



R&D update call – ASCO 2024

Focus on early oncology

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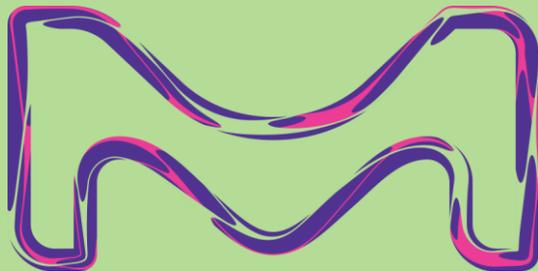
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June 03, 2024



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Today's Call Participants

R&D Oncology Leadership



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Today's Call Agenda

- 1 R&D – 'where are we today?'**
- 2 DNA damage response**
- 3 Antibody-drug conjugates**
- 4 Pre-clinical space highlights**
- 5 Conclusions & Q&A Session**





**R&D – 'where are we
today?'**



R&D – ‘Where are we today?’

Clearly defined strategic principles



FOCUSED leadership

- **Building on existing strengths & capabilities** in biology, technology and therapeutic areas
- Expanding to adjacent therapeutic areas



external innovation

- **External innovation driving over 50%** of launches
- Active in all phases of development



Agility and resource discipline

- Maintaining focus on execution and **resource discipline**
- R&D expenditure in low twenties as percentage of sales



Our focused leadership in oncology innovation

Focus areas of internal innovation

Underlying biology	Technologies	Therapeutic areas
<ul style="list-style-type: none"> ▪ DDR ▪ Apoptosis ▪ T-cell modulation 	<ul style="list-style-type: none"> ▪ ADCs ▪ Protein degradation ▪ Bi-specifics 	<ul style="list-style-type: none"> ▪ SCCHN ▪ Colorectal cancer ▪ Urothelial cancer

External innovation guided by focus areas

ADC target discovery (Caris Life Sciences)	Accelerate discovery and development of FiC ADCs
M9466 (Hengrui)	Selective PARP1 inhibitor advancing DDR portfolio
Ompenaclid (Inspirna)	SLC6A8i for RAS-mutated advanced/metastatic CRC
Pimicotinib (Abbisko)	Adjacent area: CSF1R antagonist for tenosynovial giant cell tumor

Key deals
in the last
12 months

Acronyms: **DDR** = DNA damage repair, **ADC** = antibody-drug conjugate, **SCCHN** = squamous cell carcinoma of the head and neck, **FiC** = first in class, **CRC** = colorectal cancer, **CSF1R** = colony stimulating factor 1 receptor



Two phase III assets with 2024 milestones

Xevinapant

IAP inhibitor with first-in-class potential

Aiming for curative setting in head and neck cancer, one of the most common cancer types worldwide

- Phase II data: OS at 5 years: addition of xevinapant to SoC chemoradiotherapy reduced the risk of death by more than half (HR 0.47).

Most advanced PhIII study: TrilynX, double-blind study in unresected cisplatin-eligible patients.

- Primary endpoint: EFS, event driven.
- Recruitment completed in 2023

Next milestone: interim analysis (ongoing)

Pimicotinib¹

Novel, highly selective and potent inhibitor of CSF-1R

Target indication: TGCT, a rare tumor of the joints that causes swelling, pain, stiffness; seriously affecting quality of life.

- Phase I data: ORR at w/k 25 by RECIST v1.1: 68.8% in 32 TGCT patients receiving 50mg QD, no apparent liver toxicity observed.

Ongoing PhIII study: MANEUVER, double-blind study in TGCT run by our partner Abbisko.

- Primary endpoint: ORR at week 25
- Recruitment completed in April 2024

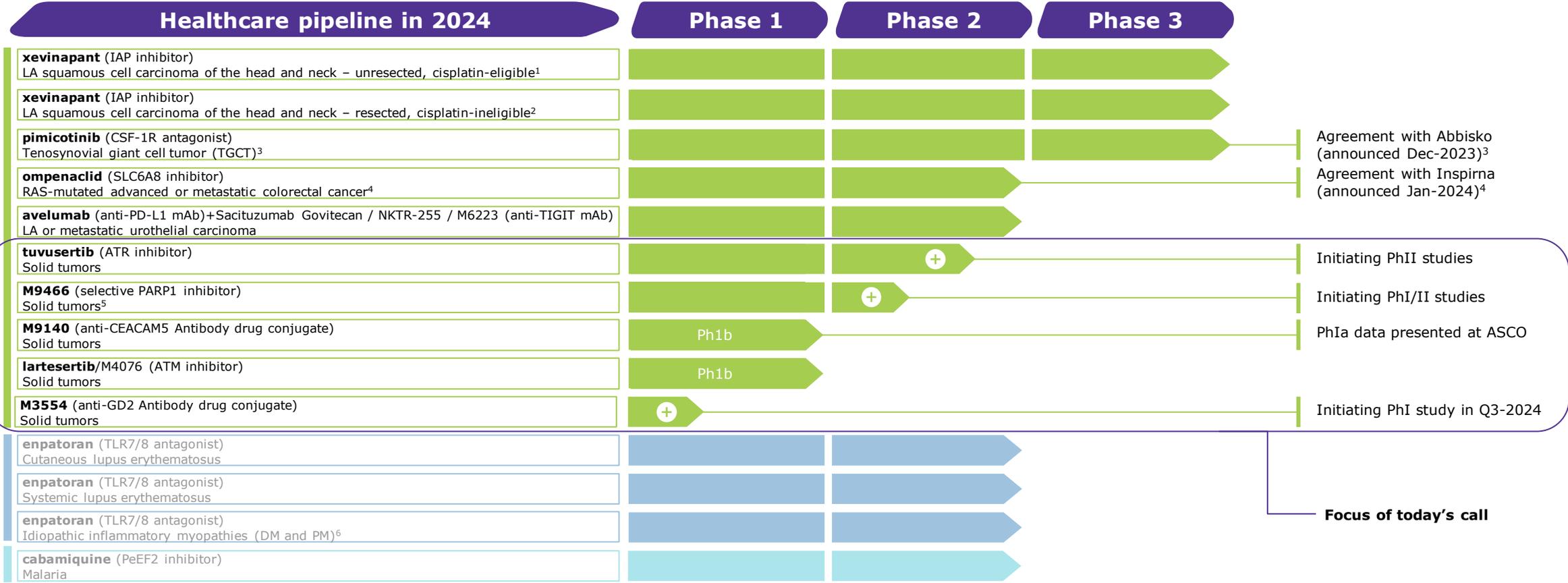
Next milestone: study readout

¹ Company entered a license agreement with Abbisko Therapeutics Co. Ltd, Shanghai, China, for pimicotinib (ABSK021), which grants a license to commercialize pimicotinib in mainland China, Hong Kong, Macau and Taiwan, with an option for rest of world.

Acronyms: IAP = inhibitor of apoptosis proteins, SOC = standard of care, EFS = event-free survival, CSF-1R = colony stimulating factor -1 receptor, TGCT = tenosynovial giant cell tumor, OS = overall survival, ORR = objective response rate, RECIST = response evaluation criteria in solid tumors, HR = hazard ratio



Dynamic oncology pipeline bolstered by external innovation



■ Oncology
 ■ Immunology
 ■ Global Health
 ➔ Asset entering new phase (projection for 2024)¹⁰
 ➔ Current phase
 ➔ Previous phase(s)

LA: Locally advanced; Ph1a: phase 1a, dose finding; Ph1b: phase 1b, dose escalation/expansion and signal seeking

¹ In combination with cisplatin and radiotherapy in unresected LA SCCHN patients eligible for cisplatin. ² In combination with radiotherapy in resected LA SCCHN patients ineligible for cisplatin. ³ Company entered a license agreement with Abbisko Therapeutics Co. Ltd, Shanghai, China, for pimicotinib (ABSK021), which grants a license to commercialize pimicotinib in mainland China, Hong Kong, Macau and Taiwan, with an option for rest of world. ⁴ Company entered into a licensing agreement with Inspirna, Inc. (New York, NY) for ompenacilid (RGX-202), which grants an exclusive license to ompenacilid outside of the United States and an option to co-develop and co-promote ompenacilid in the US. ⁵ Company entered a collaboration with Jiangsu Hengrui Pharmaceuticals Co. Ltd., China, including an exclusive license worldwide (ex-China) to develop, manufacture and commercialize M9466/HRS-1167. ⁶ Dermatomyositis and Polymyositis. ¹⁰ Projection includes studies in planning and preparation, with the intended start in H2 2024.

