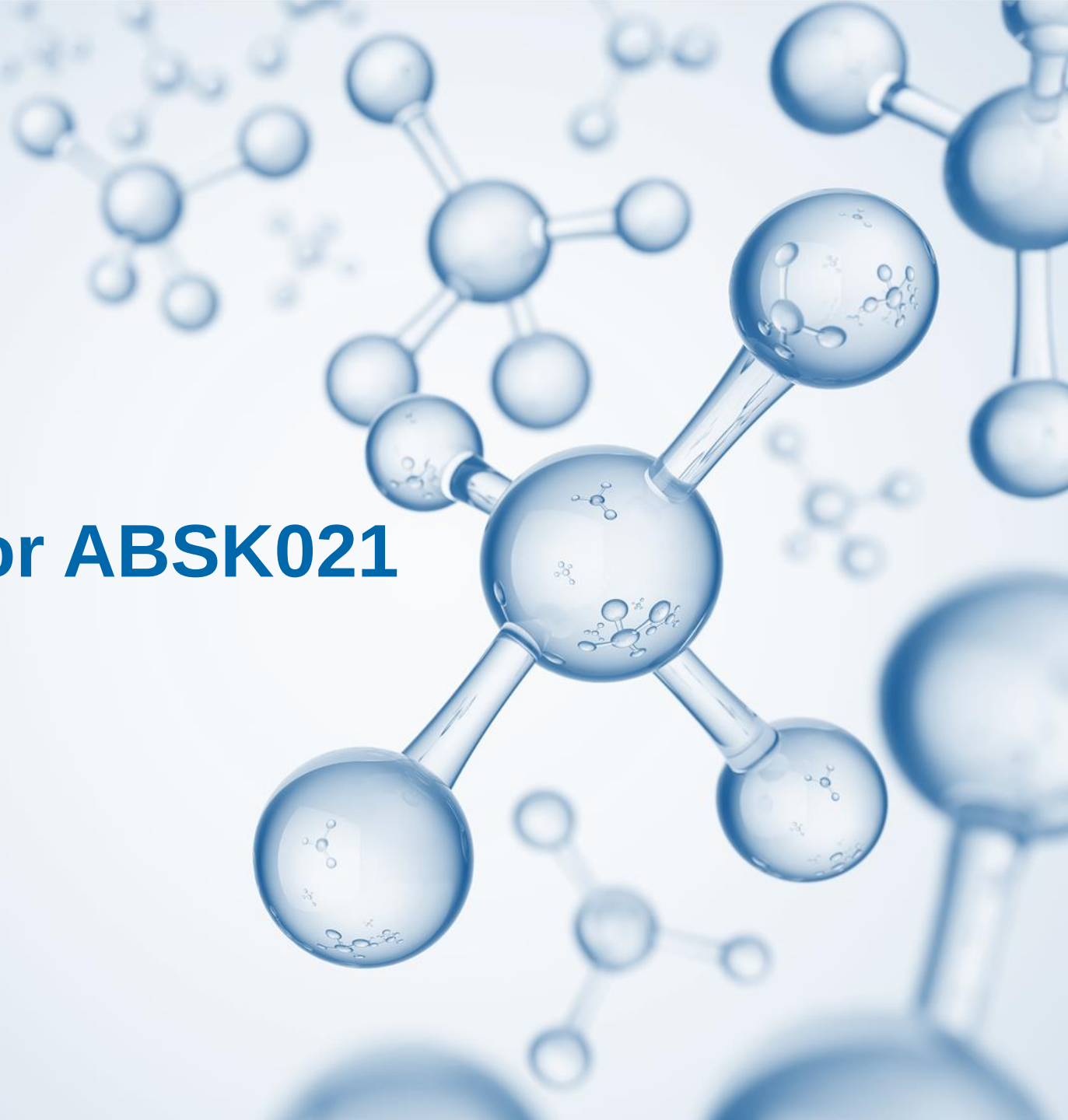
Clinical Data Readout for ABSK021

Abbisko Therapeutics

November 18th, 2022



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OPENING REMARKS

Dr. Yao-Chang Xu

We Are Rapidly Advancing A Clinical Portfolio of 7 Programs from Early to Pivotal Stage

Asset	Target	Trial / indication	Discovery	IND-enabling	Ph I / Ph Ia	POC [i]	Pivotal	Recent clinical development
ABSK021	**CSF-1R**	**TGCT**						• POC readout for TGCT cohort • CDE approval for Phase III trial • BTD granted by CDE
		Solid tumors						
		cGvHD						
		ALS [v]						
ABSK011	FGFR4	2L HCC, mono						Preliminary POC readout in 2H 2022
		1L/2L HCC, combo [ii]						Continuous patient enrollment
ABSK091 [iv]	Pan-FGFR	2L UC, mono						Preliminary POC readout in 2H 2022
		1L/2L UC, combo [iii]						First patient dosed
ABSK061	FGFR2/3	Solid tumors						Continuous patient enrollment
ABSK121	FGFR mut.	Solid tumors						U.S. IND approval for Phase I study
ABSK043	PD-L1 (oral)	Solid tumors						China first patient dosed
ABSK081 [viii]	CXCR4	TNBC and other solid tumors [vi]						Continuous patient enrollment
		WHIM [vii]						

Abbreviations: HCC = hepatocellular carcinoma; UC = urothelial cancer; GC = gastric cancer; TGCT = tenosynovial giant cell tumor; cGvHD = chronic graft- versus-host disease; ALS = amyotrophic lateral sclerosis; TNBC = triple-negative breast cancer; WHIM = warts, hypogammaglobulinemia, infections and myelokathexis; BTD = Breakthrough Therapy Designation; CDE = Center for Drug Evaluation

i. Represents Phase Ib/II clinical trial ii. In combination with anti-PD-L1 antibody atezolizumab with Roche iii. In combination with anti-PD-1 antibody tislelizumab with Beigene iv. Global right in-licensed from AstraZeneca v. Mainland China, Hong Kong and Macau rights out-licensed to Sperogenix for ALS vi. In combination with anti-PD-1 antibody toripalimab with Junshi vii. Global Ph III trial in WHIM conducted by partner X4 viii. China right in-licensed from X4

