection observed
  - 24% of patients have remained on KD025 therapy for >1.5 years as of June 30, 2019

KD025-213: Interim Analysis Results

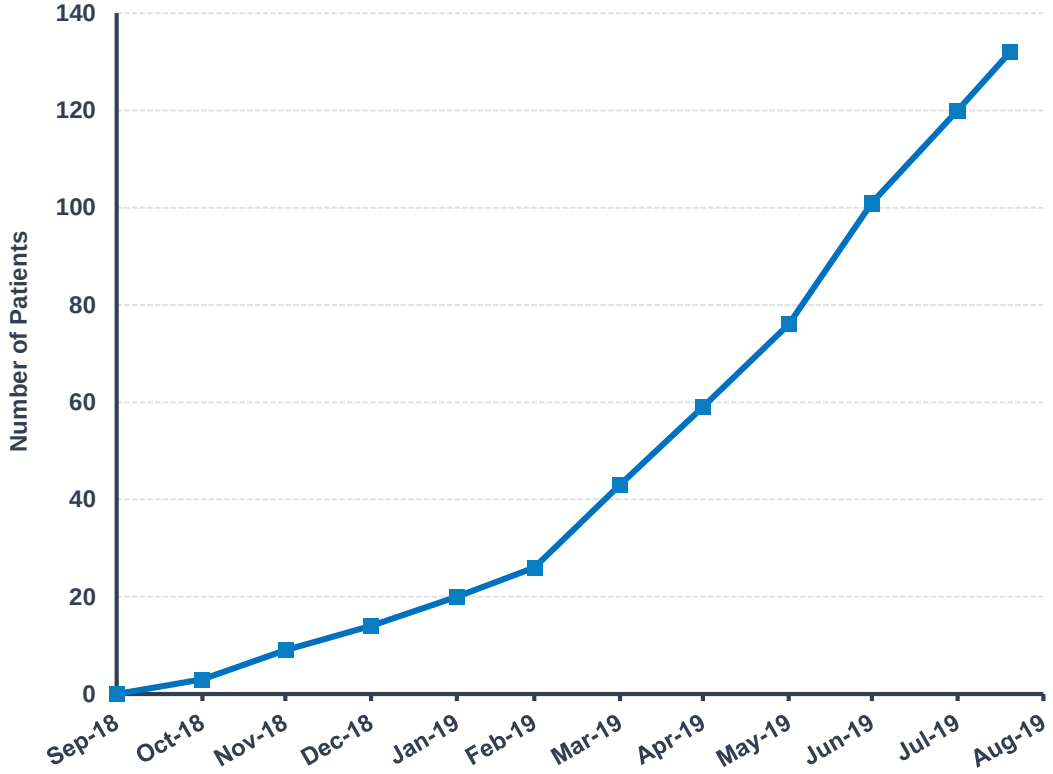
Pivotal Clinical Trial of KD025 in cGVHD

KD025-213: Ongoing Pivotal Trial of KD025 in cGVHD

KD025-213 (ROCKstar): A Phase 2, Open-Label, Randomized, Multicenter Study to Evaluate the Efficacy and Safety of KD025 in Subjects With cGVHD After At Least 2 Prior Lines of Systemic Therapy



KD025-213: Fully Enrolled in Less Than 10 Months



- **Conducted at 32 U.S. sites**
- **First Patient In: Oct 2018**
- **Last Patient In: Aug 2019**
- **Final mITT / safety: n=132**
  - 66 patients per arm

KD025-213: Real-World Patient Population

Demographics and Baseline Characteristics		
Demographics	**KD025 200 mg QD (n=66)**	**KD025 200 mg BID (n=66)**
Median age [years (range)]	53 (21-77)	57 (21-77)
Male (%)	64	50
Median prior lines of therapy	3	4
Median time from cGVHD diagnosis to enrollment (months)	25	30
≥4 Organs Involved [n (%)]	34 (52%)	35 (53%)
Median prednisone dose (mg/kg/day)	0.2	0.2
Stratification Factors:		
Severe cGVHD [n (%)]	45 (68%)	42 (64%)
Prior Ibrutinib Treatment	23 (35%)	22 (33%)