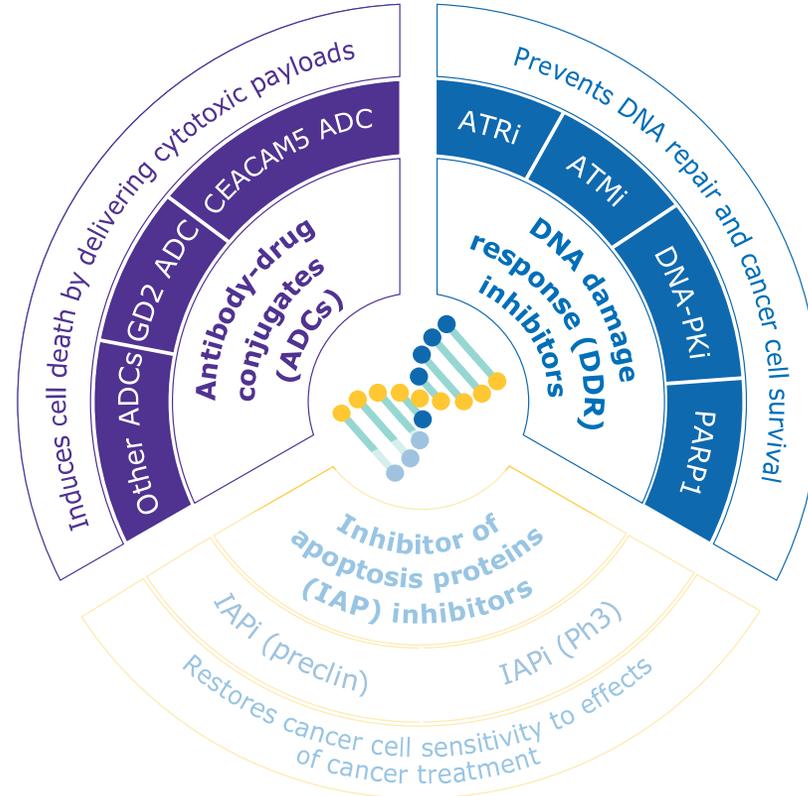


Early oncology priorities - striking the cancer at its core

Focus of today's call:

ADCs

Our competitive, in-house payload-linker technology enables us to bring safer and more efficacious therapeutics to patients with various cancers.



DNA damage response (DDR)

Focusing on combinations, our programs enable us to unlock the full potential of DDRi for patients with certain common cancer types.

Acronyms: **ADC** = antibody-drug conjugate, **GD2** = disialoganglioside, **CEACAM5** = carcinoembryonic antigen-related cell adhesion molecule 5, **ATRI** = ataxia telangiectasia and Rad3-related protein inhibitor, **ATMi** = ataxia-telangiectasia-mutated protein, inhibitor, **DNA - Pki** = DNA-dependent protein kinase inhibitor, **PARP1** = poly [ADP-ribose] polymerase 1



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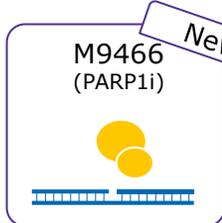
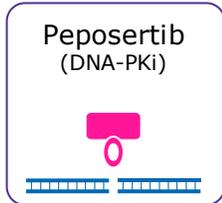
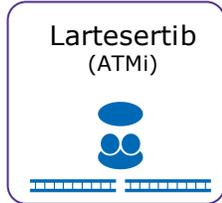
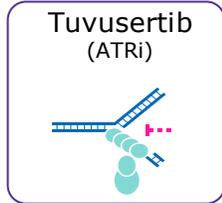
DNA damage response



DNA damage response

Realizing full potential of DNA damage response inhibition

Our DDR portfolio



Scientific hypotheses

1. Synthetic Lethality

- Validated in BRCAm tumors
- Requires specific genomic background (e.g. HRD)

2. Activation of immune response

- Limited success of PARPi+ ICI in clinic (possibly due to lack of selection)
- Early encouraging data for ATRI+ICI

3. Potentiation of cytotoxics

- Complements DNA-damaging effect of chemo and Rx, independent of HRD
- Loss of therapeutic index in combinations with 1st gen PARPi

Our differentiation

Our broad DDRi portfolio allows to pursue **unique combinations**: ATRI+PARP1/ATM/DNA-PK

Our approach: selecting tumors with ATRI-sensitizing mutations or high replication stress

Our Top1 ADC portfolio creates unique synergies and **opportunities to differentiate**

Indications

Legacy PARPi areas
PARPi-resistant and PARPi-naïve

Potential for
ICI-resistant and ICI-sensitive tumors

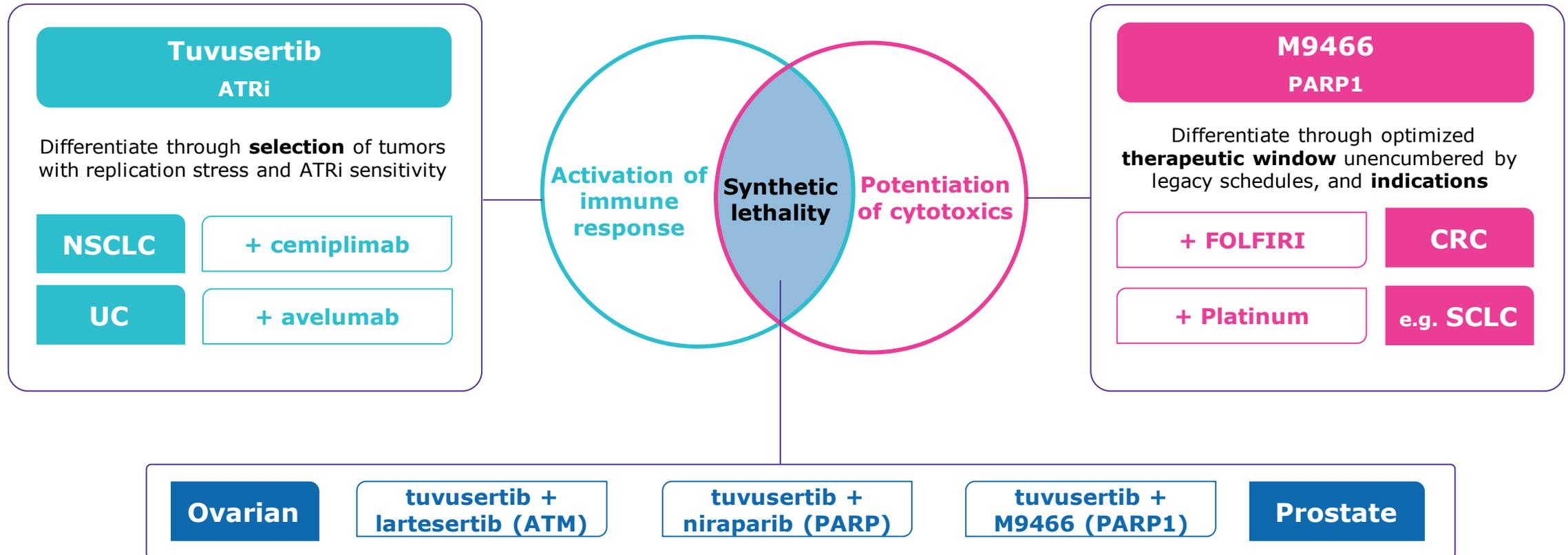
Potential for
Broad spectrum of settings with chemo SOC, and entry of ADCs

