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2022 YTD Earning Result

2022/10/28

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Disclaimer

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Agenda

1. 2022 YTD Operational Highlights
2. 2022 YTD Operational Overview
3. Research and Development
   - ONIVYDE®
   - PEP07 (SOL-578)
4. Vision for 2022
5. Q&A

Keep Deliver Sustainable Growth and Enhanced Value

Commercial

ONIVYDE ® market and new indication expansion

1. ONIVYDE® 2L PDAC treatment got China NMPA approved.
2. ONIVYDE® EU/Asia sales unit with stable growth momentum.
3. ONIVYDE® 1L PDAC phase III trial ongoing.

Pipeline

New project licensing and RD progress accelerated

1. PEP07 preclinical progress meets expectation
2. PEP07 officially licensing in from Sentinel Oncology
3. Multiple Projects Under Evaluation with External AI/CADD collaboration
4. Early stage projects under evaluation

Operation

Operation with a sustainable growth

1. 1Q22 Cash and cash equivalents:
   - NTD$3.5 bn

2022 YTD Operational Overview

ONIVYDE® Sales Unit with Stable Growth

Sales and Royalties Drives Long-term Growth

NTD $(000)

Items / Year	2017	2018	2019	2020	2021	2021 YTD/ 2022 YTD YoY (%)
Taiwan Sales	40,651	87,384	180,389	214,828	235,469	211,942 (22.5%)
Royalties from Europe and Asia	63,526	109,825	133,651	271,584	419,366	283,968 (2.2%)
Milestone	749,500	96,221	0	569,600	0	0
Total	853,677	293,430	314,040	1,056,012	654,835	495,910 (9.9%)

5 yr CAGR. 42% (ex. milestone)

Taiwan Sales belongs to PharmaEngine, Inc.

Tiered royalties (high single – low double digit) in Europe/Asia (excl. TW) from Servier/IPSEN

