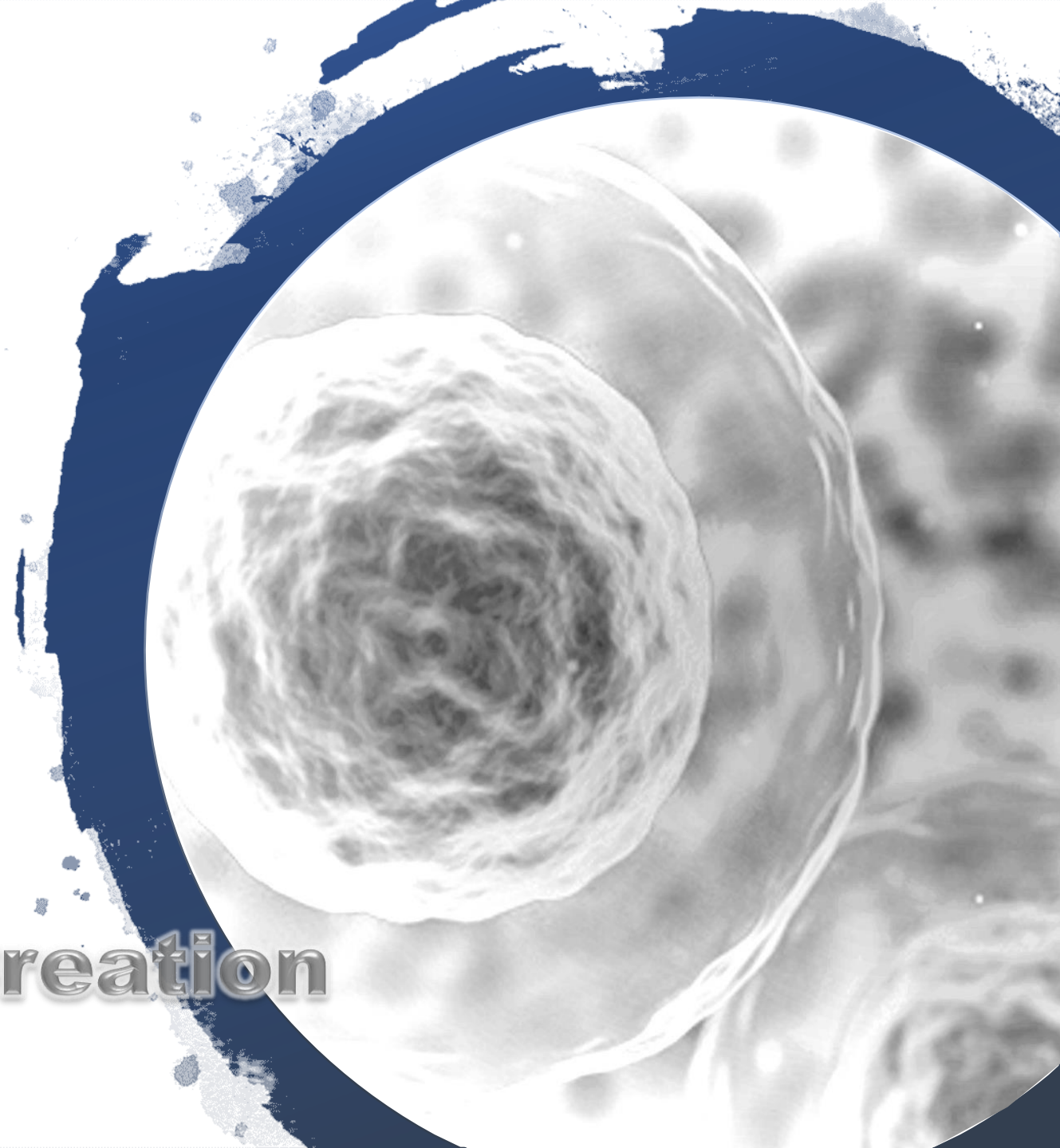
BIONOVA Pharma 烨辉医药



Focusing on Value Creation

August 2020

Company Overview

BioNova Pharma 烨辉医药

Company Profile

Seasoned management team with track records in drug development and strategic transactions

- Average > 20 years in global pharma and biotech companies and led multiple drug registrations
- In depth understanding of unmet medical needs and regulatory policies in China
- Extensive KOL and hospital networks across Chinese medical society

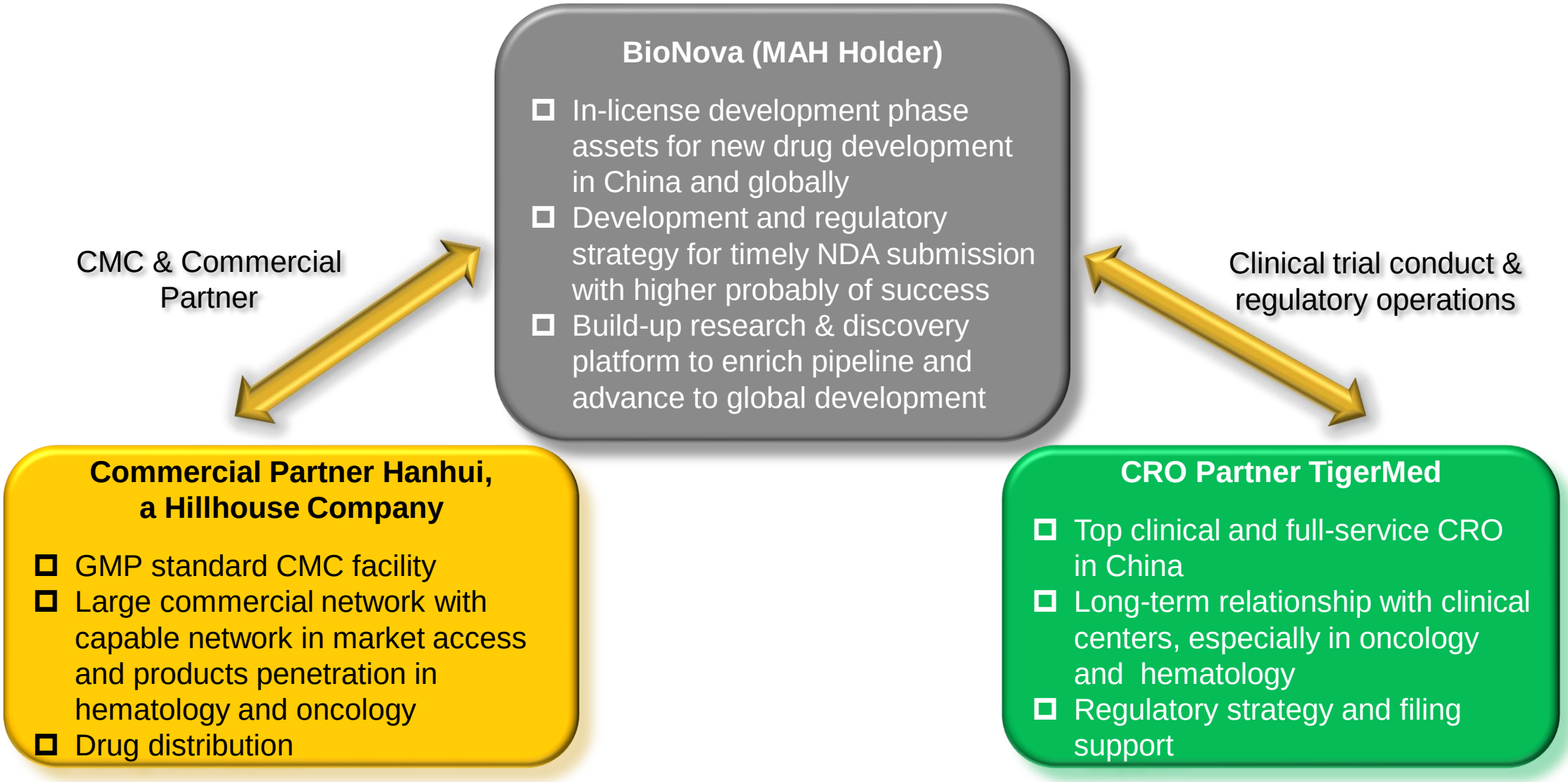
Extensive commercial coverage and market access in China with commercial partners

- > 2,000 sales force covering the tier 1-5 cities in China
- Strong ties with the largest pharmacy chains in China
- Strong government affairs capability with capable market access at both state and province level

Strong financial support by top tier life science VC funds

- Company is funded by premier VC funds, including Hillhouse, TF capital, Lilly Asia Ventures and BioTrack Capital