Acronyms: **ATRI** = ataxia telangiectasia and Rad3-related protein inhibitor, **ATMi** = ataxia-telangiectasia-mutated protein, inhibitor, **DNA/PKi** = DNA-dependent protein kinase inhibitor, **ICI** = immune checkpoint inhibitor, **DDRi** = DNA damage response inhibitor, **PARP1i** = poly [ADP-ribose] polymerase 1, inhibitor, **HRD** = homologous recombination deficiency, **ADC** = antibody-drug conjugate, **SOC** = standard of care



DNA damage response

Key pillars of DDR strategy: tuvusertib and M9466



Acronyms: NSCLC = non-small cell lung cancer, UC = urothelial carcinoma, CRC = colorectal cancer, SCLC = small cell lung cancer, FOLFIRI = fluorouracil-folinic acid-irinotecan



DNA damage response

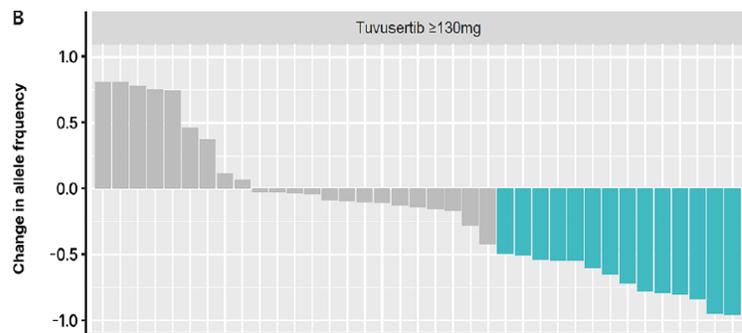
Tuvusertib monotherapy profile enables combination potential

Achieves strong target coverage

Tuvusertib dosing regimen	C _{av} fold for pCHK1 IC ₉₀	% of time typical patient above pCHK1 IC ₉₀
130 mg QD	19 x IC ₉₀	100 %
180 mg QD	36 x IC ₉₀	100 %
180 mg 2w on/1w off		71 %

Demonstrates molecular responses

Molecular response in Ph1 pts (>50% VAF reduction in ctDNA), n=37	38%
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Tuvusertib
ATRi

Compares favorably on safety

	Tuvusertib 180 mg QD 2w on/1w off (N=63)*	Camonsertib# 160 mg QD, 3d on/4d off (N=34)
Grade ≥ 3 haematological adverse events (%)		
Anaemia (%)	16.4	26.5
Neutropenia (%)	3.2	14.7
Thrombocytopenia (%)	0	5.9
Leading to treatment discontinuation (%)	3.6**	not reported
Leading to dose reduction (%)	10.7	17.6
Transfusion	25	32.4

*Dose escalation (n=7) + preliminary data from dose expansion (n=56)

** Based on first 28 participants; discontinuation unrelated to M1774

E. Fontana et al. ESMO TAT Mar 2022, oral presentation #202

Acronyms: IC₉₀ = 90% inhibitory concentration, ctDNA = circulating tumor DNA, C_{av} = average plasma concentration, VAF = variant allele frequency



DNA damage response

Selected combination schedule for tuvusertib delivers clinical efficacy in PARP-pretreated indications

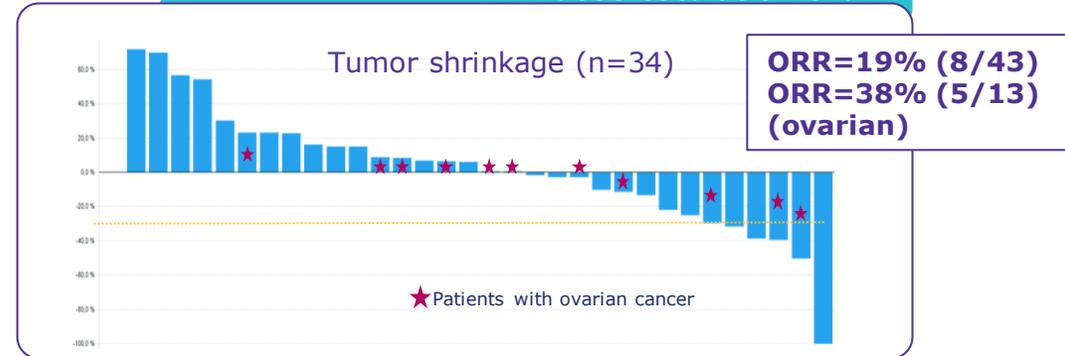
Combination vs monotherapy doses

Recommended combination doses of ATR with PARP inhibitors vs respective monotherapy doses

Combinations	Mono ATRi dose	Dose intensity in combination*	
		For ATRi	For PARPi
Ceralasertib + olaparib	160mg BID 2w on/2w off	25%	100%
Camonsertib+ PARPi (olaparib, talazoparib, niraparib)	160mg QD 3d on/4d off	25%-33%	13%-44%
Tuvusertib+ niraparib	180 mg QD 2w on/1w off	75%	25%

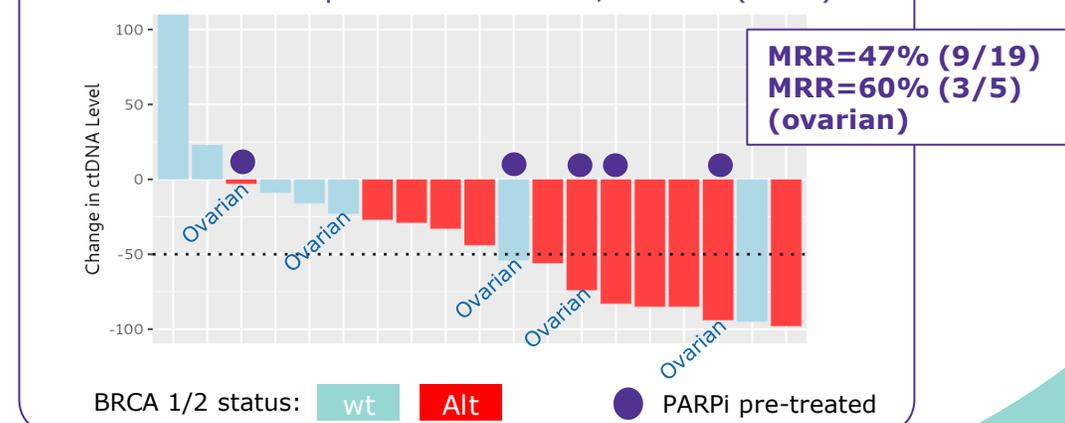
* Safety profile is managed mainly through reduced daily doses (for PARPi) AND increased off-treatment interval (for ATRi)

Tuvusertib+niraparib Ph1 dose escalation trial*



N=34 with post baseline assessment

Molecular responses and BRCA 1/2 status (n=19)