Immuno-oncology programs

Precision oncology programs

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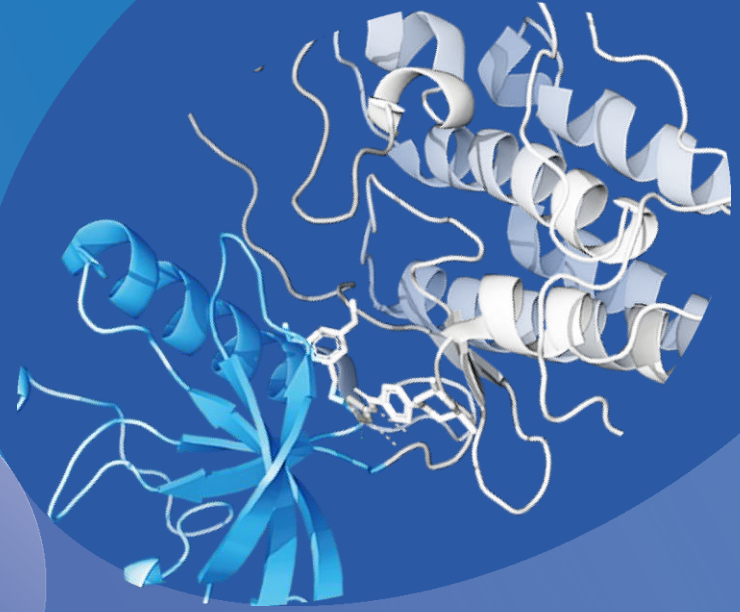
Phase Ib Proof-of-Concept data for ABSK021

Potential Best-in-Class CSF-1R Inhibitor



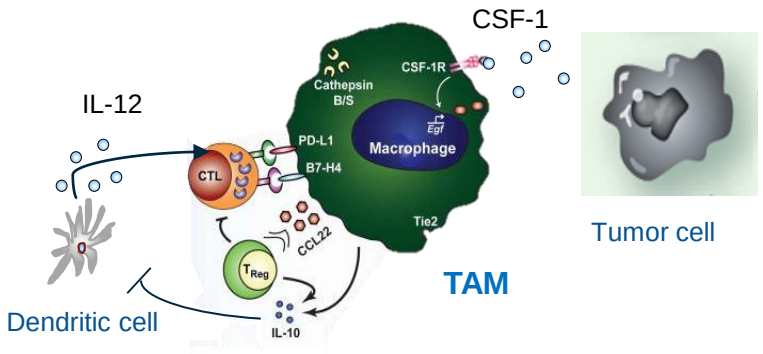
OVERVIEW OF CSF-1R INHIBITOR AND TGCT

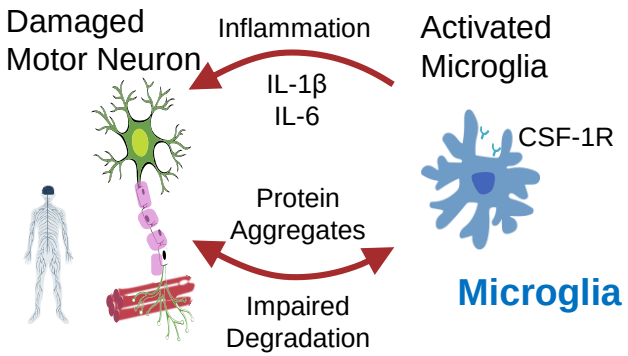
Dr. Zhui Chen

CSF-1R Is A Clinically Validated Target and Plays Critical Roles in Various Macrophage-Dependent Diseases with Significant Unmet Medical Needs

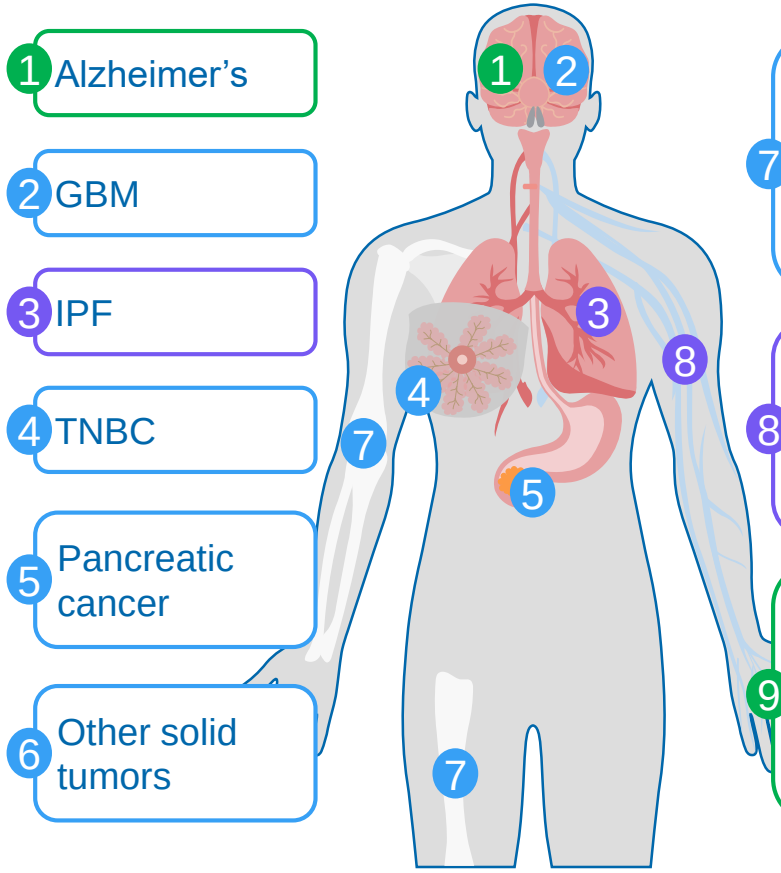
CSF-1R regulates many types of macrophages in human including:

- Tumor-associated macrophage (TAM), which plays a critical role in anti-tumor immunity.
- Microglia, which modulates neurogenesis and the function of neuron, associated with many neurodegenerative diseases.