Efficient VIC Operating Model

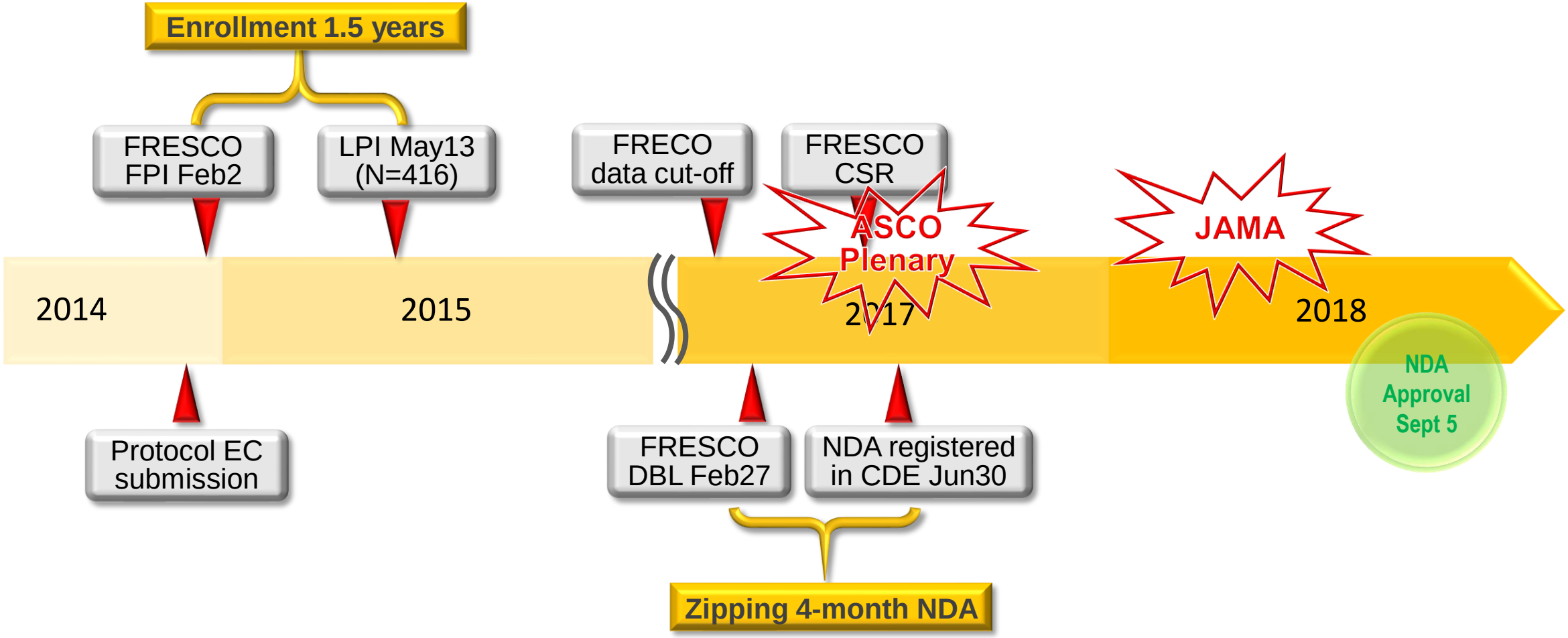


Seasoned Management Team with Track Records

- **Ye Hua, MD, MPH, Chairman and CEO**
  - Over 20 years of experience in clinical development and regulatory submissions in global Pharma/Biotech industry
  - Contributed multiple blockbuster brands global regulatory approval, including Humira, Reclast/Zometa, Revlimid and Pomalyst in USA, EU and China
- **Bryan Huang, Ph.D., MBA, CFO and Chief Strategy Officer**
  - Over 20 years of experience in pharmaceutical industry and healthcare investment banking
  - Recently Head of business development and strategy at Immunomedics and former lead of business development search, valuation and portfolio strategy at Celgene
- **Ying Huang, Ph.D., SVP & Head of Drug Discovery (Small Molecule)**
  - Competent leader in leading multi-functional team to develop small molecule cancer drugs with 20+ years industrial experience
  - Led a global oncology project at Novartis in delivering first-in-class EED inhibitor MAK683 from hit finding to FIH within 4.5 years
- **Yu Wang, Medical Director**
  - Hematologist by training and research physician for new drug development in hematology
  - Former Medical Director at FusonKite, leading CAR-T program
- **Wenwu Huang, Head of Regulatory Affairs**
  - Over 15 years of experience in domestic pharmaceutical industry leading development and regulatory strategy
  - Former Deputy GM of Shanghai Shyndec Pharmaceutical Co. Ltd R&D center

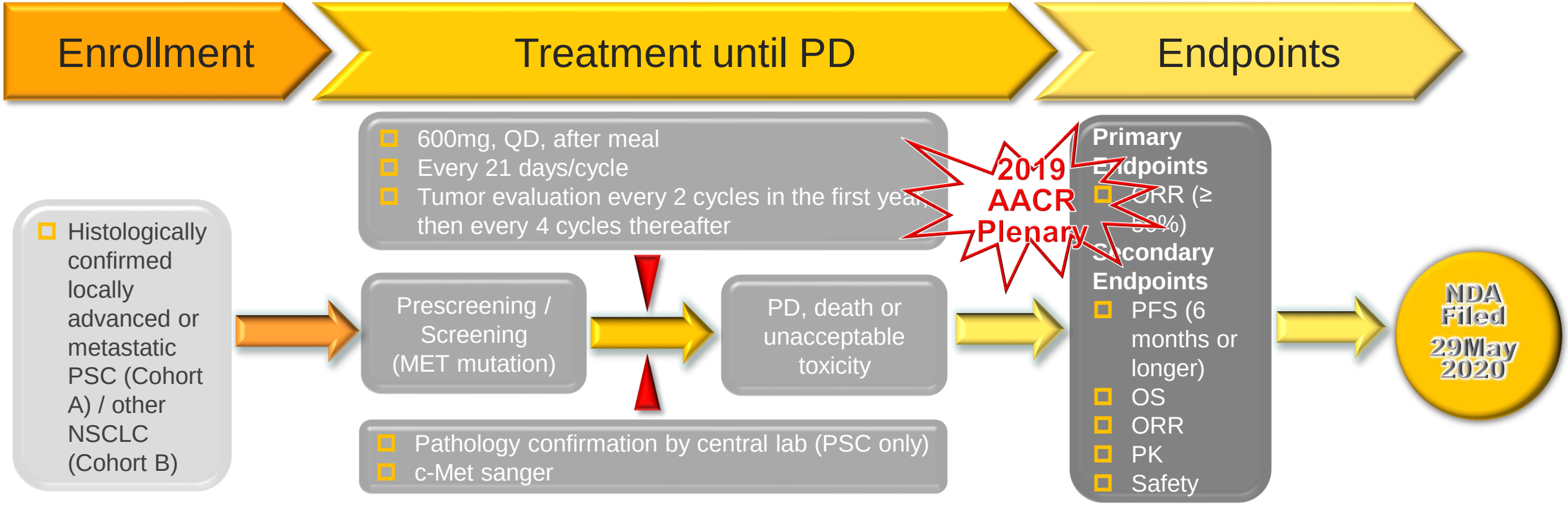
Fruquintinib in 3L mCRC (FRESCO)

– A management case study of trial conduct excellence



Savolitinib MET exon 14 mut NSCLC

– A management case study from impossible to breakthrough



- **Multi-center, single-arm, open-label Phase 2 trial, treatment until PD, death, toxicity, or withdrawal**
- **Simon two-stage design**
  - Null hypothesis: ORR≤30%, alternative hypothesis: ORR ≥50%
  - Significance level of 0.05 for a two-sided test, with a power of 80%
  - Stage one: 15 patients for each cohort, PR patients≤5, reject alternative hypothesis
  - Stage two: 35 patients, all together 50 evaluable exon 14+ patients

Triple Jump - Pipeline Build-up and Growth Strategy

"Jump start" with licensing in clinical or IND-ready assets

- Quickly build-up pipeline with near-term clinical catalysts
- Focus on China right in areas that present with huge unmet medical needs but less "crowed"
- Innovative development and regulatory pathways that add value to partners

"Walking with 2 legs" by selective discovery for novel targets

- Carefully chosen targets with proven biology and fast to market potential
- Speedy discovery by capable partners with track record and capabilities
  - 1 year to PCC
  - 1.5 to 2 years to IND
- Limited investment with fully owned IP and substantial upside

Biotech with global presence

- US IND for "home grown" novel target agents for global simultaneous development
- Out-licensing opportunities for ex-China development and commercialization

Pipeline Overview

Product Candidate	Target	Indication	Discovery	IND Enabling	Phase 1	Phase 2	Phase 3	Commercial Rights
BN101/ KD025	ROCK2	cGVHD, aGVHD				Pivotal		China
BN102	BTK (reversible)	CLL/SLL, MCL, WM, MZL						China
BN103	Undisclosed	Hematology						Global
BN104	Undisclosed	Hematology						Global