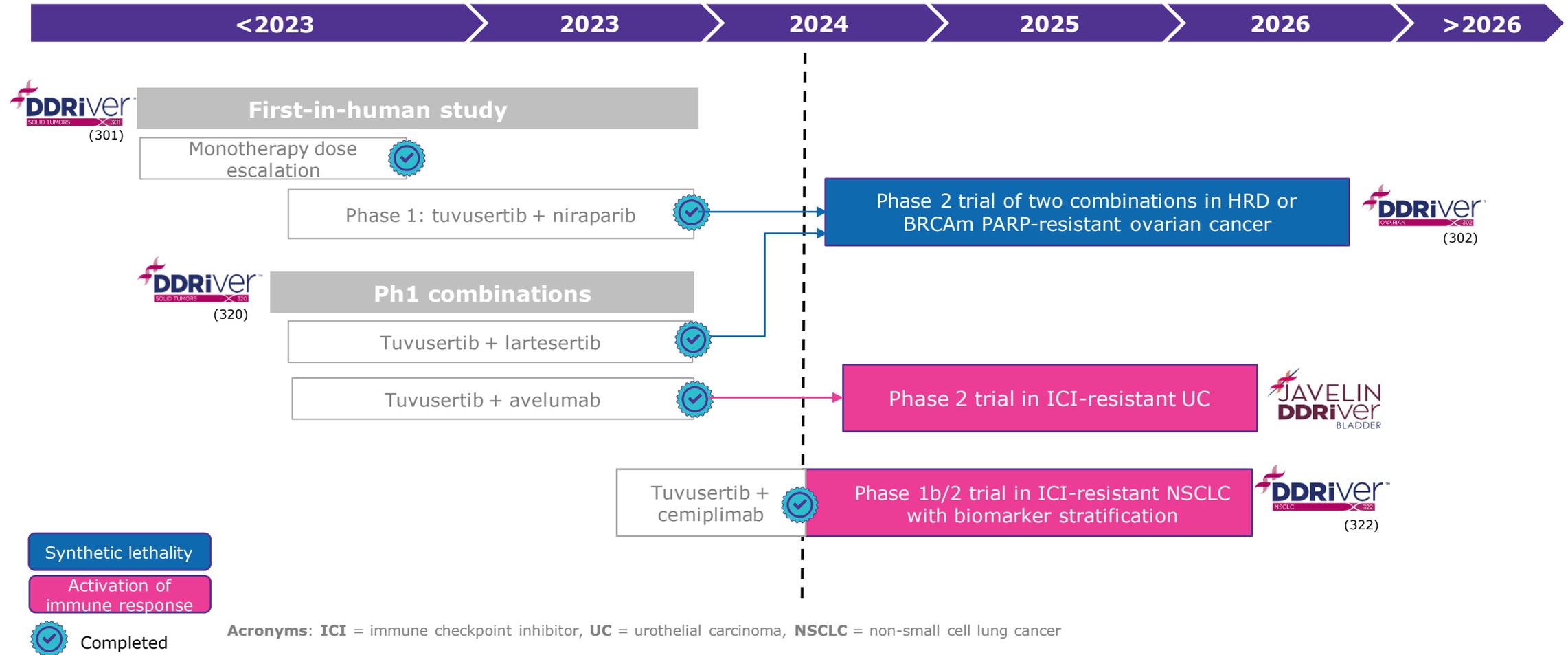
*ASCO 2024, Abstract 3018; T. Yap , rapid oral abstracts -Development Therapeutics session, 6/3/2024

Acronyms: ORR = overall response rate; MRR= molecular response rate



DNA damage response

Targeted Phase 2 program of tuvusertib with key inflection efficacy readouts by 2026



DNA damage response

M9466: next-gen PARP1i key to realizing combination potential

M9466: 2nd gen PARP inhibitor with trapping activity

- PARylation inhibition and PARP trapping are key for PARPi mechanism of action
- Preclinically, PARPi efficacy is tied to PARP1 inhibition, while PARP2 inhibition may be more associated with off-target effects

Enzyme inhibition of PARP1/2*

IC50 (nM)	M9466	Olaparib
PARP1	2.03	1.9
PARP2	94.3	1.1
Ratio PARP2/PARP1	46.5	0.6

DNA Trapping activity of PARP1/2*

IC50 (nM)	M9466	Olaparib
PARP1	2.49	30.98
PARP2	>10,000	11.7
Ratio PARP2/PARP1	>4,000	0.4

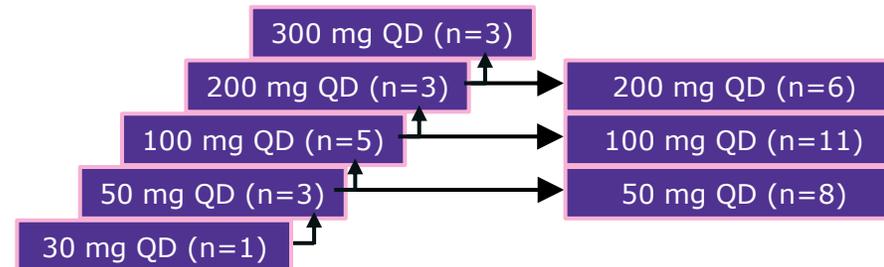
* Jiangsu Hengrui data on file



Hengrui: Ph1 study of M9466/ HRS-1167

Dose escalation:
pts with solid tumors

Dose expansion: pts with
*BRCA1/2, PALB2, or
RAD51C/D* mutations



NCT05473624

Company, next steps: enabling combinations

	Combination partner	Indication	Proof of concept
1	+ tuvusertib	CRPC, Ovarian	2027
2	+TOP1	CRC	2027
3	+ platinum	tbd, e.g. SCLC	2027

Acronyms: IC50 = 50% inhibitory concentration, CRPC = castrate-resistant prostate cancer, CRC = colorectal cancer, SCLC = small cell lung cancer, TOP1 = topoisomerase I

*M9466 is also known as HRD-1167 in development by Jiangsu Hengrui Pharmaceuticals Co. Ltd., China



DNA damage response

M9466: Further development plans supported by compelling safety profile and early efficacy in PARP-sensitive tumors

Safety profile supports combinability

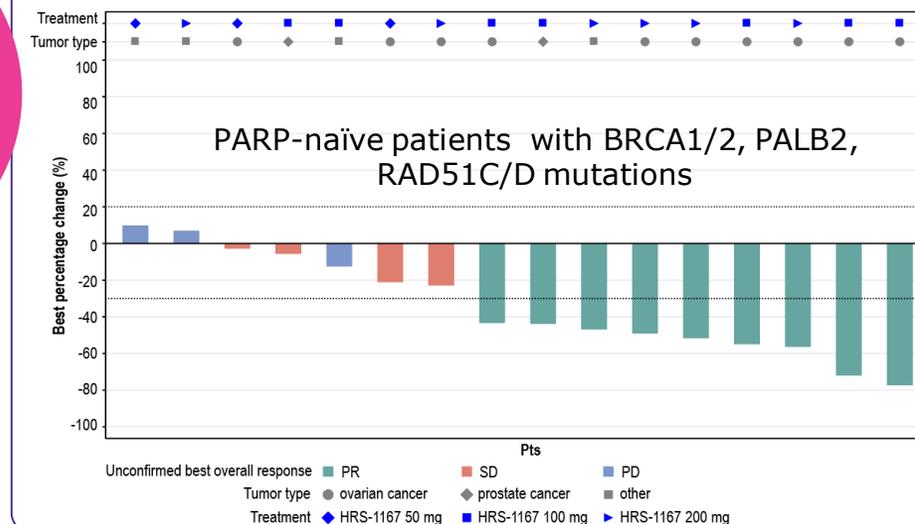
N=40	All grade	Grade 3/4
Any, n (%)	39 (97.5)	12 (30.0)
Anemia	29 (72.5)	6 (15.0)
White blood cell count decreased	28 (70.0)	5 (12.5)
Neutrophil count decreased	22 (55.0)	5 (12.5)
Platelet count decreased	19 (47.5)	0
Nausea	18 (45.0)	0
Hypertriglyceridemia	11 (27.5)	0
Asthenia	8 (20.0)	0

- Heavily pretreated population with mixed tumor types
- No dose-limiting toxicities seen across dose levels
- No MTD reached



Early Efficacy provides PoC in PARP indications

Objective response : HRR mutations		Objective response: HRR mutations and PARP-naïve	
All (N=24)	Ovarian (N=16)	All (N=18)	Ovarian (N=10)
10 (41.7)	8 (50.0)	9 (50.0)	7 (70.0)



2024 ASCO, Abstract 3154, Lingying Wu et al

Acronyms: MTD = maximum tolerated dose, PoC = proof-of-concept, HRR = homologous recombination repair, PR = partial response, PD = progressive disease, SD = stable disease