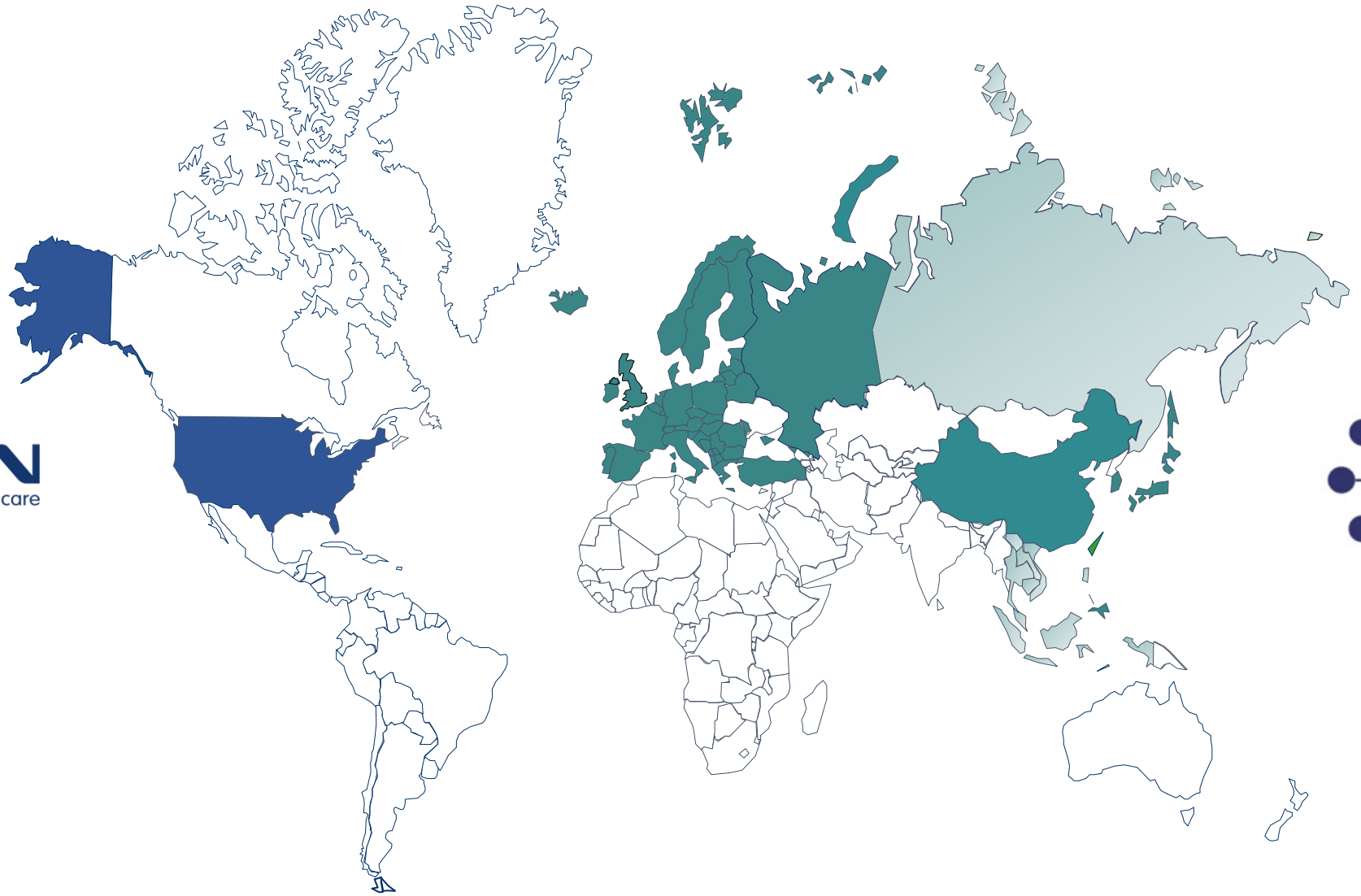
2022 YTD Financial Results

NTD$ (000)	2022 YTD	2021 YTD	Amount Change	% Change
Operating revenue	495,910	451,034	44,876	10%
Operating costs	37,416	29,472	7,944	27%
Gross profit	458,494	421,562	36,932	9%
Sales expenses	29,111	23,765	5,346	22%
G&A expenses	74,226	62,820	11,406	18%
R&D expenses	122,037	107,504	14,533	14%
Total operating expenses	225,374	194,089	31,285	16%
Operating income	233,120	227,473	5,647	2%
Total non-operating income and expenses	94,987	178,659	(83,672)	(47%)
Income before income tax	328,107	406,132	(78,025)	(19%)
Income tax expense	62,941	91,631	(28,690)	(31%)
Profit for the period	265,166	314,501	(49,335)	(16%)
EPS(NT$)	1.85	2.17	(0.32)	(15%)

Research and Development

- ONIVYDE® 1L PDAC Phase III Readout at YE22
- PEP07 File IND at YE22
- PEP07 Officially Licensing in from Sentinel Oncology
- Multiple Projects Under Evaluation with External AI/CADD collaboration