BN101

FDA Breakthrough Therapy Designation for cGVHD

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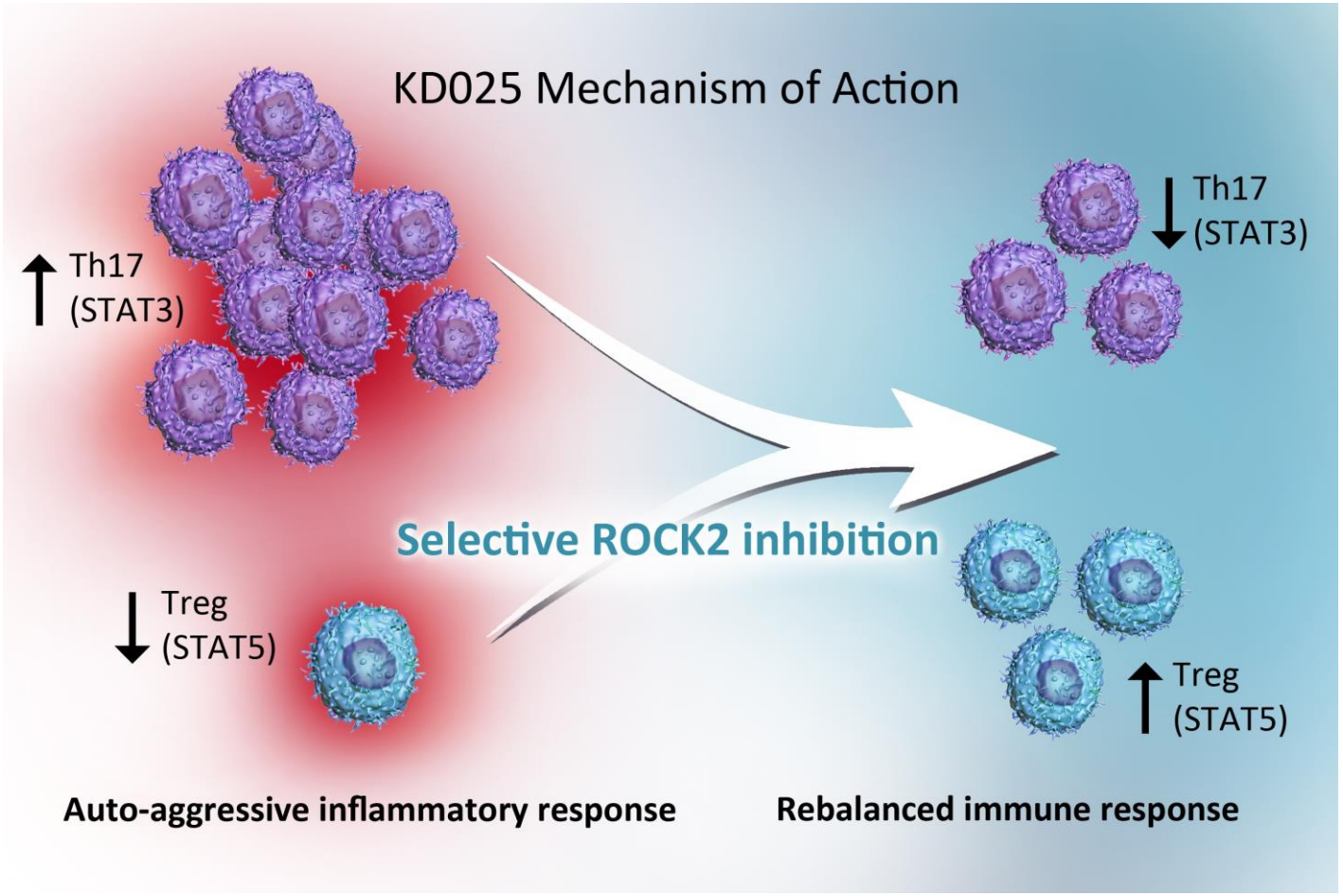
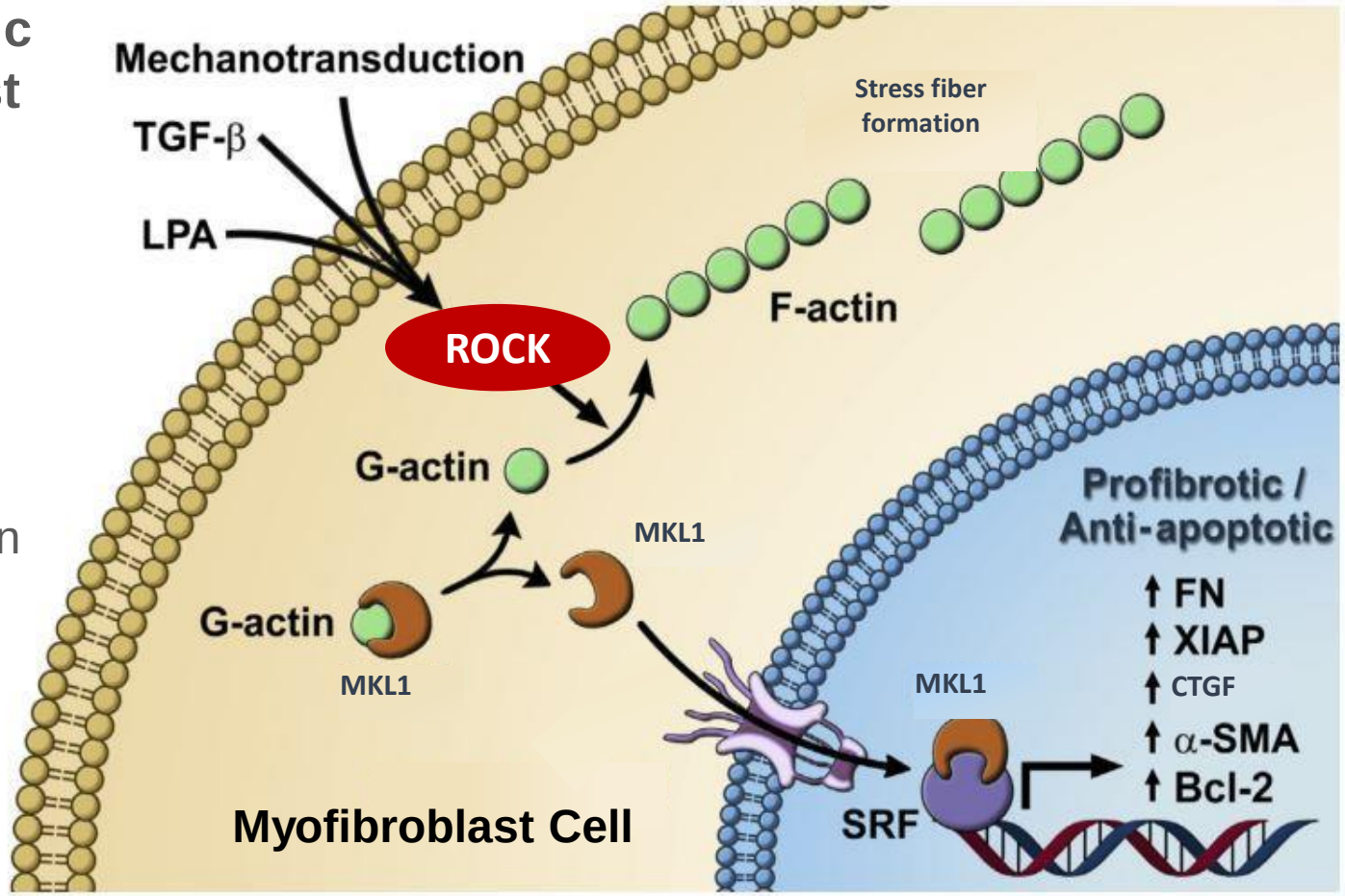
BN 101 /KD025 – A selective ROCK2 Inhibitor

- **ROCK2 inhibition downregulates pro-inflammatory Th17 responses and increases Treg function**
  - Reduces STAT3 phosphorylation and increases STAT5 phosphorylation
- **ROCK2 inhibition re-establishes immune homeostasis**



ROCK is an Intracellular Integrator of Pro-fibrotic Signal

- **ROCK regulates multiple profibrotic processes, including myofibroblast activation**
  - ROCK is downstream of major pro-fibrotic mediators
  - ROCK regulates fibroblast differentiation to myofibroblasts, a pathological cell type in fibrosis
  - ROCK mediates stress fiber formation
  - ROCK regulates transcription of pro-fibrotic genes



BN 101 /KD025 Clinical Development Summary

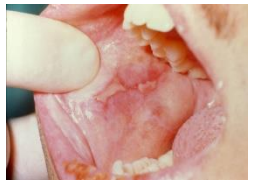
CT Code	Phase	Objective	Status
SLx-2119-09-01	Phase 1	Dose-Escalating, Safety, Tolerability, and PK Study in Healthy Male Subjects	Completed
KD025-101	Phase 1	Dose-Escalating Study to Examine the Safety and Tolerability of KD025 in Healthy Male Subjects	Completed
KD025-102	Phase 1	Dose-Escalating Study to Examine the Safety and Tolerability of KD025 in Healthy Male and Post-Menopausal Female Subjects	Completed
KD025-103	Phase 1	Study to Examine the Safety, Tolerability, and Pharmacokinetics of 500 mg KD025 Administered Twice Daily in Healthy Male and Post-Menopausal Female Subjects	Completed
KD025-105	Phase 1	Study to Examine the Safety, Pharmacokinetics, and Food Effect of 500 mg KD025 Administered Orally in Fed and Fasted States to Healthy Male Subjects	Completed
KD025-106	Phase 1	Study to Compare the Bioavailability of KD025 Tablet and Capsule in Healthy Male Subjects	Completed
KD025-107	Phase 1	Study to Evaluate the Effect of Itraconazole, Rifampicin, Rabeprazole and Omeprazole on the Pharmacokinetics of KD025	Completed
KD025-108	Phase 1	Study to assess the absolute bioavailability of KD025 and to determine the mass balance recovery, metabolite profile and identification of metabolite structures for [14C]-KD025 in healthy male subjects	Completed
KD025-109	Phase 1	Hepatic Impairment Study in Subjects With Normal Hepatic Function and Subjects With Varying Degrees of Hepatic Impairment	Ongoing
KD025-208	Phase 2	Study to Evaluate the Safety, Tolerability, and Activity of KD025 in Subjects With Chronic Graft Versus Host Disease	Completed
KD025-213	Phase 2	Study to Evaluate the Efficacy and Safety of KD025 in Subjects With cGVHD After At Least 2 Prior Lines of Systemic Therapy	Ongoing