*M9466 is also known as HRD-1167 in development by Jiangsu Hengrui Pharmaceuticals Co. Ltd., China



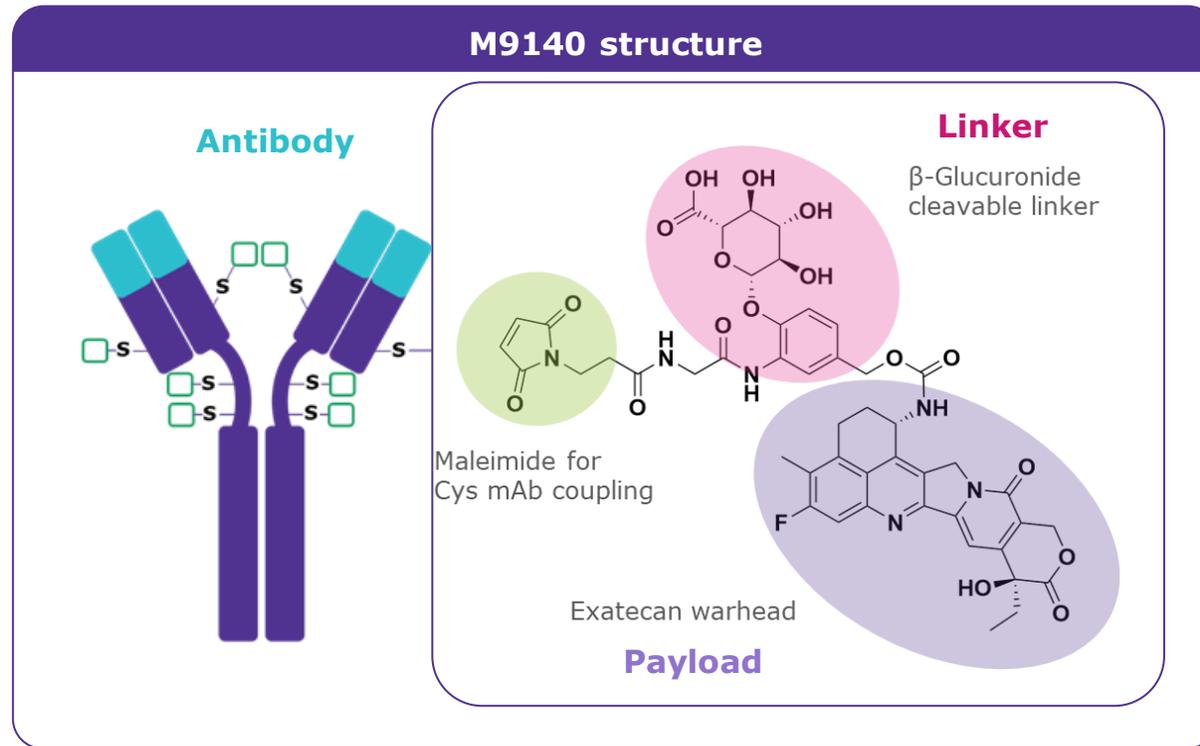
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Antibody-Drug conjugates



Antibody-drug conjugates

Leveraging our proprietary technology for BiC exatecan-based ADCs



Key features

Antibody	<ul style="list-style-type: none">Innovative Ab formats and Fc modification technologies
Payload	<ul style="list-style-type: none">Highly potent TOP1 inhibitor exatecanHigh bystander activity
Linker	<ul style="list-style-type: none">Stable β-Glucuronide linkerSpecifically cleaved in tumorsFull DAR flexibility, adaptable for payload potency and target characteristics

- Allows the design of ADCs with optimal pharmacokinetics and -dynamics, such as **M9140**.
- Platform for other exatecan-based ADCs like **M3554** and followers

Acronyms: TOP1i = topoisomerase 1 inhibitor, DAR = drug-antibody ratio



Antibody-drug conjugates

M9140: Developing First-in-Class ADC in CEACAM5-positive tumors

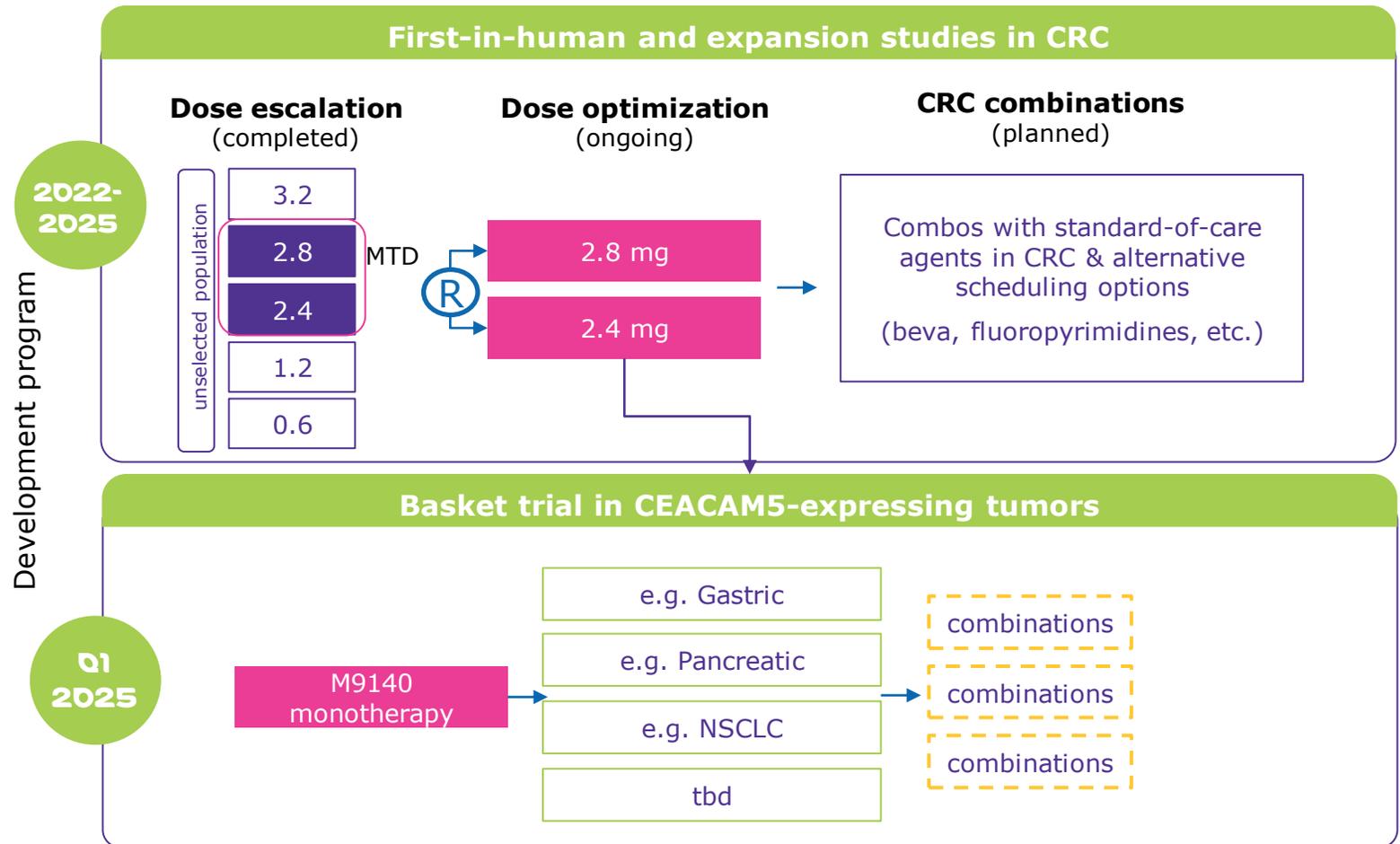


M9140

- Highly specific for CEACAM5
- TOP1i payload (exatecan)
- DAR: 8

Tumor type	CEACAM5 expression
Colorectal	> 90%
Pancreatic	>80%
Gastric	~ 80%
NSCLC nsq	35%