Neuro-degenerative | Oncology | Other TAs



1. Alzheimer's
2. GBM
3. IPF
4. TNBC
5. Pancreatic cancer
6. Other solid tumors

7 TGCT

1 approved drug only with **limited efficacy and high toxicity**

Turalio pexidartinib 200 mg capsules

8 GvHD

High mortality after onset

axatilimab

PoC from CSF-1R mAb

9 ALS

Short survival with limited treatment[1]

masitinib

25% delay in disease progression[2]

1. Majority patients die 2-5 year within diagnosis. 2. Non-selective CSF-1Ri masitinib trial in ALS show inhibition of CSF-1R leads to increased PFS from 16mo (control) to 20mo (N=218).

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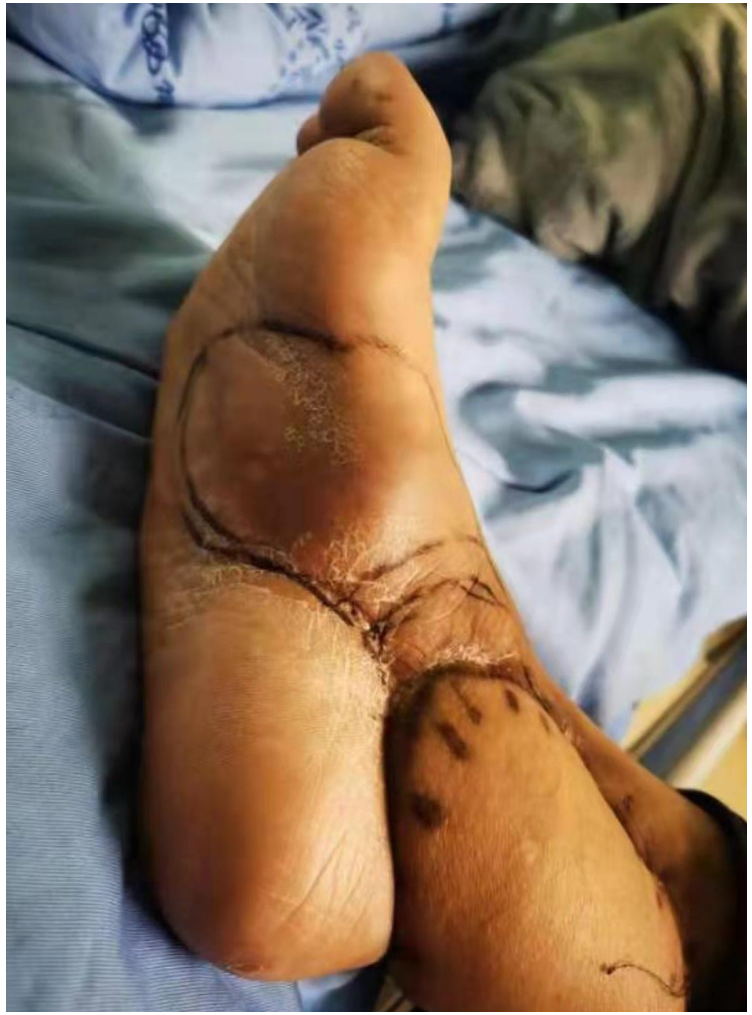
We Aim to Expand ABSK021 into Many CSF-1R-Dependent Diseases with Multi-Billion Dollars of Market Potential

Strategy	1 Accelerated development in TGCT	2 Expansion into other indications (many with potential orphan drug status)		3 Combo in broad oncology indications
Addressable patient no. (1)	**TGCT** China: ~60k US: ~14k	**cGvHD** China: ~6k US: ~14k (2)	**ALS** China: ~43k US: ~19k	**Solid tumors** >400k
Commercial potential (1)	>US$1.5bn	>US$0.5bn	>US$1.5bn	>US$6bn
CSF-1R SMI class competition	• 1 approved drug (pexidartinib) • 1 in pivotal trial (vimseltinib)	• No CSF-1R agents approved		• No CSF-1R agents approved
ABSK021 development status	• **POC achieved** • **BTD and Phase III trial approval** granted by CDE	• IND filed for cGvHD	• Trials in planning	• Trials in planning

1. Based on market research and internal analysis
2. Based on estimates by Syndax Pharmaceuticals

Tenosynovial Giant Cell Tumor (TGCT) Is A Disease with Large Patient Population and Significant Unmet Medical Needs Globally



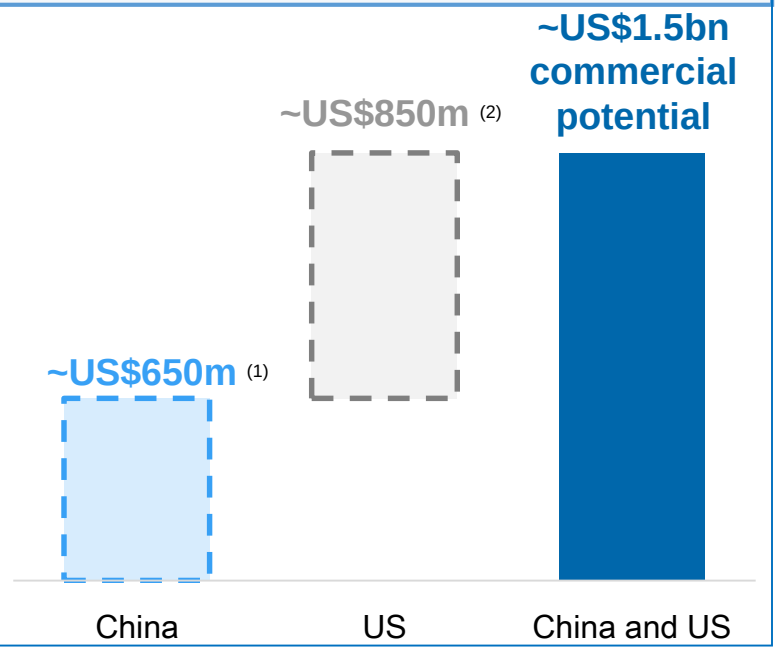
- Surgical resection is the standard treatment but with high recurrence rate.
- The only approved CSF-1R inhibitor, pexidartinib, has severe hepatotoxicity and was approved with black-box warning.