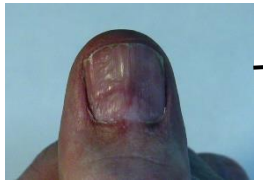
GVHD: A Debilitating Disease with High Unmet Need

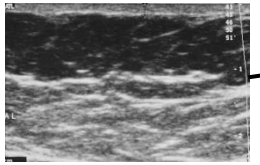
- Despite recent progress in the treatment of hematologic malignancies, bone marrow transplant remains the mainstay curative treatment
- With the emergence of highly effective CAR-T cell therapy, the number of patients eligible for allogenic stem cell transplant will grow significantly
- Graft versus Host Disease (GVHD) is a major complication post transplant. It is a serious, life threatening complications which often lead to multiple organ injuries and even to patient death.
- Acute GVHD (aGVHD) usually occurs within weeks or up to 100 days post transplant. Chronic GVHD (cGVHD) usually develops 3-6 months post transplant with or without prior aGVHD and can persist for years
- Approximately 30%-70% of stem cell transplant patients will develop a chronic form of GVHD with or without preexisting aGVHD
- Current standard care remains empirical with corticosteroid being the first line therapy albeit seriours side effects. More recently, targeted therapies such BTK inhibitor and JAK inhibitor have shown promising results in clinical trials, and ibrutinib has been approved in the US for relapsed/refractory cGVHD

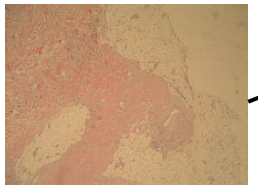
Spectrum of Manifestations in Chronic GVHD

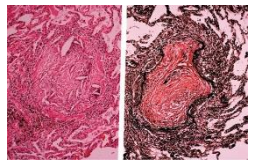

Ocular sicca

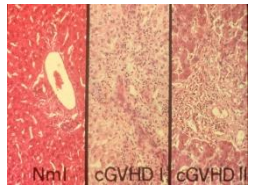

Oral ulcers


Nail dystrophy

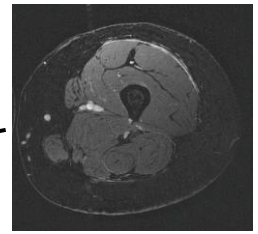

Skin sclerosis

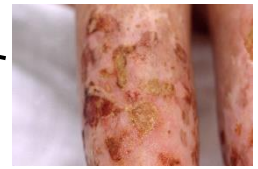

Deep sclerosis


Bronchiolitis obliterans

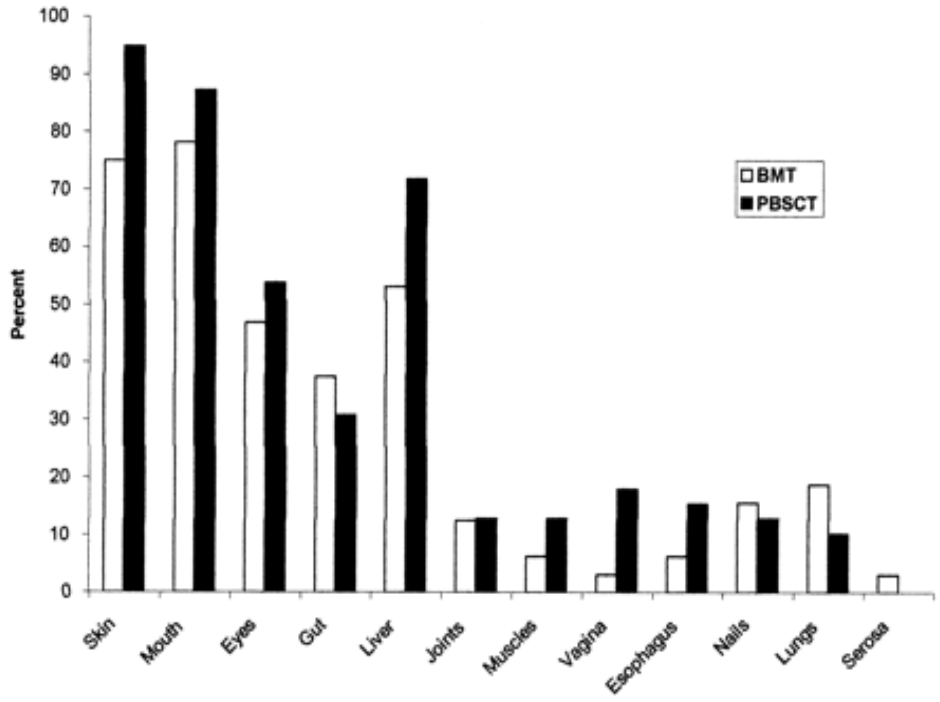


Loss of bile ducts


Fasciitis


Skin ulcers

cGVHD involves multiple organs



KD025-208: PoC Trial in cGVHD

- Adults with steroid-dependent or steroid-refractory cGVHD
- Have persistent active cGVHD after at least 2 months of steroid therapy
- 1-3 prior lines of treatment for cGVHD
- Receiving glucocorticoid therapy +/- calcineurin inhibitor therapy for cGVHD

Cohort 3: 400mg QD (N=21)

Cohort 2: 200mg BID (N=16)

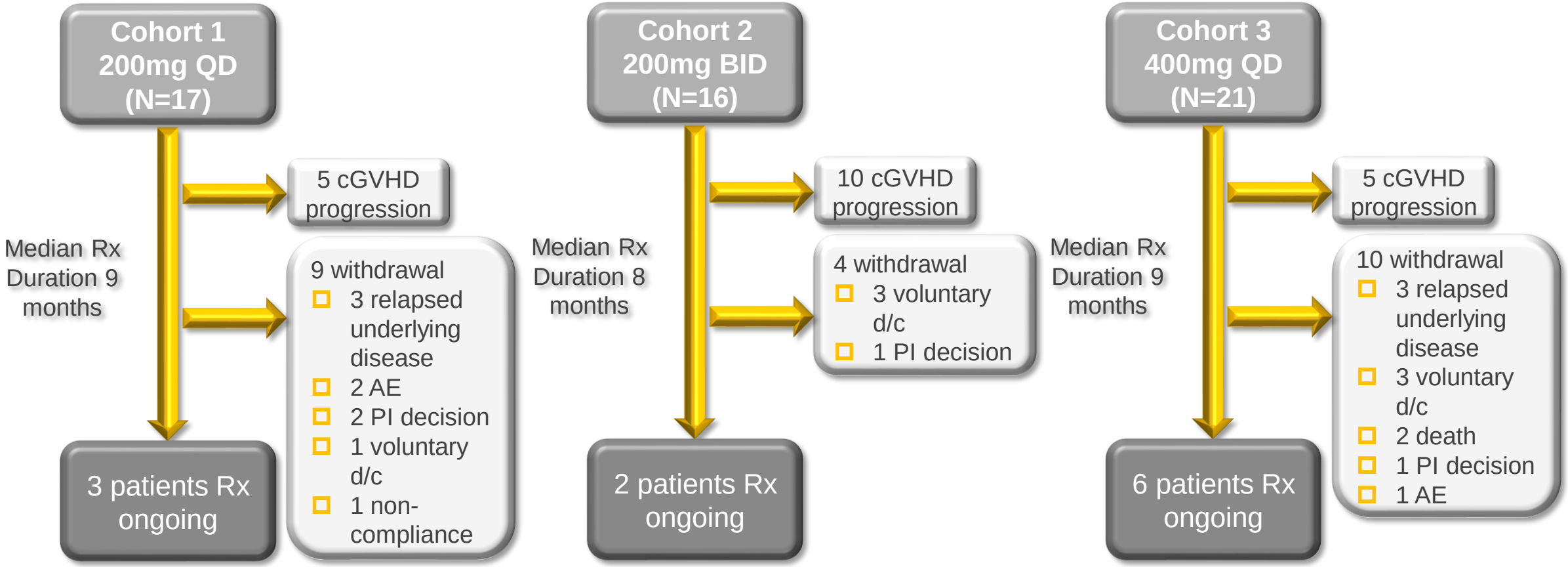
Cohort 1: 200mg QD (N=17)

Three cohorts enrolled sequentially, following safety assessment of previous cohort