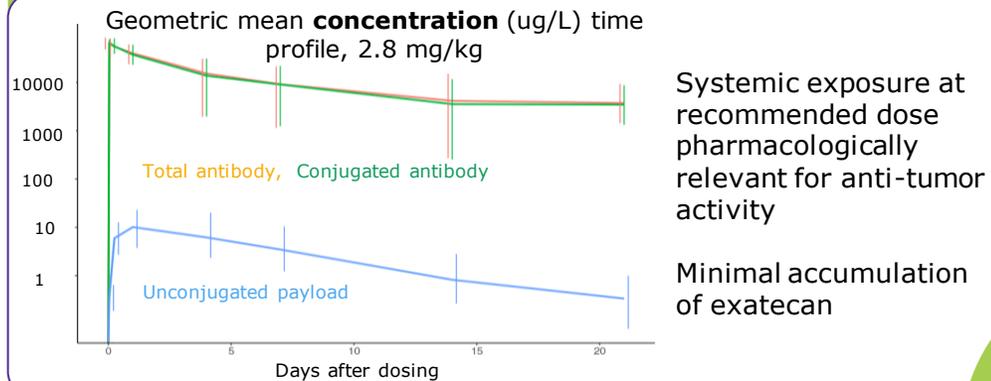
Acronyms: **CEACAM5** = carcinoembryonic antigen-related cell adhesion molecule 5, **CRC** = colorectal cancer, **NSCLC** = non-small cell lung cancer, **MTD** = maximum tolerated dose



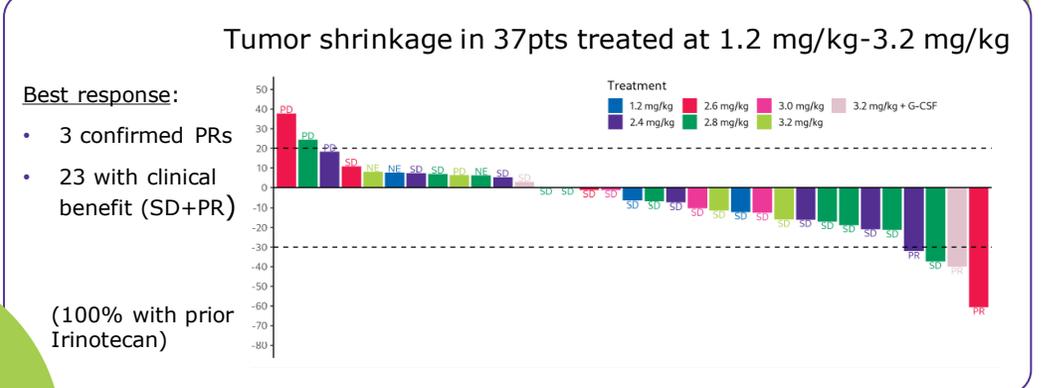
Antibody-drug conjugates

Early clinical data for M9140 shows activity and predictable safety profile*

M9140 shows systemic stability



Most patients benefitted at predicted active doses



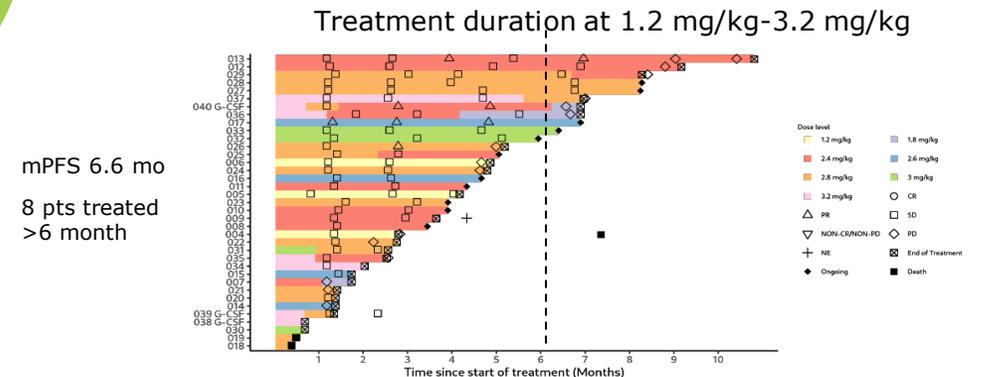
Predictable and manageable safety profile

First clinical evidence validating safety of exatecan payload:

- Adverse events consistent with exatecan: myelosuppression as only DLTs
- GI toxicity appears less frequent/severe vs other TOP1i
- No cases of ILD, ocular effects or other unexpected AEs, including Asian patients and at the highest doses tested

M9140
(CEACAM5)

Clinical benefit appears durable



*ASCO 2024, Abstract 3000; oral presentation by S. Kopetz in the Development Therapeutics session, 6/1/2024

Acronyms: DLT = dose limiting toxicity, ILD = interstitial lung disease, PR = partial response, SD = stable disease, mPFS = median progression-free survival



Antibody-drug conjugates

M3554: aiming at First-in-Class ADC, overcoming limitations of anti-GD2 antibodies

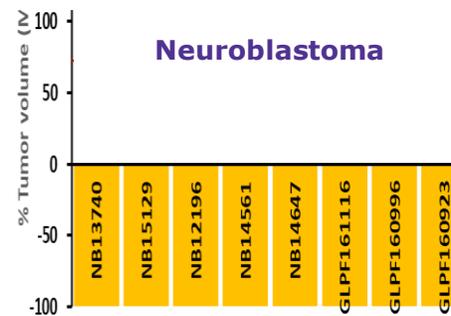


M3554

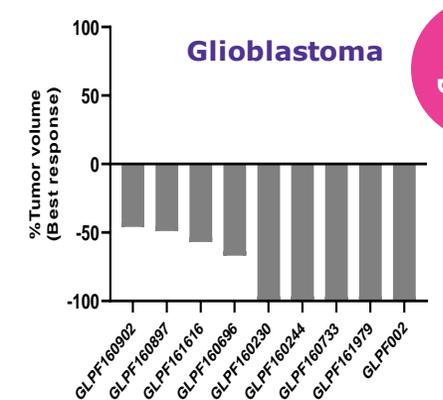
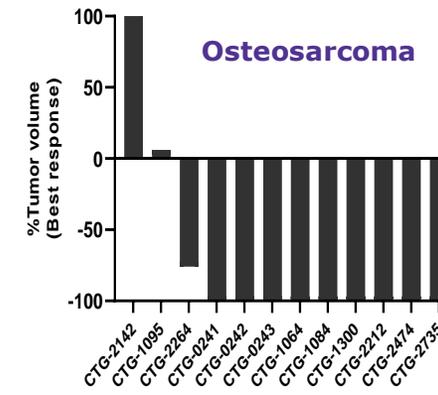
- Anti-GD2 antibody with modified Fc-region to abrogate ADCC and CDC putatively responsible for side effects
- TOP1i payload (exatecan)
- DAR: 8

Tumor type	GD2 expression
Soft tissue sarcoma	90%
Neuroblastoma	>85%
Glioblastoma	80%
Osteosarcoma	>80%

Strong activity in panel of PDx models from tumors with high GD2 prevalence



- Stronger antitumor response vs dinutuximab +
- Active in neuroblastoma models resistant to GD2-mAb



pre-clinical

First-in-human trial initiation in H2 2024

Patients with solid tumors with high GD2 prevalence¹

¹Chang et al (1992), Ziebart et al (2012), Zhang (1997) Wikstrand et al (1992), Long (2016), Heiner et al, (1987), Dobrenkov et al (2016)

Acronyms: GD2= disialoganglioside , **FC- region** = fragment crystallizable region, **ADCC** = antibody-dependent cell-mediated cytotoxicity, **CDC** = complement-dependent cytotoxicity, **PDx** = patient-derived xenografts