Commercial potential of CSF-1R inhibitors in TGCT (US$)

Annual incidence [3]:

~14,000 in U.S.

~60,000 in China



1. Based on internal analysis
2. Based on estimates from Deciphera Pharmaceuticals
3. Based on annual incidence rate of 43 cases per million people

ABSK021 – Translation of Preclinical Best-in-Class Profile into Clinic

Superior Pre-clinical Profile

- Significantly improved selectivity and activities
- Superior brain penetration and other drug-like properties across species
- Strong preclinical validation in oncology and ALS models
- Strong combination synergy with anti-PD-1/L1 or other agents

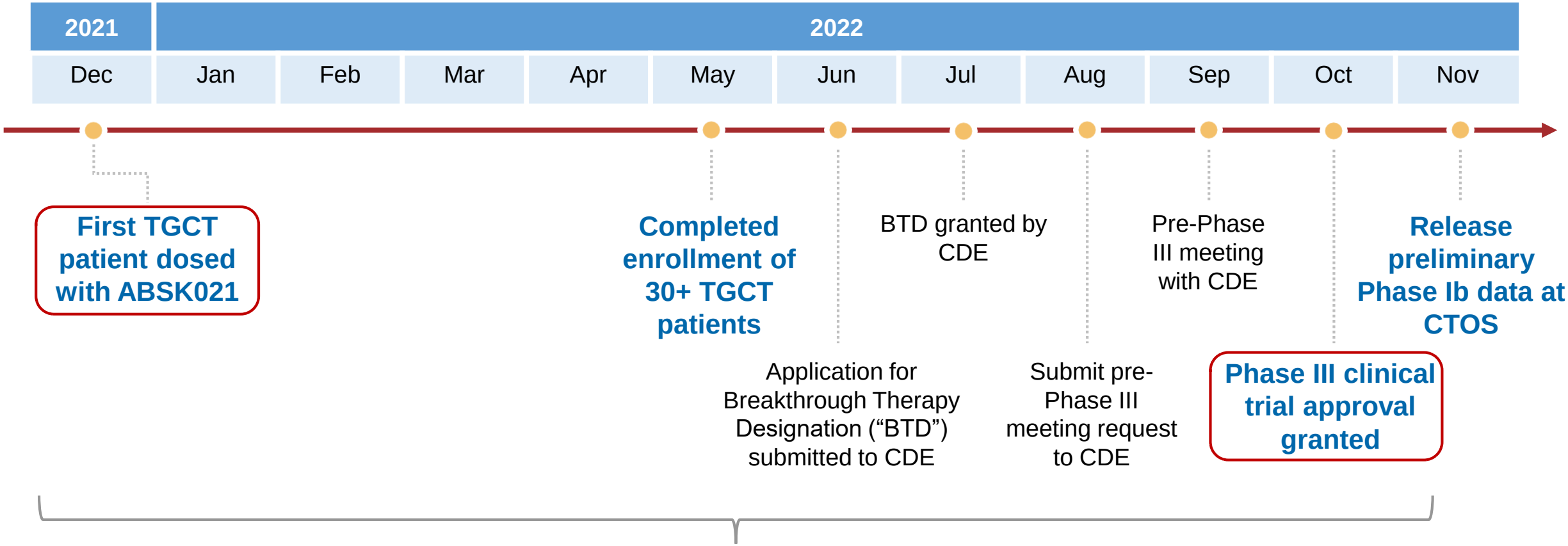
Clinical Advantages

1. **Excellent PK/PD profile in Phase Ia / Ib**
2. **Favorable safety profile in TGCT patients without apparent (grade 3 and above) hepatotoxicity**
3. **Potentially best-in-class efficacy and response in Phase Ib TGCT trial**