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

KD025-208: Patient Disposition

All data as of 30Jun2019
Median follow up time: 24 months



KD025-208: Demographics and Baseline Characteristics

Demographics and Baseline Characteristics	Cohort 1 200 mg QD (N=17)	Cohort 2 200 mg BID (N=16)	Cohort 3 400 mg QD (N=21)
Median age [years (range)]	50 (20-63)	55 (30-75)	46 (25-75)
Male (%)	76	56	57
Median time cGVHD diagnosis to study (months)	26	18	16
Organ involvement, n (%)			
≥4 organs involved	8 (47)	10 (63)	9 (43)
Eyes	14 (82)	11 (69)	17 (81)
Skin	13 (76)	12 (75)	15 (71)
Mouth	13 (76)	11 (69)	11 (52)
Joints and fascia	11 (65)	11 (69)	12 (57)
Lungs	4 (24)	3 (19)	10 (48)
Upper GI	2 (12)	4 (25)	2 (10)
Esophagus	2 (12)	0 (0)	4 (19)
Lower GI	1 (6)	2 (13)	1 (5)
Liver	0 (0)	2 (13)	0 (0)

- 50% of all patients had ≥4 organs affected - included both inflammatory and fibrotic manifestations

KD025-208: Baseline Severity and Prior Therapies

Demographics and Baseline Characteristics	Cohort 1 200 mg QD (N=17)	Cohort 2 200 mg BID (N=16)	Cohort 3 400 mg QD (N=21)
Severe cGVHD[1], n (%)	12 (71)	14 (88)	16 (76)
Median prednisone dose at BL (mg/kg/day)	0.22	0.19	0.15
Prior lines of therapy[2]			
Median	3	2	2
≥2 prior lines of therapy , n (%)	15 (88)	8 (50)	12 (57)
Refractory to prior line of therapy[3] , n (%)	11/15 (73)	9/13 (69)	15/20 (75)

[1]Defined as at least 1 organ with NIH Activity Assessment score of 3, or lung score ≥2 at baseline

[2] ECP was not counted as a prior systemic therapy

[3] Status unknown for 6 subjects

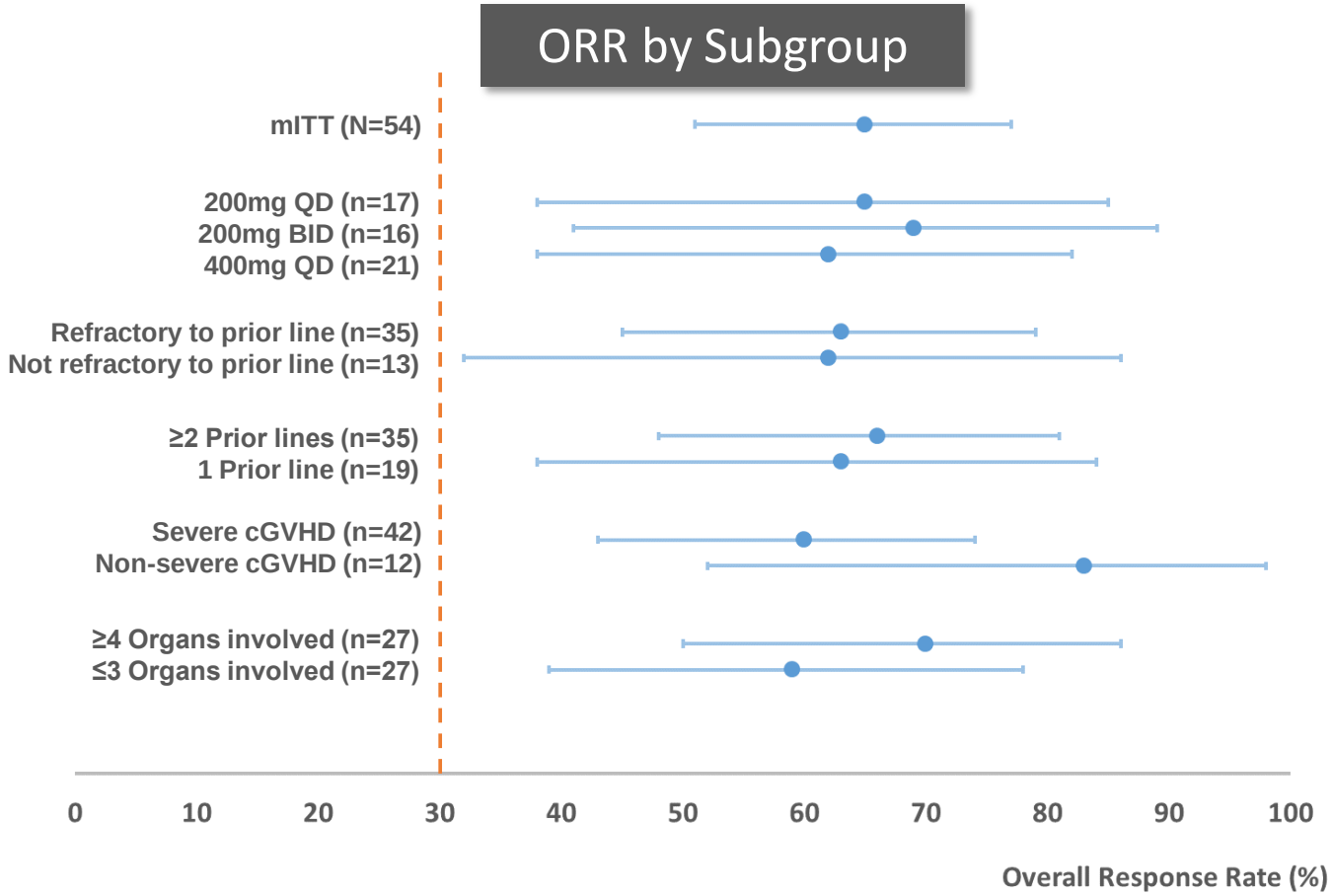
- 65% of all patients had received ≥2 prior lines of cGVHD therapy
- 73% refractory to prior line of therapy3

KD025-208: Overall Response Rate (ORR)

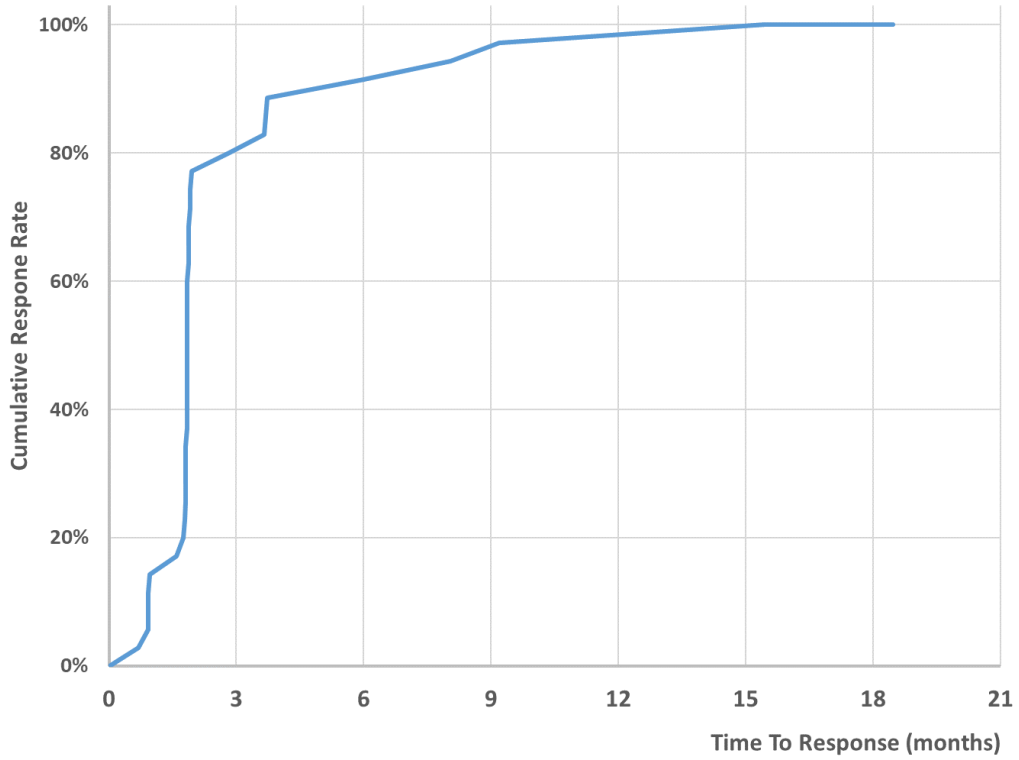
Cohort	N	ORR	95% CI
mITT	54	65%	(51, 77)
200 mg QD	17	65%	(38, 86)
200 mg BID	16	69%	(41, 89)
400 mg QD	21	62%	(38, 82)