4

pre-clinical space highlights



Pre-clinical space

Diversified research activities to sustain organic delivery

Intensive oncology research in

- ➔ Antibody-drug conjugates
- ➔ DNA damage inhibitors
- ➔ Next generation immuno-oncology
- ➔ Oncology signaling

Execution priorities

- ➔ Drive innovation for FiC and BiC ADCs
- ➔ Leverage strengths in small molecules and antibody design
- ➔ Aim at BiC in oncogenic signaling and DDRs
- ➔ Focus on targeted IO for patient selection

Expected research/discovery output:
~3 molecules entering the clinic yearly
(mid-term average)

Acronyms: **FiC** = first in class, **BiC** = best in class, **ADC** = antibody-drug conjugate, **IO** = immuno-oncology, **DDR** = DNA damage response

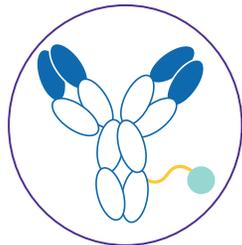


Pre-clinical space

Enhancing our position as a major ADC player

ADC priorities

- Maximize exatecan platform
- Embark into immune agonist ADCs
- Deliver next-gen cytotoxins and targeted payloads (including protein degraders)
- Expand to novel antigens (recent collaboration with Caris)



Organic ADC portfolio growth in the next 3 years

M3554 (GD2)

M9140 (CEACAM5)

SRH -A1904 (CLDN 18.2)*

Step 1:

ADCs with exatecan warhead

+

M7152 (NaPi2b)

M0251 (EGFRxMUC1)

M7437**

M0121**

Step 2:

ADCs with next-gen payloads

+

ADC with STING

ADC with cytotoxin 2

ADC with degrader

Acronyms: **ADC** = antibody-drug conjugate, **GD2** = disialoganglioside, **CEACAM5** = carcinoembryonic antigen-related cell adhesion molecule 5, **NaPi2b** = sodium-dependent phosphate transport protein 2B, **EGFR** = epidermal growth factor receptor, **MUC1** = mucin 1, **STING** = stimulator of interferon genes, **CLDN** = claudin 18.2

*Company entered a collaboration with Jiangsu Hengrui Pharmaceuticals Co. Ltd., China, including an option to an exclusive license worldwide (ex-China) to develop, manufacture and commercialize Hengrui's Claudin-18.2 antibody-drug conjugate (ADC) SHR-A1904. **Programs from an undisclosed collaboration.

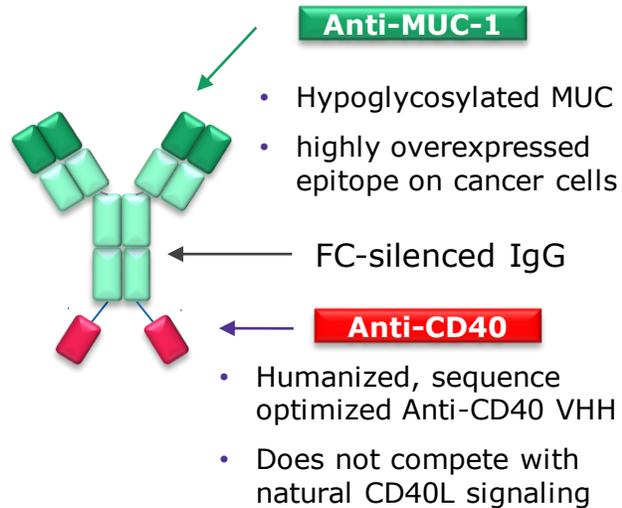


Pre-clinical space

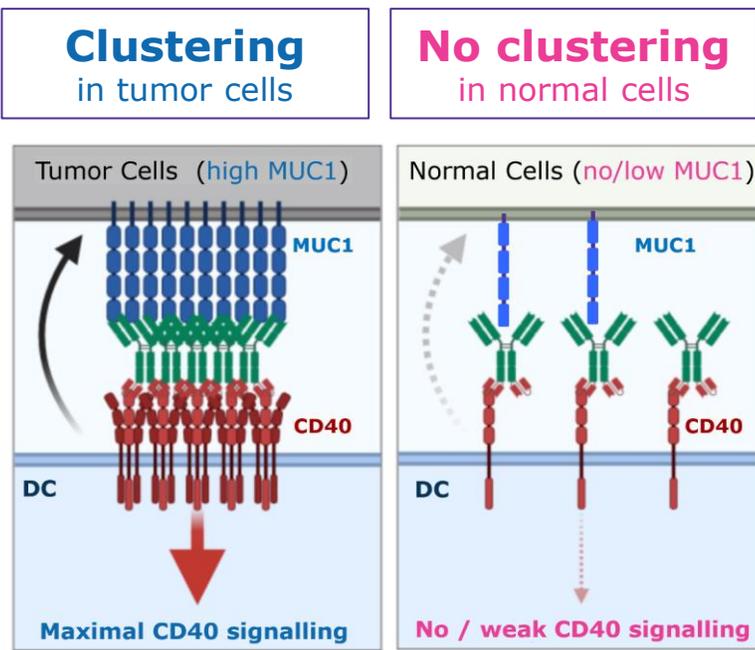
Next-generation IO drugs: M0324, leveraging conditional agonism

M0324 (Anti-MUC-1 x CD40)

M0324 facilitates conditional CD40-mediated activation of dendritic cells (DCs) by tumor MUC-1 and leads to robust T cell dependent anti-tumor responses.

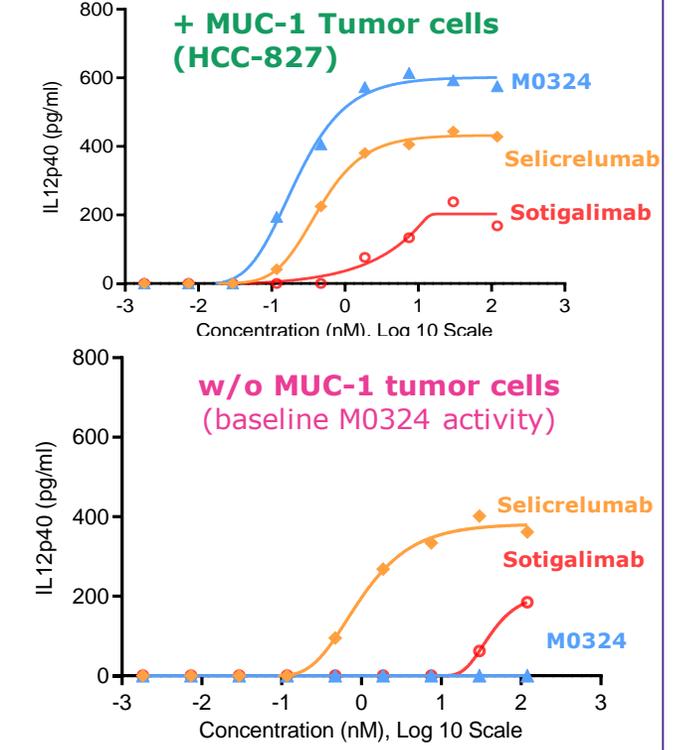


Conditional Agonism



Abbreviations: DC: dendritic cell; TME: tumor-microenvironment; TAA: tumor-associated antigens.
Reference: modified from Salomon et al. 2022

Exquisite tumor selectivity



Acronyms: IO = immuno-oncology, CD40 = cluster of differentiation 40, MUC1 = mucin 1, FC - silenced = fragment crystallizable - silenced, VHH = heavy chain variable domain, CD40L = cluster of differentiation 40 L

5

key takeaways & Q&A session



R&D Update call 2024

Key take-away points

1

Clearly defined R&D strategic principles

- Focused leadership in well-defined areas with possible adjacencies
- External innovation a driving force for pipeline progress
- Ongoing resource discipline and focus on execution; with R&D expenditure in low-twenties as % of sales