PROOF-OF-CONCEPT DATA OF ABSK021 IN TGCT

Dr. Jing Ji

Fast Clinical Development of ABSK021 in TGCT



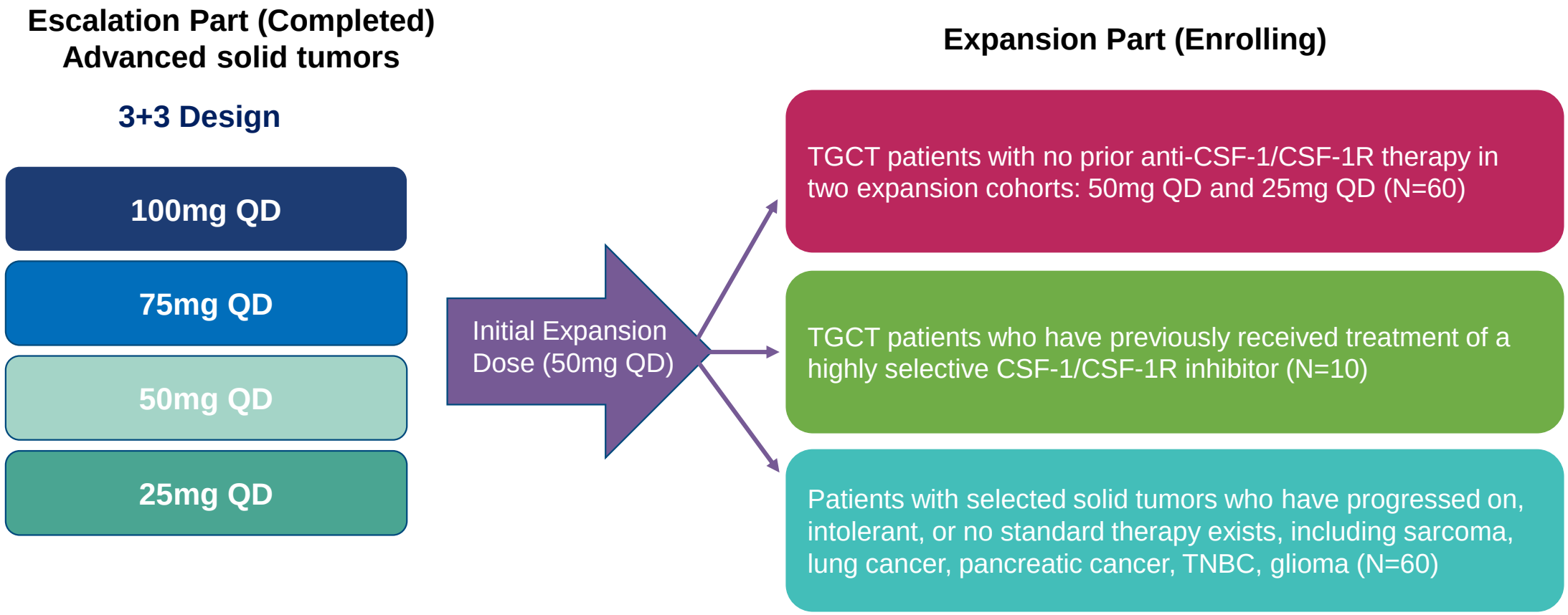
11 months

from first TGCT patient dosed to Phase III clinical trial approval granted by CDE

Study Design of ABSK021-101

Key Objectives:

- Escalation Part (Phase Ia): Safety, tolerability, PK, PD, MTD and RDE;
- Expansion Part (Phase Ib): RP2D and preliminary efficacy



Abbreviations: PK = Pharmacokinetics; PD = Pharmacodynamics; MTD = Maximum tolerated dose; RDE = Recommended dose for expansion; RP2D = Recommended Phase II dose

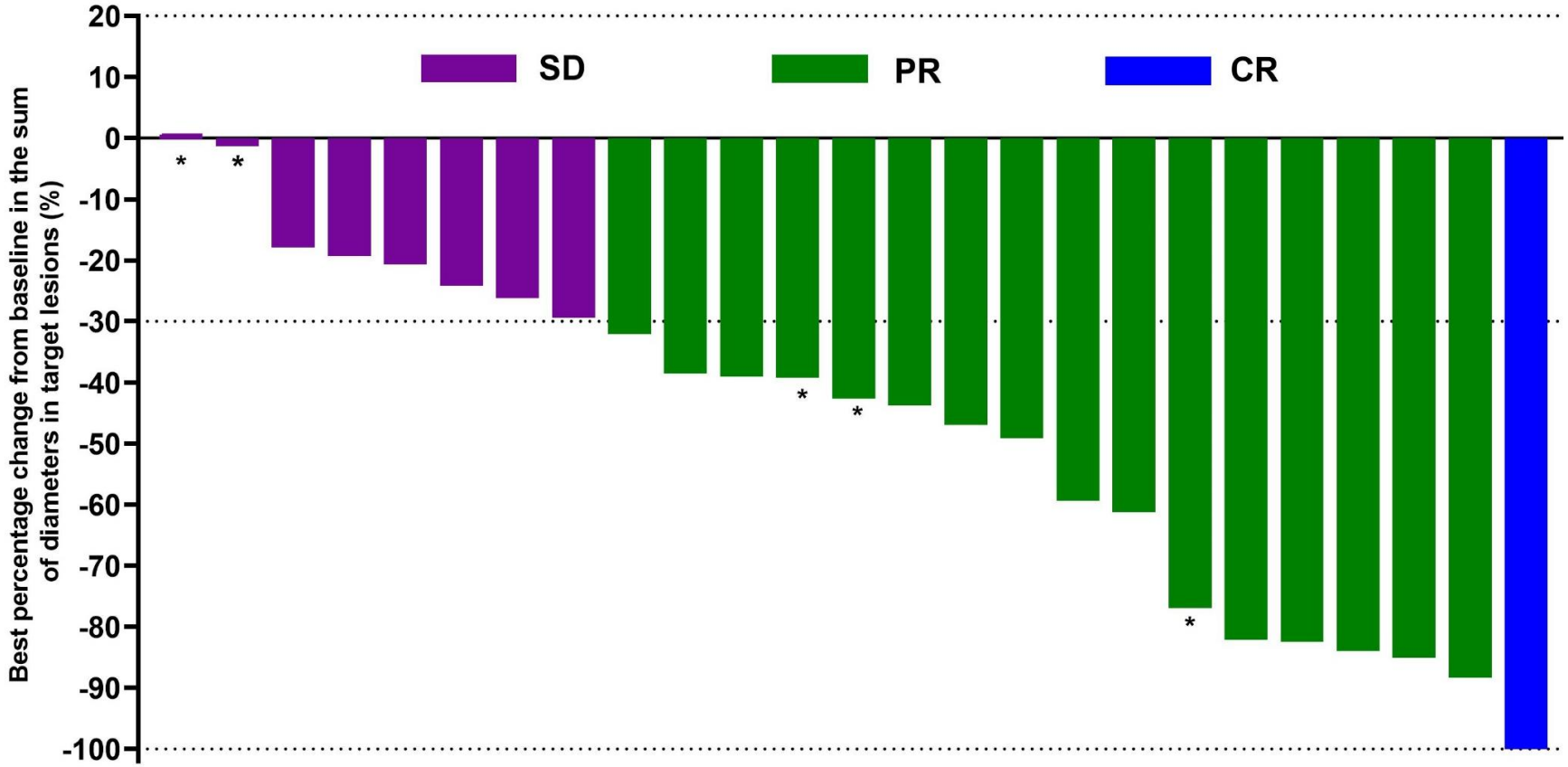
Baseline Demographics and Clinical Characteristics