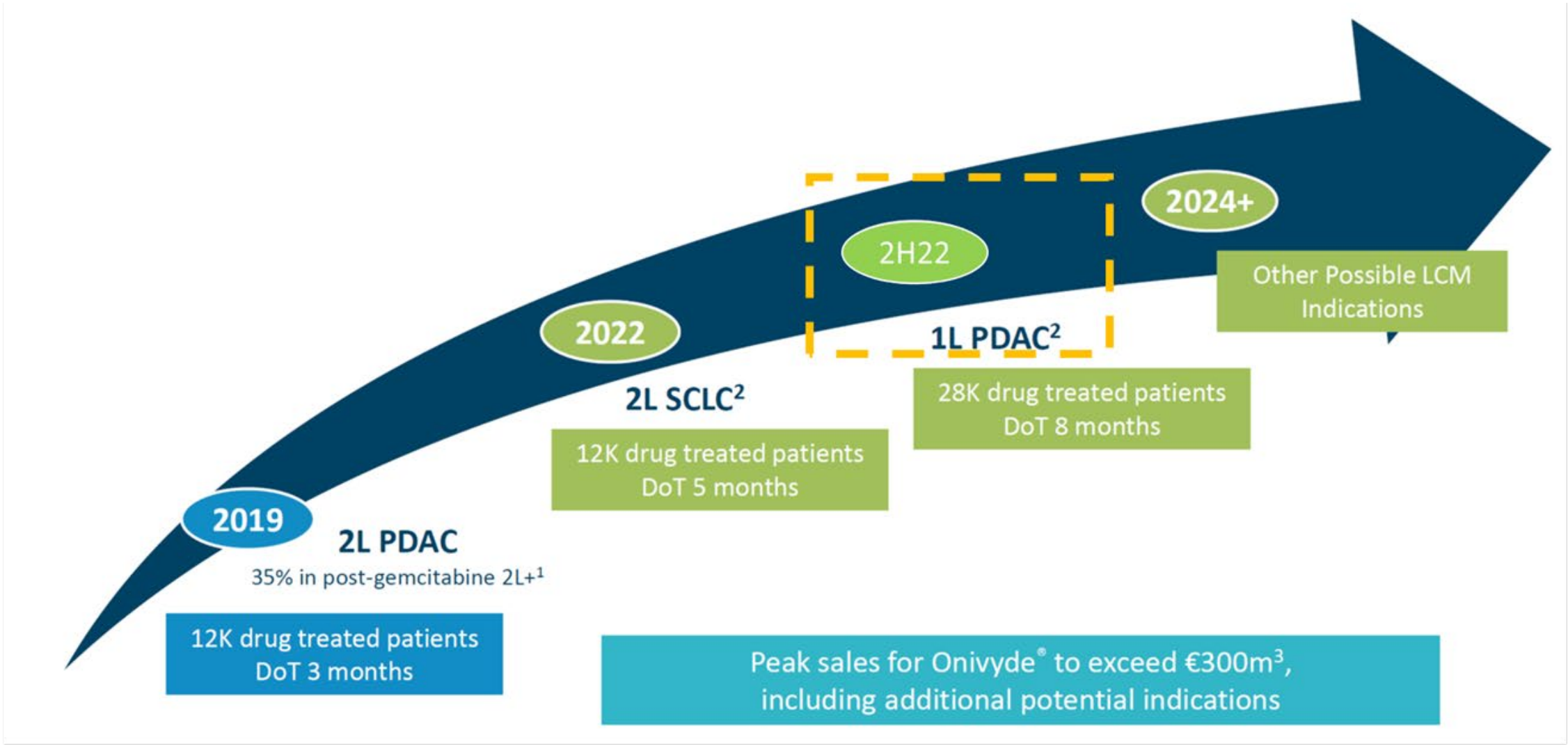
ONIVYDE® Keep Global Market Expansion at 2L PDAC



Approved

Yet approved

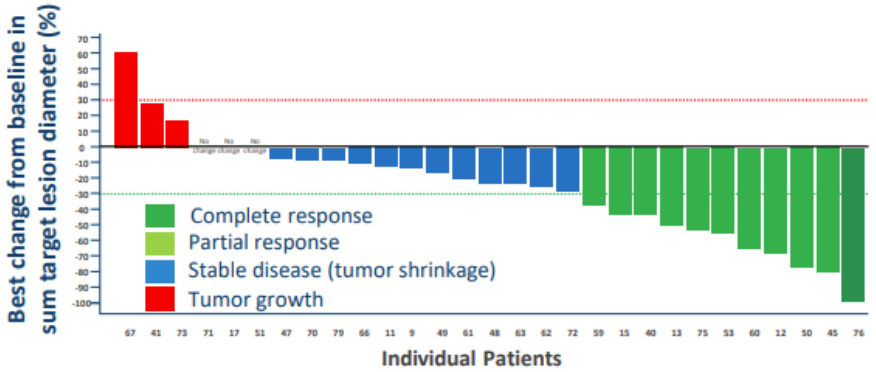
ONIVYDE® LCM: Expansion into New Tumor Types Globally



LCM: Life cycle management; PDAC: Pancreatic ductal adenocarcinoma; SCLC: Small cell lung cancer; DoT: Duration of treatment; 1L: First line; 2L: Second line; 1. IQVIA APLD claims, September 2020 ; 2. Expected submission dates ; 3. Risk adjusted; IPSEN Capital Market Day 2020