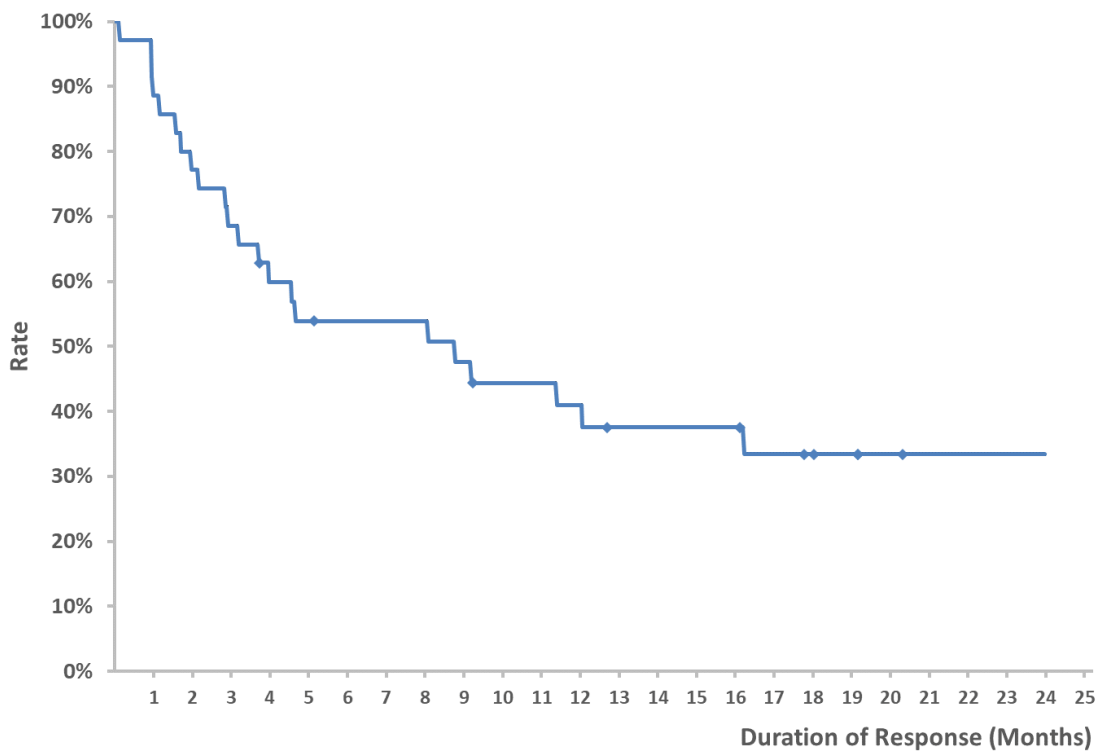
Responses observed across key subgroups

- Refractory to prior line: 63%
- ≥2 Prior lines of therapy: 66%
- Severe cGVHD: 60%
- ≥4 Organs involved: 70%



KD025-208: Timely and Durable Response





- Amongst responders, 75% of responses occurred by week 8 assessment
- Median DoR of 35 weeks (8 months) in mITT responders with 51% maintained for ≥ 20 weeks

KD025-208: Corticosteroid Dose Reduction during Therapy

Cohort	Cohort 1 (N=17) n (%)	Cohort 2 (N=16) n (%)	Cohort 3 (N=21) n (%)
Patients with corticosteroid dose reduction	13 (76)	9 (56)	13 (62)
Responders, % (n)	75 (n=11)	55 (n=11)	65 (n=13)
Non-Responders, % (n)	21 (n=6)	33 (n=5)	0 (n=8)

- **19% of patients have completely discontinued corticosteroids**
- **65% achieved corticosteroid dose reductions**
- **Median corticosteroid dose reduction: 50%**
- **Corticosteroid dose reductions observed in responders and non-responders**

KD025-208: Safety and Tolerability

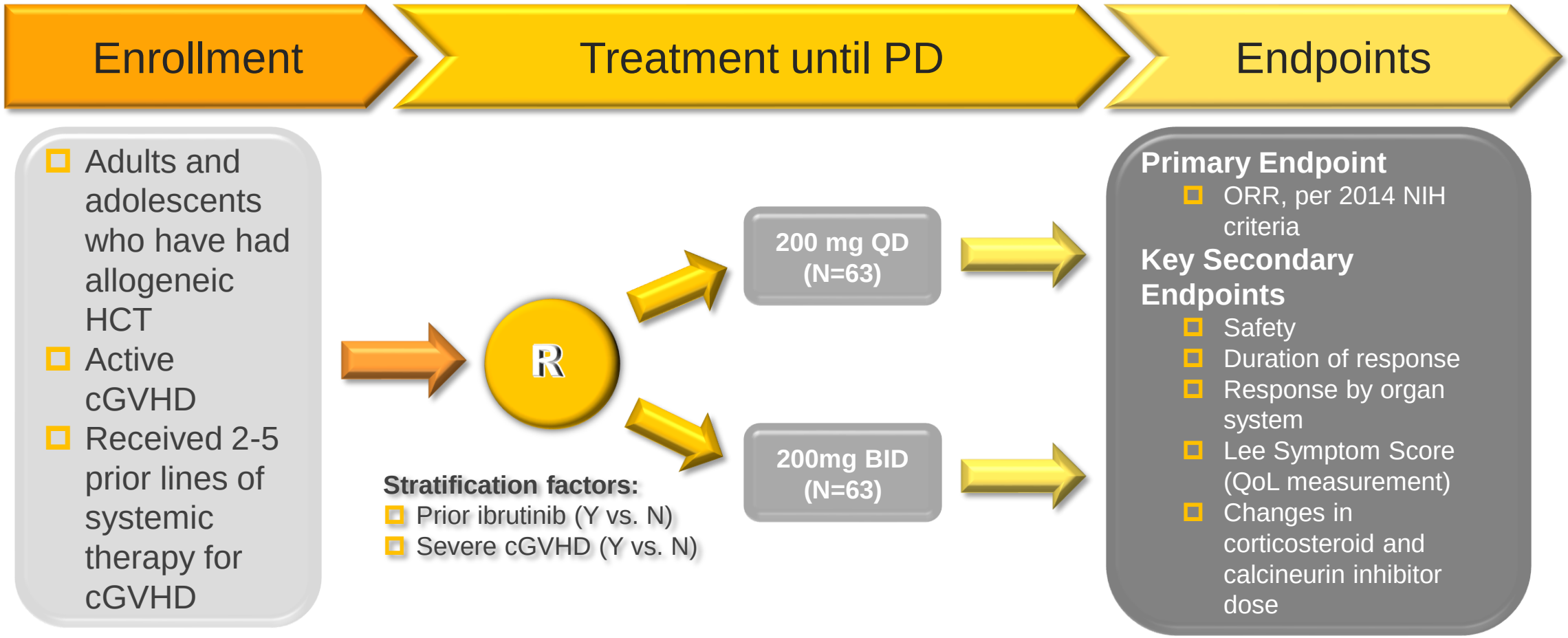
Safety Overview	Cohort 1 (N=17) n (%)	Cohort 2 (N=16) n (%)	Cohort 3 (N=21) n (%)	ITT (n=54) n (%)
Median weeks of treatment	37	33	39	36
Any Adverse Event (AE)	17 (100)	16 (100)	20 (95)	53 (98)
Grade 3/4 AE	9 (53)	11 (69)	10 (48)	30 (56)
SAE	5 (29)	6 (38)	12 (57)	23 (43)
Drug related AE				
Any related AE	7 (41)	9 (56)	14 (67)	30 (56)
Related AE leading to discontinuation[1]	2 (12)	0	1 (5)	3 (6)
Related Grade ≥3 event	1 (6)	4 (25)	2 (10)	7 (13)

[1] Cohort 1: Headache; Diarrhea. Cohort 3: Fatigue

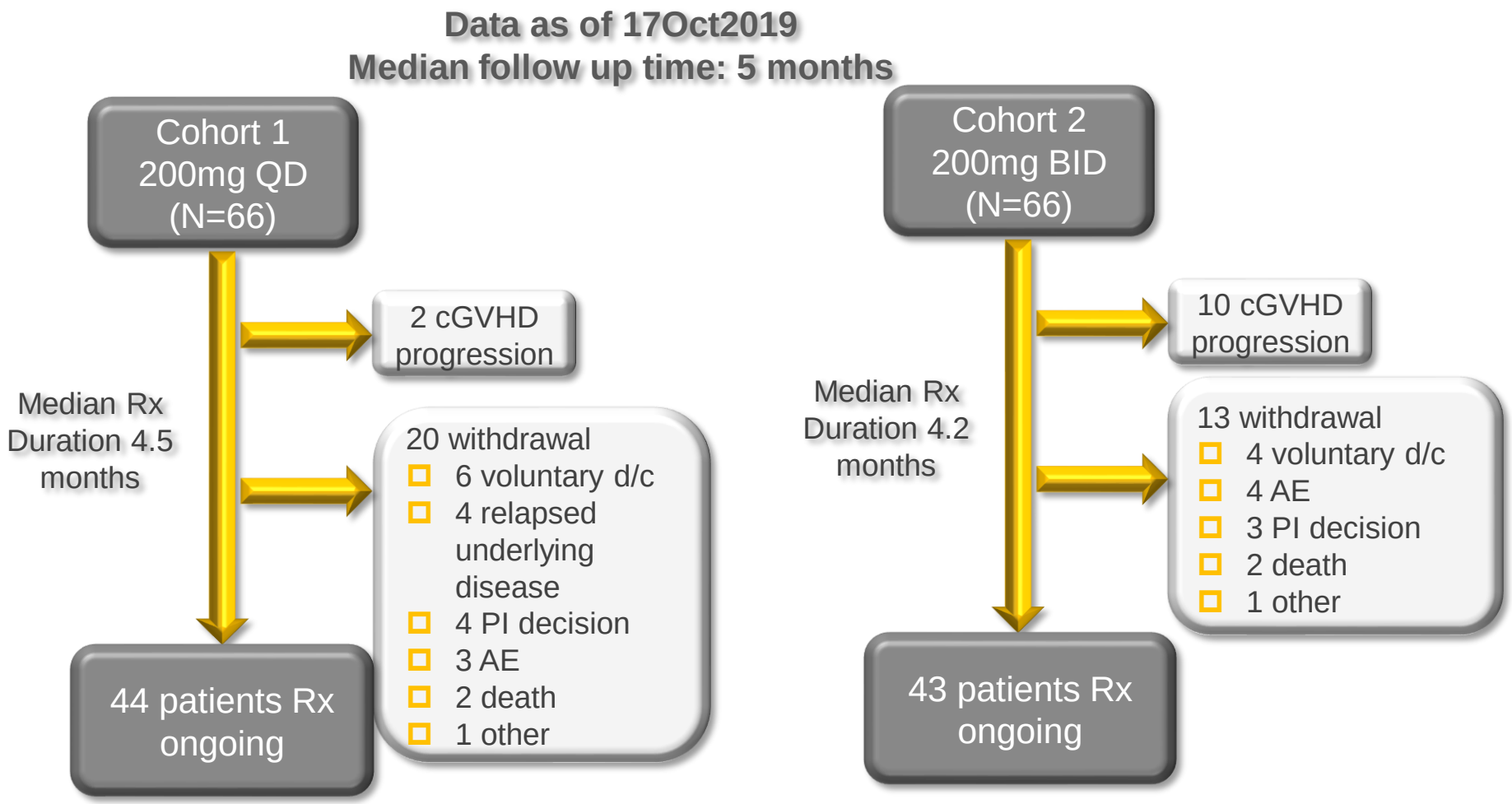
- **AEs were overall consistent with those expected in cGVHD patients receiving corticosteroids**
- **No apparent increased risk of infection**
  - No CMV infection reported
  - No significant drug-related cytopenias