TGCT (N=32)		
Median age (min, max), years	41 (24, 76)	
Sex, n (%)	Male	13 (40.6)
	Female	19 (59.4)
Race, n (%)	Asian	32 (100.0)
	Other	0
Disease location, n (%)	Knee	16 (50.0)
	Hip	7 (21.9)
	Ankle	4 (12.5)
	Foot	3 (9.4)
	Missing	2 (6.3)
Patients with prior systemic therapy, n (%)	No	31 (96.9)
	Anlotinib	1 (3.1)
Patients with at least one prior surgery, n (%)	No	12 (37.5)
	Yes	20 (62.5)

Cut-off date: 21 Sep 2022.

Preliminary Efficacy of ABSK021 in TGCT Patients of ABSK021-101

The preliminary objective response rate ("ORR") was **68.0%** (17/25, 95%CI: 46.50%-85.05%) by Independent Review Committee ("IRC") based on RECIST1.1, including **1 complete response** and **16 partial responses** within 6 months in patients receiving 50mg QD treatment. The preliminary disease control rate ("DCR") was **100%**.



Best percentage change from baseline by IRC (ORR: 68%; DCR: 100%)

* Represents tumor response at week 13.
25 out of 32 TGCT patients have completed at least one post-dose tumor response assessment by IRC. Cut-off date: 21 Sep 2022.

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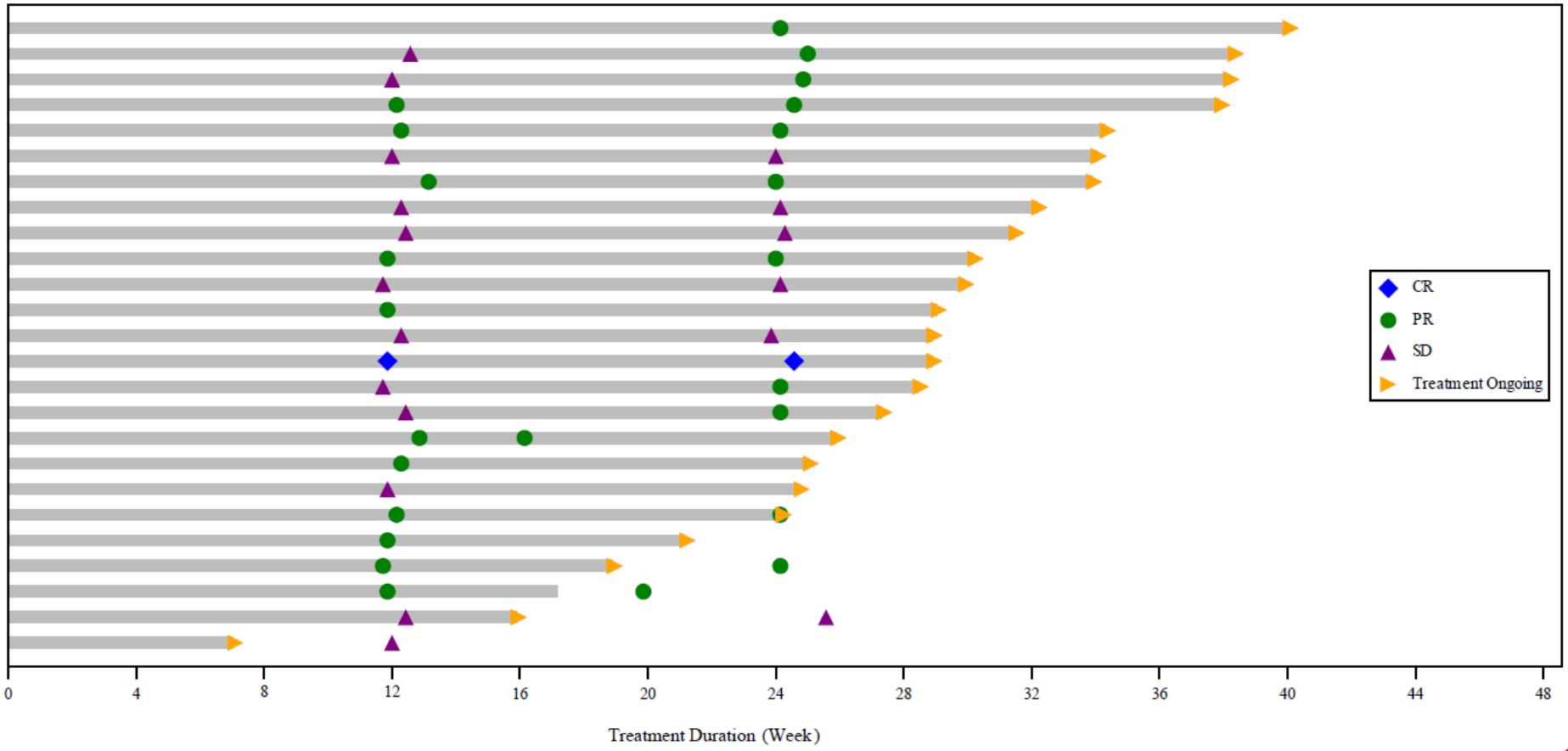
Preliminary Efficacy of ABSK021 in TGCT Patients of ABSK021-101 (cont'd)

Majority of patients **responded quickly** to ABSK021 and displayed **continuous improvement** over treatment time in patients receiving 50mg QD treatment.



25 out of 32 TGCT patients have completed at least one post-dose tumor response assessment by IRC. Cut-off date: 21 Sep 2022.