ONIVYDE®: 1L pancreatic ductal adenocarcinoma (PDAC)

Phase 2 results

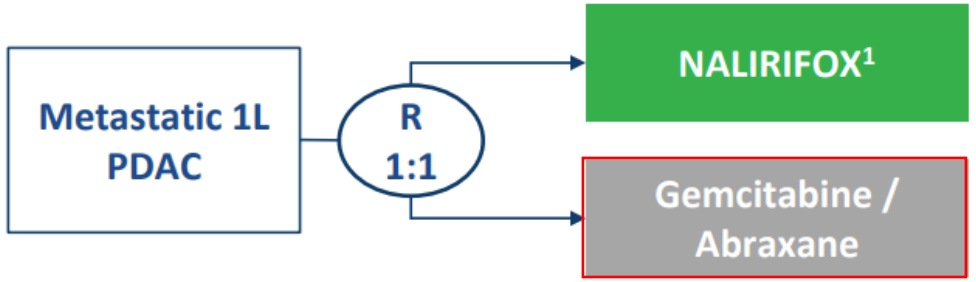


Among 29 evaluable patients who received selected dose, 23 **(79%) had tumor shrinkage**

	NALIRIFOX[1] Phase 1/2 - 50/60 Cohort
N	32 (29 metastatic & 3 locally advanced)
Complete Response	1 (3.1%)
Partial Response	10 (31.3%)
Stable Disease	15 (46.9%)
ORR; % (95%)	11 (34.4%)
DCR; % (95%)	26 (81.3%)
DOR (median); % (95% CI)	9.4 months (3.52-NE)
PFS (median); % (95% CI)	9.2 months (7.69-11.96)
OS (median); % (95% CI)	12.6 months (8.74-18.69)

Phase 3 NAPOLI-3 study status & design

- Phase 3 study ongoing
- Received FDA Fast Track designation in June 2020
- Expected topline readout: 2023



1L mPDAC (N=750)
- Histologically/cytologically confirmed PDAC
- Not previously treated in the metastatic setting
- >1 metastatic tumor measurable per RECIST v1.1
- ECOG performance status of 0 or 1

Primary endpoint
- OS

Secondary endpoints
- PFS
- ORR
- Safety

PDAC: Pancreatic ductal adenocarcinoma; ORR: Overall response rate; DCR: Disease control rate; DOR: Duration of response; PFS: Progression free survival; OS: Overall survival; RECIST: Response evaluation criteria in solid tumors; ECOG: Eastern cooperative oncology group functional status measure; FDA: Food and Drug Administration 1.Onivyde , administered in combination with oxaliplatin, fluorouracil (also known as 5 FU) and leucovorin (which is often abbreviated as LV)

Source: ESMO World Congress on Gastrointestinal Cancer 2020 Oral Presentation. Abstract LBA 1 ; IPSEN Capital Market Day 2020