2

Driving forward key DDR assets

- Two-pillar strategy of tuvusertib and M9466
- Tuvusertib: strong monotherapy data, start of combination studies to deliver efficacy readouts by end of 2026
- M9466: development plans supported by compelling safety profile and early efficacy in PARP-sensitive tumors

3

Enhancing our position as a major ADC player

- M9140 proceeding to dose expansion, aiming at FiC
- M3554 enters the clinic in Q4; aiming at FiC anti-GD2 ADC
- Strong pre-clinical pipeline of ADCs maximizing exatecan and expanding to next-gen payloads

Acronyms: **FiC** = first in class, **ADC** = antibody-drug conjugates , **DDR** = DNA damage response



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DATE

EVENT

June 3, 2024

Early Oncology
R&D Update Call

August 1, 2024

Q2 2024 Earnings release

October 17, 2024

Capital Markets Day

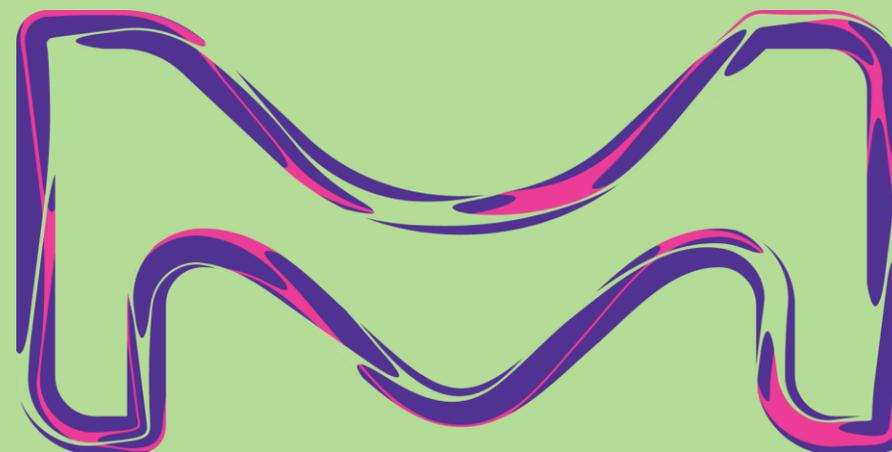
November 14, 2024

Q3 2024 Earnings release

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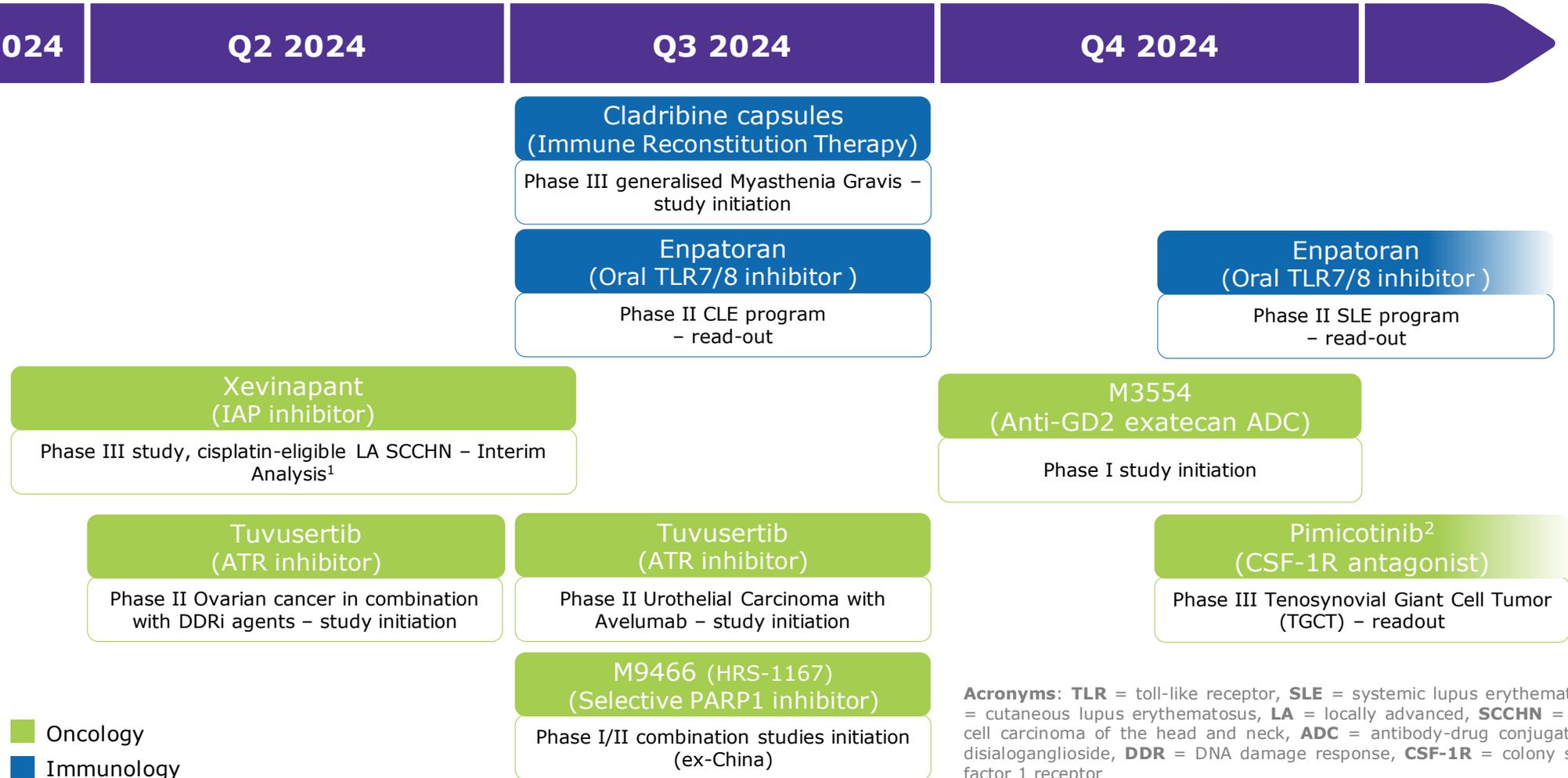


Appendix



R&D Update call 2024

Healthcare catalysts



¹event-driven, note: required number of events expected in Q2, followed by database lock and IDMC interactions, ²Study sponsor: Abbisko Therapeutics Co, Ltd. Company entered a license agreement with Abbisko Therapeutics Co. Ltd, Shanghai, China, for pimicotinib (ABSK021), which grants a license to commercialize pimicotinib in mainland China, Hong Kong, Macau and Taiwan, with an option for rest of world.



Acronyms

ADC = antibody-drug conjugate

AE = adverse event

ATM = ataxia-telangiectasia-mutated protein

ATMi = ataxia-telangiectasia-mutated protein, inhibitor

ATR = ataxia telangiectasia and Rad3-related protein

ATRI = ataxia telangiectasia and Rad3-related protein, inhibitor

BID = twice a day

BRCAm = BRCA-mutated

CEA = carcinoembryonic antigen

DAR = drug-antibody ratio

DNA-Pki = DNA-dependent protein kinase

DLT = dose limiting toxicity

FiH = first in human

GI = gastrointestinal

HRD = homologous recombination deficiency

MOA = mode of action

PALB2 = partner and localizer of BRCA2

PAR = protein poly ADP-ribosylation

PARP = poly [ADP-ribose] polymerase

PARPi = poly [ADP-ribose] polymerase inhibitor

PARP1 = poly [ADP-ribose] polymerase 1

PARP1i = poly [ADP-ribose] polymerase 1, inhibitor

Ph = phase

PoC = proof of concept

QD = once a day

TOP1 = topoisomerase I

TOP1i = topoisomerase I inhibitor