Potentially Best-in-Class Profile of ABSK021 – Efficacy

	ABSK021
Trial	Phase Ib (NCT04192344)
Patient no.	25
Dosage regimen	50mg QD
ORR at 25 week (%)	**68%**

	Pexidartinib*
Trial	ENLIVEN study-Part 1 (NCT02371369)
Patient no.	61
Dosage regimen	400mg BID
ORR at 25 week (%)	39%

	Vimseltinib*
Trial	Phase II, Cohort A (NCT03069469)
Patient no.	46
Dosage regimen	30mg BIW
ORR at 25 week (%)	38%

*: Data of pexidartinib comes from Tap WD et al (Lancet. 2019;394(10197):478-487); Data of Vimseltinib comes from Blay JY et al (1509P, ESMO. 2022; 33: S1236-1237).

Preliminary Safety Profile in TGCT Patients of ABSK021-101

Most treatment emergent adverse events (“TEAEs”) were Grade 1 or 2. Most CPK and transaminase elevations were asymptomatic and reversible. **No serious liver injury** or hair color changes cases were reported.

Table 1. TEAEs in ≥15% of Patients with TGCT receiving ABSK021 50mg QD

Preferred term	TGCT (N=32)	
	All Grades	Grade 3/4
Blood CPK increased	24 (75.0)	1 (3.1)*
LDH increased	24 (75.0)	0
α-HBDH increased	21 (65.6)	0
AST increased	17 (53.1)	0
Amylase increased	10 (31.3)	0
ALT increased	9 (28.1)	0
Rash	9 (28.1)	0
Pruritus	7 (21.9)	0
Dizziness	7 (21.9)	0
Somnolence	7 (21.9)	0
Periorbital edema	5 (15.6)	0
Face edema	5 (15.6)	0
Nausea	5 (15.6)	0
Lipids increased	5 (15.6)	0
Dyslipidemia	5 (15.6)	0

* The patient experienced extensive work-out. Cut-off date: 21 Sep 2022.
ALT, alanine aminotransferase; AST, aspartate aminotransferase; CPK, creatine phosphokinase; LDH, lactate dehydrogenase; α-HBDH, α-hydroxybutyrate dehydrogenase.

Potentially Best-in-Class Profile of ABSK021 – Safety

	ABSK021
Trial	Phase Ib (NCT04192344)
Patient no.	32
Dosage regimen	50mg QD

Any G3/4 TEAEs [PT, n (%)]

CPK increased	1 (3%)
Pyrexia	1 (3%)
Drug eruption	1 (3%)

	Pexidartinib*
Trial	ENLIVEN study-Part 1 (NCT02371369)
Patient no.	61
Dosage regimen	400mg BID

Any G3/4 TEAEs [PT, n (%)]

AST increased	6 (10%)
ALT increased	6 (10%)
ALP increased	4 (7%)
Hypertension	3 (5%)
Arthralgia	2 (3%)
Vomiting	1 (2%)
Rash	1 (2%)
Dizziness	1 (2%)
Periorbital edema	1 (2%)
Lactate dehydrogenase increase	1 (2%)

	Vimseltinib*
Trial	Phase II, Cohort A (NCT03069469)
Patient no.	46
Dosage regimen	30mg BIW

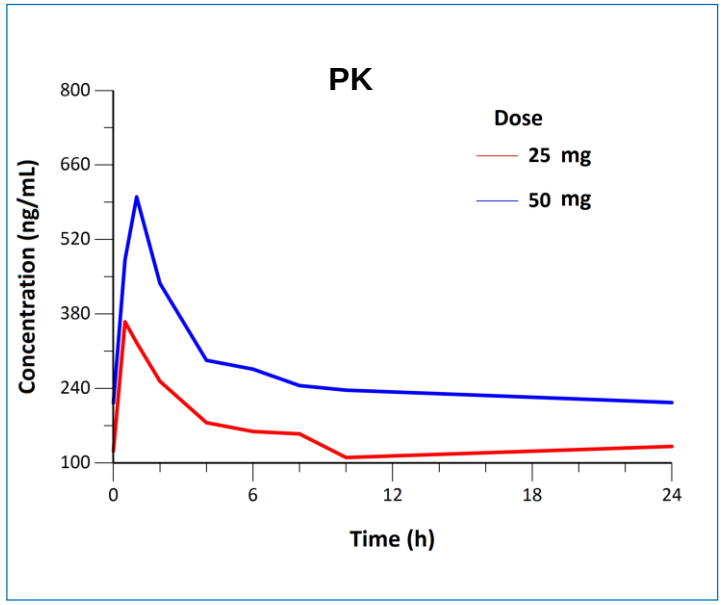
Any G3/4 TEAEs [PT, n (%)]

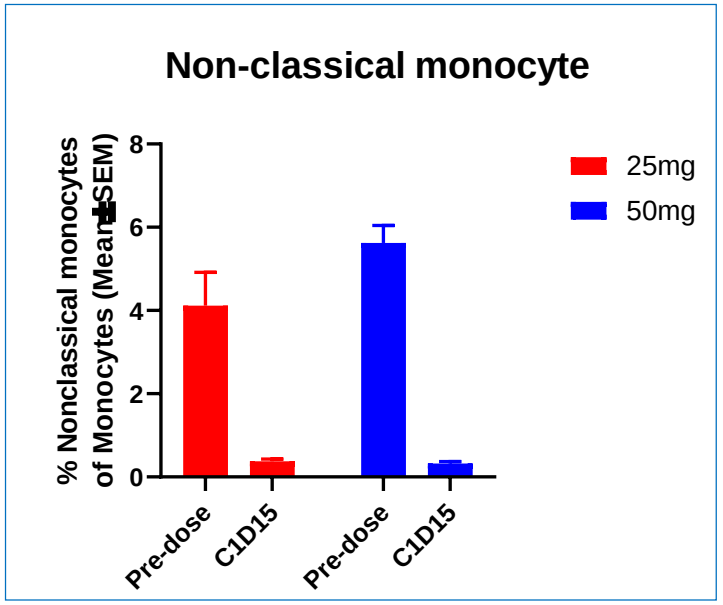
CPK increased	20 (44%)
Asthenia	1 (2%)
Rash maculopapular	1 (2%)