Commonly reported AE n (%)	Cohort 1 (N=17) n (%)	Cohort 2 (N=16) n (%)	Cohort 3 (N=21) n (%)	ITT (n=54) n (%)
All Grade AE (≥20%)				
Upper respiratory tract infection	9 (53)	9 (56)	7 (33)	25 (46)
Diarrhea	6 (35)	5 (31)	7 (33)	18 (33)
Nausea	6 (35)	4 (25)	8 (38)	18 (33)
ALT/AST increased (SMQ Broad)	8 (47)	7 (44)	3 (14)	18 (33)
Fatigue	5 (29)	3 (19)	9 (43)	17 (32)
Dyspnea	3 (18)	6 (38)	7 (33)	16 (30)
Headache	4 (24)	3 (19)	6 (29)	13 (24)
Edema	3 (17)	4 (25)	6 (29)	13 (24)
Cough	1 (6)	4 (25)	7 (33)	12 (22)
Hypertension	5 (29)	2 (13)	4 (19)	11 (20)
Grade ≥3 AE (≥5%)				
Dyspnea	1 (6)	2 (13)	5 (24)	8 (15)
Lung Infection / Pneumonia	1 (6)	2 (11)	5 (24)	8 (15)
ALT/AST increased (SMQ Broad)	2 (12)	3 (19)	0	5 (9)
Hypoxia	1 (6)	1 (6)	3 (14)	5 (9)
Hyperglycemia	2 (12)	0	2 (10)	4 (7)
Anemia	2 (12)	1 (6)	0	3 (6)

ROCKstar (KD025-213) Registration Trial for cGVHD



ROCKstar (KD025-213) Patient Disposition



ROCKstar (KD025-213) Baseline Severity and Prior Therapies
(Data as of 19Feb2020, 6 months post LPI)

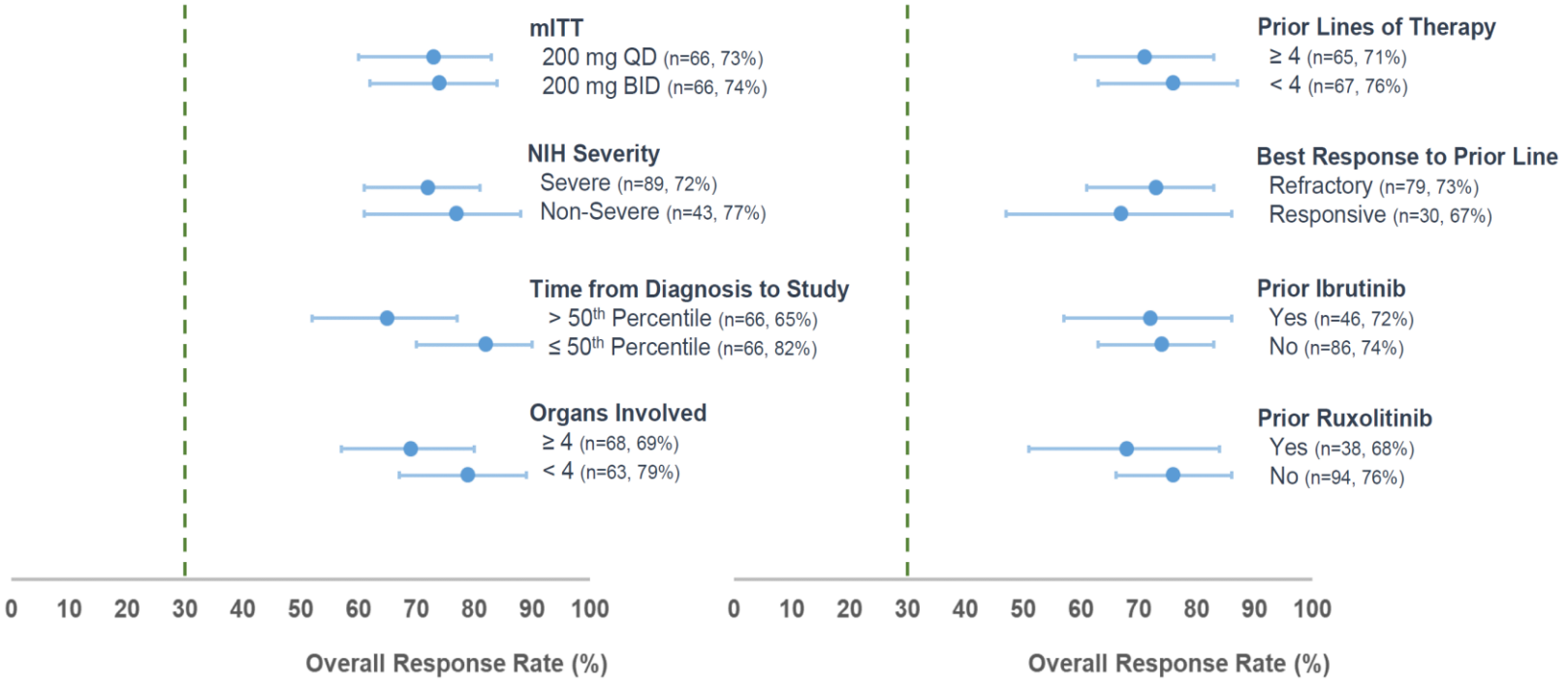
Demographics and Baseline Characteristics	Cohort 1 200 mg QD (N=66)	Cohort 2 200 mg BID (N=66)	Overall (N=132)
Severe cGVHD[1], n (%)	45 (68)	42 (64)	87 (66)
Median prior lines of therapy	3	4	4
Median prednisone dose at BL (mg/kg/day)	0.2	0.2	
≥4 organs involved, n (%)	33 (50)	35 (53)	68 (52)
Refractory to prior line of therapy (excluding UKN), n/N (%)	45/56 (80)	34/53 (64)	79/109 (72)

[1]Defined as at least 1 organ with NIH Activity Assessment score of 3, or lung score ≥2 at baseline

- **Majority of patients had received ≥2 prior lines of cGVHD therapy**
- **Majority of patients had ≥2 organ involved**
- **72% refractory to prior line of therapy**

ROCKstar (KD025-213) Topline Results of Primary Analyses
(Data as of 19Feb2020, 6 months post LPI)

Cohort	N	ORR	95% CI
200 mg QD	66	73%	(60, 83)
200 mg BID	66	74%	(62, 84)



- KD025 achieved clinically and statistically significant ORR in both arms
- Complete responses have observed in all affected organ systems
- Four patients achieved overall CR
- Consistent ORRs across all key subgroups
- Durable responses at 6 months data cut-off (median follow-up=34 weeks)
  - 49% of responders have maintained responses for ≥ 20 weeks
  - Median duration of response (DOR) has not yet been reached

ROCKstar (KD025-213) Safety and Tolerability
(Data as of 17Oct2019, 2 months post LPI data)

Safety Overview n (%)	Cohort 1 200 mg QD (N=66)	Cohort 2 200 mg BID (N=66)	Overall (N=132)
Median months of treatment	4.2	4.5	4.3
Any Adverse Event (AE)	64 (97)	61 (92)	125 (95)
Grade 3/4 AE	23 (35)	27 (41)	50 (38)
SAE	22 (33)	15 (23)	37 (28)
Drug related AE			
Any related AE	38 (58)	28 (42)	66 (50)
Related SAE	3 (5)	1 (2)	4 (3)
On study death[1]	4 (6)	1 (2)	5 (4)

[1] KD025 QD: Aspiration pneumonia; Hemoptysis; MODS/Septic shock; Relapse AML.
KD025 BID: Cardiac arrest.