Frontline Regimens for Patients With Metastatic Pancreatic Cancer

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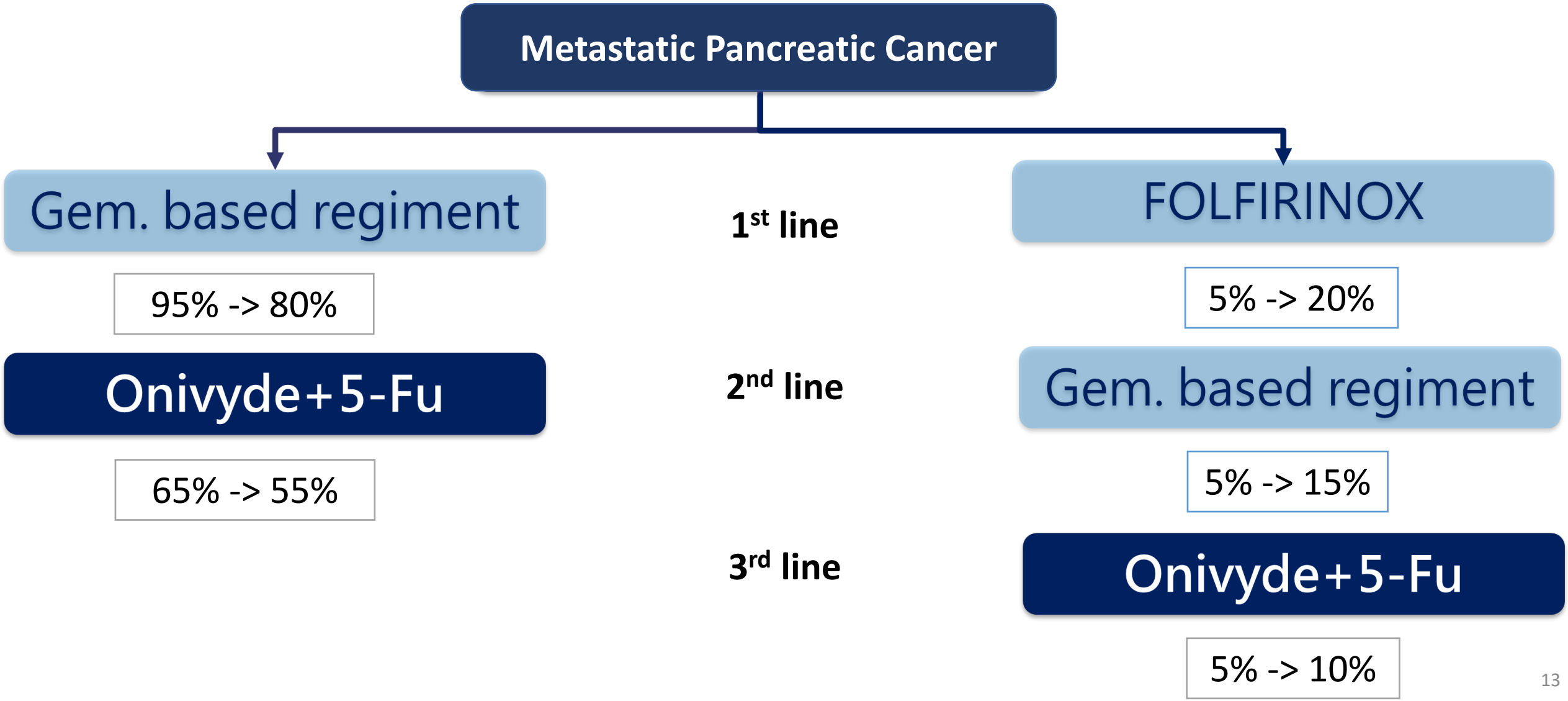
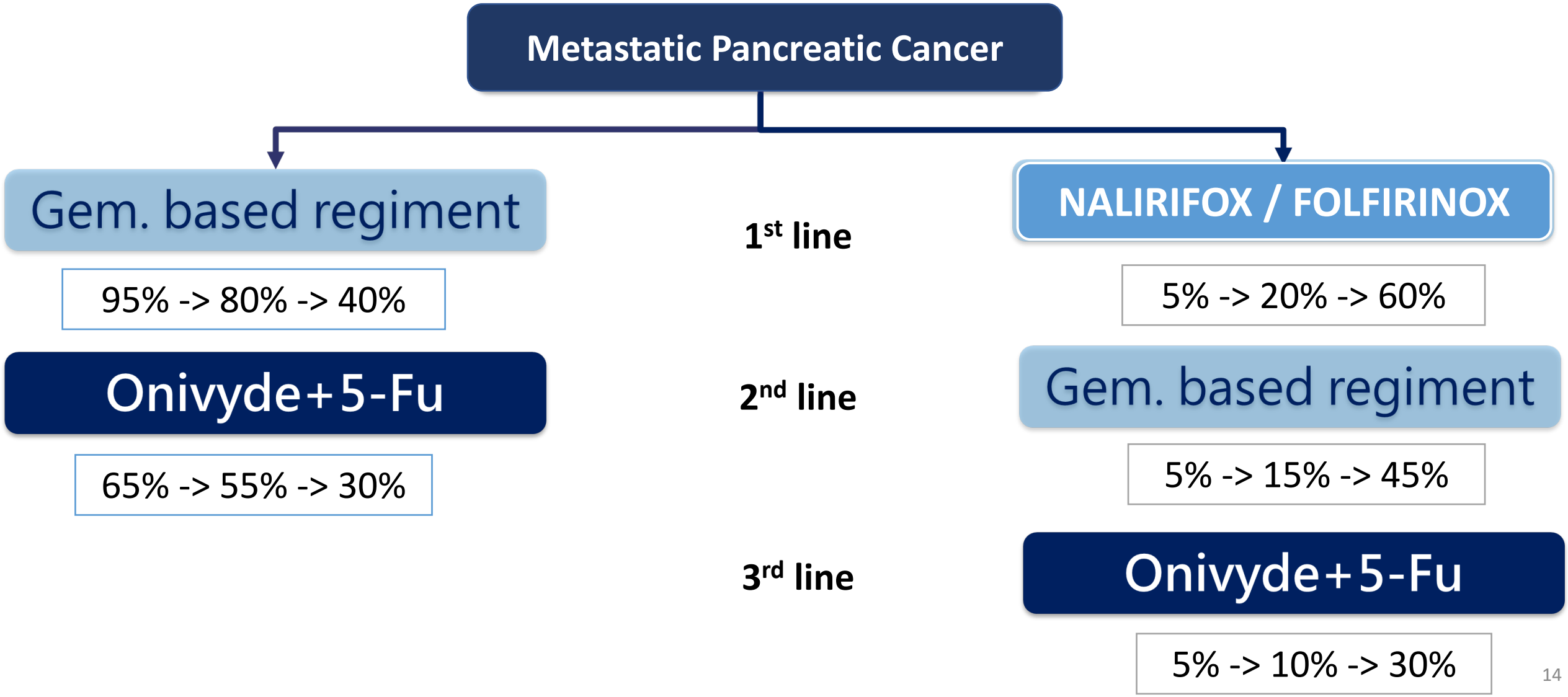
Trial Characteristics and Outcomes	FOLFIRINOX vs Gem (N = 342)[1]	nab-Pac + Gem vs Gem (N = 861)[2]
Median age, yrs (range)	61 (25-76)	62 (27-86)
Male, %	62	57
Region (NA/WE/EE/A), %	0/100 (France)/0/0	62/9/15/14
ECOG PS/KPS (0/100, 1/80-90, 2/60-70), %	37/62/1	16/76/8
Tumor location (H/B/T), %	39/31/26	43/31/25
Median involved metastatic sites, n	2	2.5
ORR, %	32 vs 9	23 vs 7
Disease control rate, %	70 vs 51	48 vs 33
Median PFS, mos	6.4 vs 3.3	5.5 vs 3.7
Median OS, mos	11.1 vs 6.8	8.5 vs 6.7