KD025-213: Statistical Analysis Plan

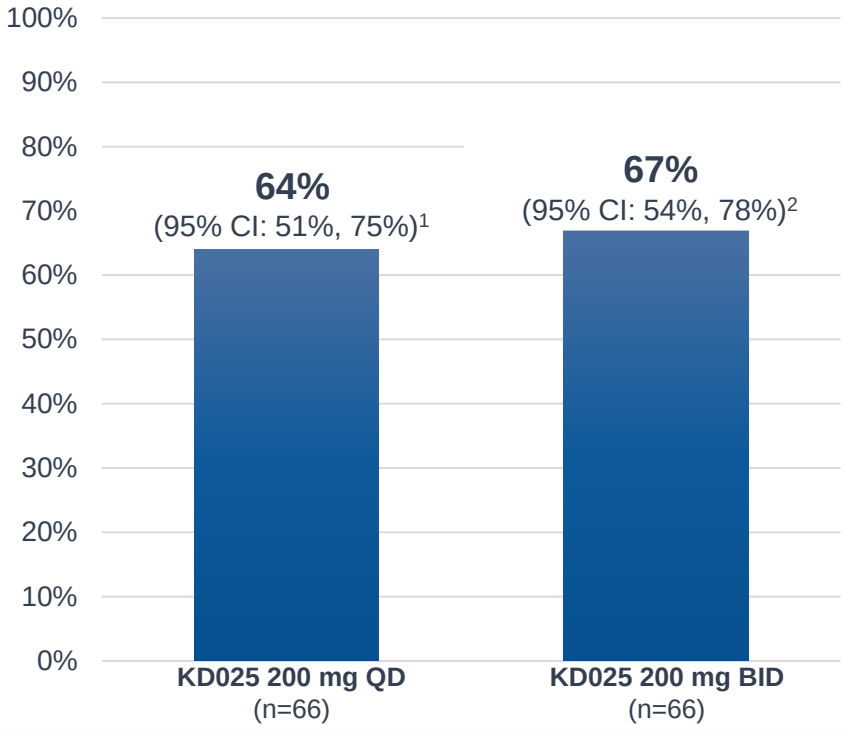
Primary Endpoint: ORR

Statistical significance is achieved if the lower bound of the 95% CI of ORR exceeds 30%

	Timepoint	Status
Interim Analysis	2 months after completion of enrollment (Oct 2019)	**Reported November 2019**
Primary Analysis	6 months after completion of enrollment (Feb 2020)	**Planned Q1 2020**

KD025-213 Met Primary Endpoint at Interim Analysis

ORR Results Have Exceeded Threshold For Success



- **KD025 achieved clinically and statistically significant ORRs in both arms**
- **KD025 has been well tolerated**
  - AEs have been consistent with those expected in this patient population

[1]p<0.0001; [2]p<0.0001

Closing Remarks

Harlan W. Waksal, M.D., President and CEO

KD025 in cGVHD: Path Forward

- **KD025 met the primary endpoint at interim analysis of pivotal trial in cGVHD (KD025-213)**
  - 64% ORR with KD025 200 mg QD (95% CI: 51%, 75%)
  - 67% ORR with KD025 200 mg BID (95% CI: 54%, 78%)
- **FDA granted Breakthrough Therapy Designation to KD025 in cGVHD after at least 2 prior lines of systemic therapy (Oct 2018)**
- **Pre-NDA meeting with FDA for KD025 in cGVHD anticipated Q1 2020**
- **Results from primary analysis expected Q1 2020**
- **Data will be submitted for presentation at an upcoming scientific meeting**
- **Kadmon plans to file an NDA for KD025 in cGVHD in 2020, subject to FDA feedback**

Q&A