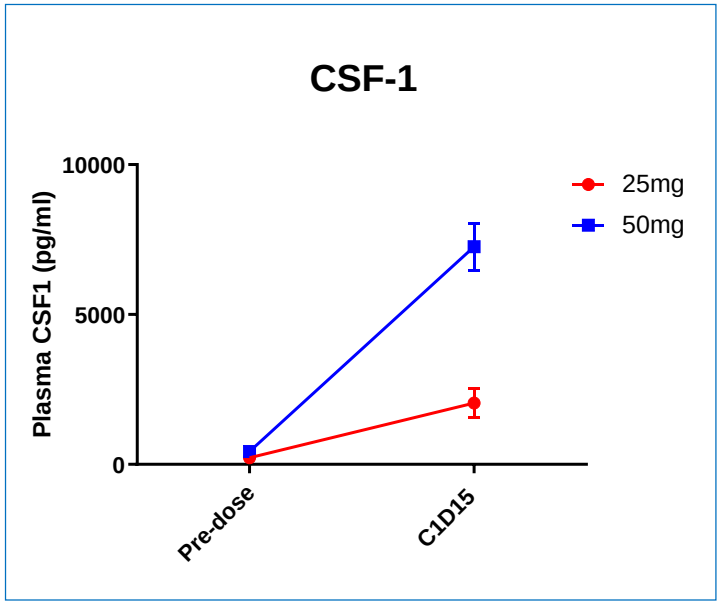
*: Data of pexidartinib comes from Tap WD et al (Lancet. 2019;394(10197):478-487); Data of Vimseltinib comes from Blay JY et al (1509P, ESMO. 2022; 33: S1236-1237).

ABSK021 Demonstrated Desirable PK Exposure and PD Modulation

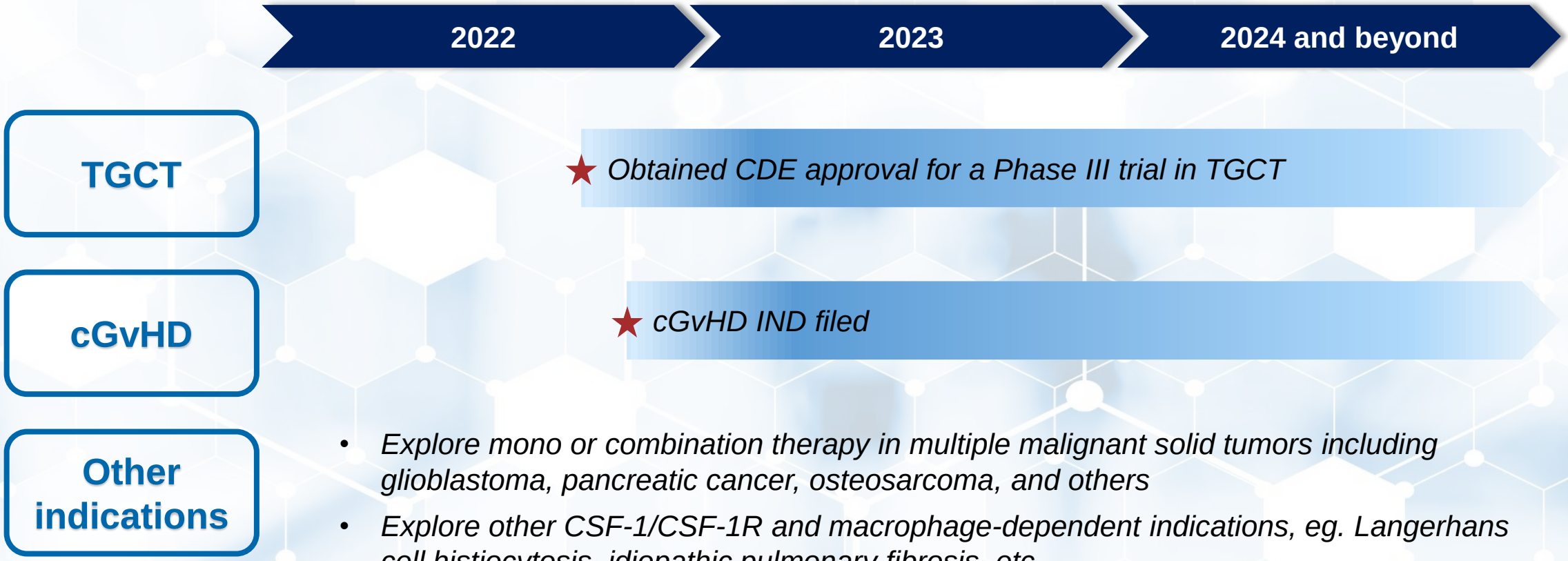
- Desirable PK profile
- Relative flat terminal phase and long terminal half life support the QD dosing regimen and sustained on-target effects
- Strong reduction of CD14dim/CD16+ nonclassical monocytes and a rise of circulating CSF-1 levels







Future Development Plan of ABSK021



CLOSING REMARKS

Dr. Yao-Chang Xu

Closing Remarks

- **ABSK021** has demonstrated superior efficacy and safety in TGCT patients, with **68.0%** ORR (17/25) achieved within 6 months and **no serious liver injury**
  - BTD granted by CDE in July 2022
  - CDE approval received for a Phase III trial of ABSK021 in TGCT
  - Global Phase III MRCT in planning
- Potential commercial value of **>US$1.5bn** globally for TGCT
- NDA filing expected in 2024 / 2025, potentially first-in-class in China and best-in-class globally
- We are actively exploring ABSK021 in other indications


Thank You