1. Conroy. NEJM. 2011;364:1817. 2. Von Hoff. NEJM. 2013;369:1691.

Metastatic Pancreatic Cancer Treatment Market Analysis (I)

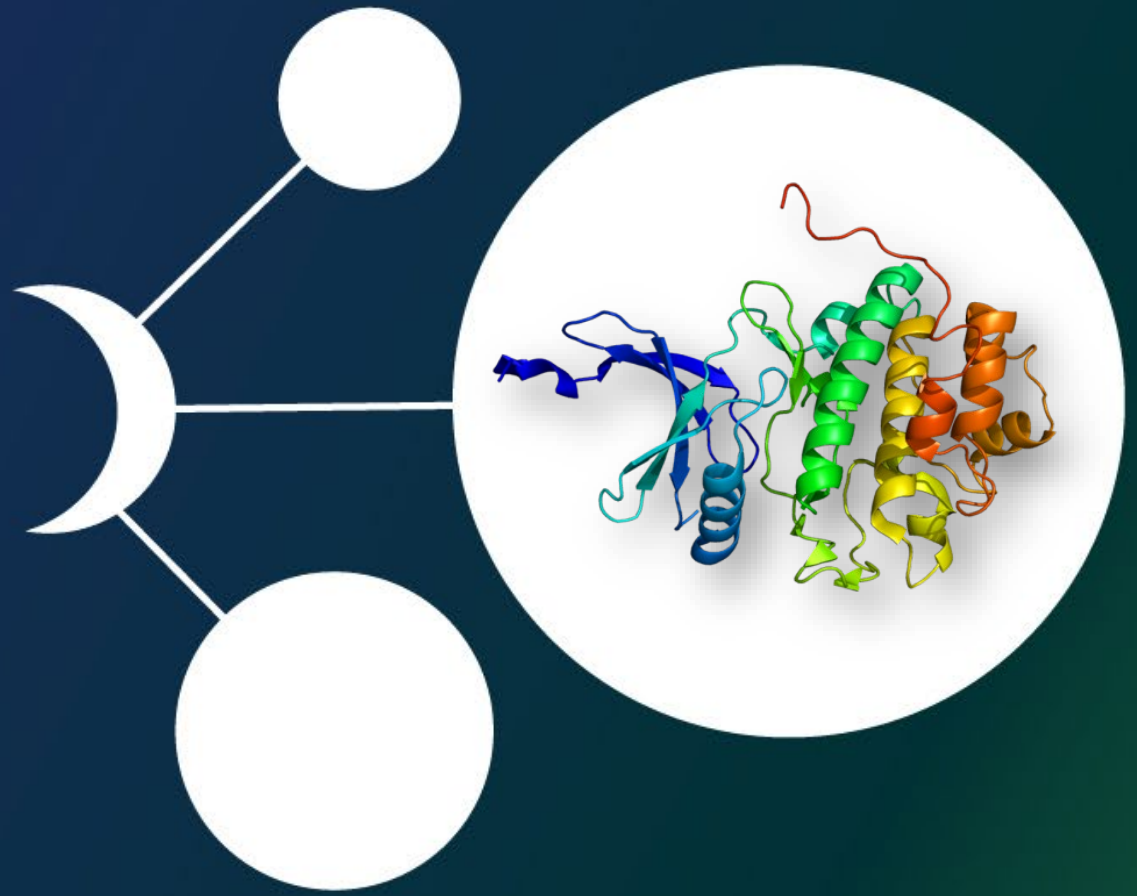


Metastatic Pancreatic Cancer Treatment Market Analysis (II)