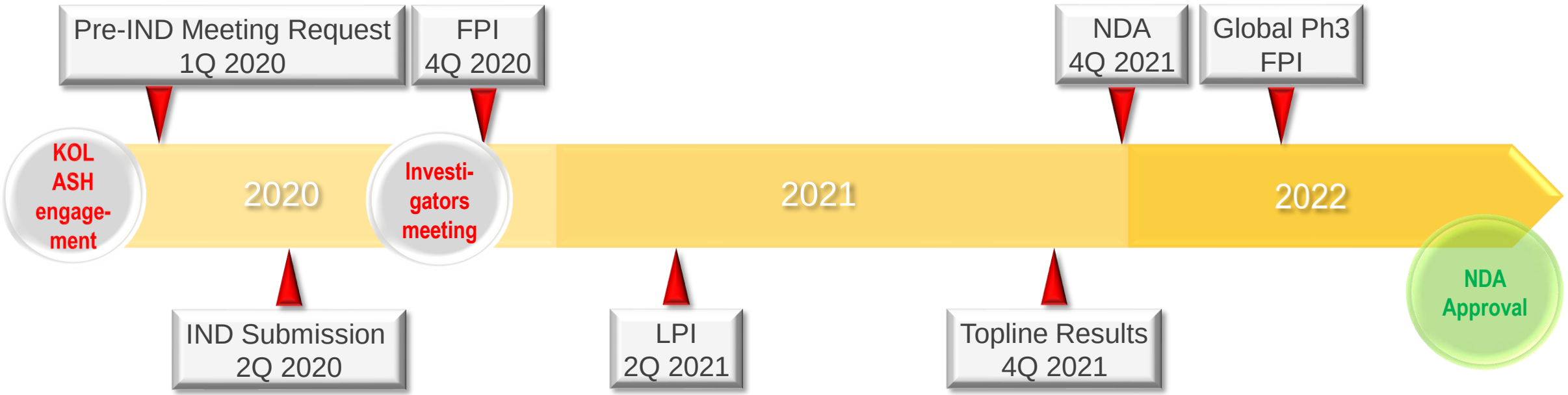
- **AEs were overall consistent with those expected in cGVHD patients receiving corticosteroids**
- **No apparent increased risk of infection**
  - No CMV infection reported

Commonly reported AE n (%)	Cohort 1 200 mg QD (N=66)	Cohort 2 200 mg BID (N=66)	Overall (N=132)
All Grade AE (≥10%)			
Fatigue	20 (30)	12 (18)	32 (24)
Diarrhea	16 (24)	12 (18)	28 (21)
Nausea	15 (23)	13 (20)	28 (21)
Liver related investigations (SMQB)	13 (20)	14 (21)	27 (20)
Peripheral edema	16 (24)	10 (15)	26 (20)
Cough	12 (18)	9 (14)	21 (16)
Dyspnea	13 (20)	8 (12)	21 (16)
Headache	10 (15)	9 (14)	19 (14)
Vomiting	11 (17)	7 (11)	18 (14)
Hypertension	8 (12)	9 (14)	17 (13)
Muscle spasm	9 (14)	7 (11)	16 (12)
URTI	6 (9)	10 (15)	16 (12)
Pyrexia	11 (17)	4 (6)	15 (11)
Hyperglycemia	7 (11)	7 (11)	14 (11)
≥ Grade 3 (≥ 3%)			
Hypertension	3 (5)	4 (6)	7 (5)
Hyperglycemia	2 (3)	3 (5)	5 (4)
Pneumonia	2(3)	3(5)	5 (4)
GGT increased	3 (5)	1 (2)	4 (3)
Nausea	3 (5)	1(2)	4 (3)
Vomiting	3 (5)	1 (2)	4 (3)

BN101/KD025 in cGVHD: US Regulatory Pathway

- **BN101/KD025 met the primary endpoint at interim analysis of the pivotal trial (KD025-213) in cGVHD**
  - 64% ORR with BN101/KD025 200 mg QD (95% CI: 51%, 75%)
  - 67% ORR with BN101/KD025 200 mg BID (95% CI: 54%, 78%)
- **FDA granted Breakthrough Therapy Designation in cGVHD after at least 2 prior lines of systemic therapy (Oct 2018)**
- **Positive pre-NDA meeting with FDA for BN101/KD025 in cGVHD 12Mar2020**
- **Superb topline results released on 21May2020**
- **Data to be presented at upcoming scientific meetings in its due course**
- **Kadmon on track for completing BN101/KD025 NDA rolling submission in 4Q2020 under the Real-Time Oncology Review (RTOR)**

BN101/KD025 Development Timeline in China



BN102

A highly selective, potent reversible BTK inhibitor

BIONOVA Pharma 烨辉医药

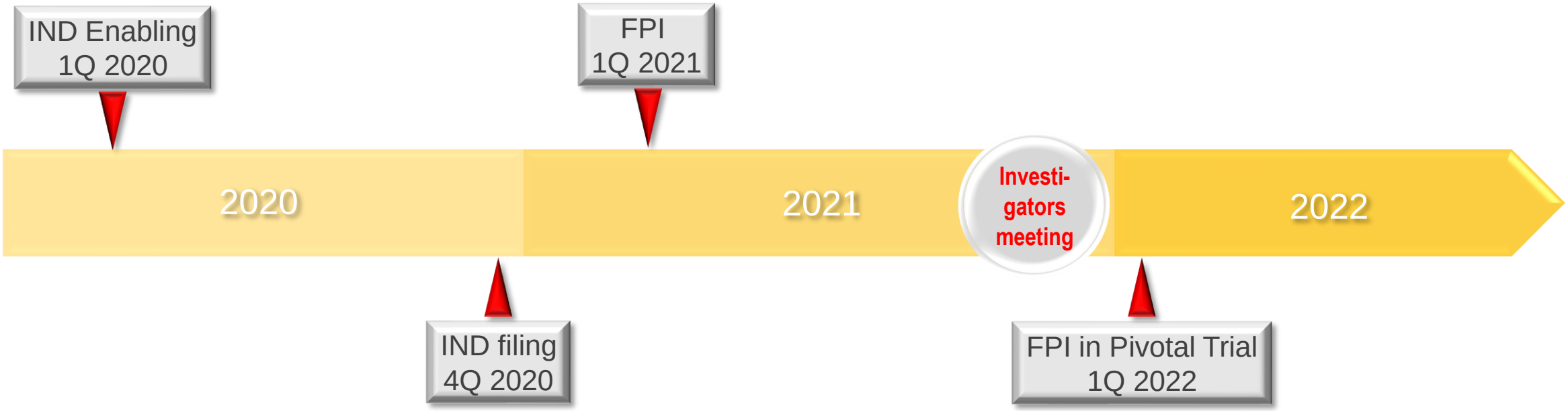
BTK - The Validated Target in B-cell Signaling Pathway

- **First generation covalent bound BTK inhibitors have achieved great success**
  - First generation BTK inhibitors are covalent bound and irreversible
  - 2019 global sales were >8B USD; peak sales is expected to be >9B USD in 2024
  - Irreversible BTK inhibitors are expected to become a mainstay therapy for B-cell malignancies such as CLL/SLL, MCL, MZL and WM
- **However, acquired resistance to first generation BTK inhibitors are emerging**
  - C481S mutation, the most common type of treatment resistance occurs in >50% patients treated with irreversible BTK inhibitors
  - No effective therapy to date for patients developed C481S mutation which presents a high unmet medical need and large commercial opportunity
- **Next generation reversible BTK inhibitors are effective against BTK WT & MT**
  - Currently 3 reversible BTK inhibitors are in Phase 1 clinical stage in the US, but none in China
  - While >7 domestic companies are developing irreversible BTK inhibitors including BeiGene, we are not aware of reversible BTK inhibitors through due diligence patent search

Reversible BTK Inhibitors in Development

- **Most advanced reversible BTKi ARQ531 (ArQule),**
  - Just completed Phase 1 dose escalation, entering Phase 2 dose expansion
  - Updated data at ASH 2019 showed 8/9 responses in relapsed/refractory CLL patients with C481S
  - As a result, ArQule was acquired by Merck for $2.7B
- **SNS-062 (Sunesis)**
  - in Phase 1 dose escalation with current dose level at 300 mg BID
  - No responses observed to date
  - Dose escalation is expected to continue
- **LOXO-305 (now Lilly)**
  - In Phase 1 dose escalation
  - Promising initial efficacy data presented at ASH 2019 across all dose levels
    - 10/13 CLL showed responses of which 4/6 PR were observed in patients progressed on BTK inhibitor
  - Safety profile appears very clean for up to 200mg QD
- **BN102 is a highly selective and potent reversible BTK inhibitor, with IND expected in 4Q2020**

BN102 Development Timeline in China



Thank you

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