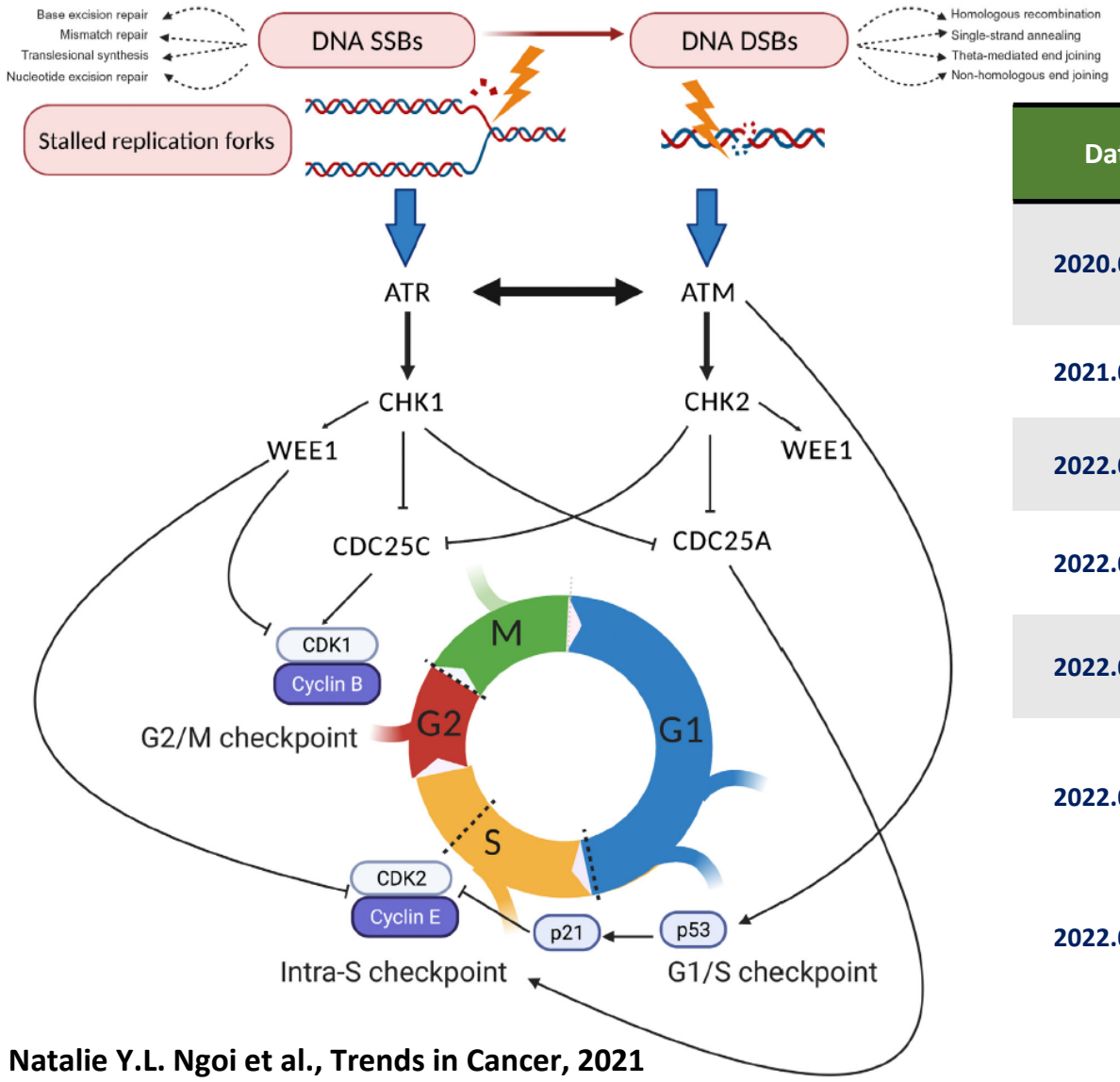


PEP07 (CHK1 inhibitor)

- PEP07 Officially Licensing in from Sentinel Oncology
- Early-stage DDR Project Transactions Became Hotter
- Keep Moving Forward to Phase I IND



DNA Damage Repair
One Critical Pathway, Multiple Targets



Natalie Y.L. Ngoi et al., Trends in Cancer, 2021

DDR deal transactions became hotter

Date.	Licensor	Licensee	Target	Pipeline Stage	Deal Size
2020.05.26	Repare	BMS	Undisclosed x 10	Discovery	• Upfront: $65M • Milestone: $3.0bn • Royalties: high SD - Low DD
2021.04.07	Artios	Novartis	Undisclosed x 3	Discovery	• Upfront: $20M • Milestone: $1.3bn
2022.03.21	Volastra	BMS	Undisclosed	Discovery	• Upfront: $30M • Milestone: $1.1bn
2022.04.27	Zentalis	Pfizer	WEE1	Ph I/II	• $25M • Equity investment
2022.05.16	Atrin	Aprea	ATR, WEE1	Pre-clinical	• Buy out
2022.06.02	Repare	Roche	ATR	Ph I/II	• Upfront: $125M • Milestone: $1.2bn • Royalties: high SD- High teens
2022.09.21	Nerviano Medical Sciences	Merck	PARP1	Ph I	• Upfront and Option: $65M

Deep understanding and targeted query of DDR pathways may identify novel therapeutic opportunities and biomarkers for optimal patient selection

PEP07 – Potential Best in Class CHK1 Inhibitor

PEP07 is a brain penetrating oral inhibitor which is more potent, selective, specific than the competitors.

	Drug	Stage	Potency	Selectivity	Specificity	Oral Bioavailability
Acrivon (Eli Lily)	Prexasertib	Ph II				
Genetech	GDC-0575	Discontinued				
gsk (Sierra Oncology)	SRA-737	Ph I/II (Complete)				
Esperas Pharma	LY2880070	Ph I/II (Complete)				
PharmaEngine	PEP07	IND Ready				

Excellent Good Fair Poor Unknown

PEP07 : Significant Efficacy in Hematologic Malignancies as Monotherapy and Combination Therapy

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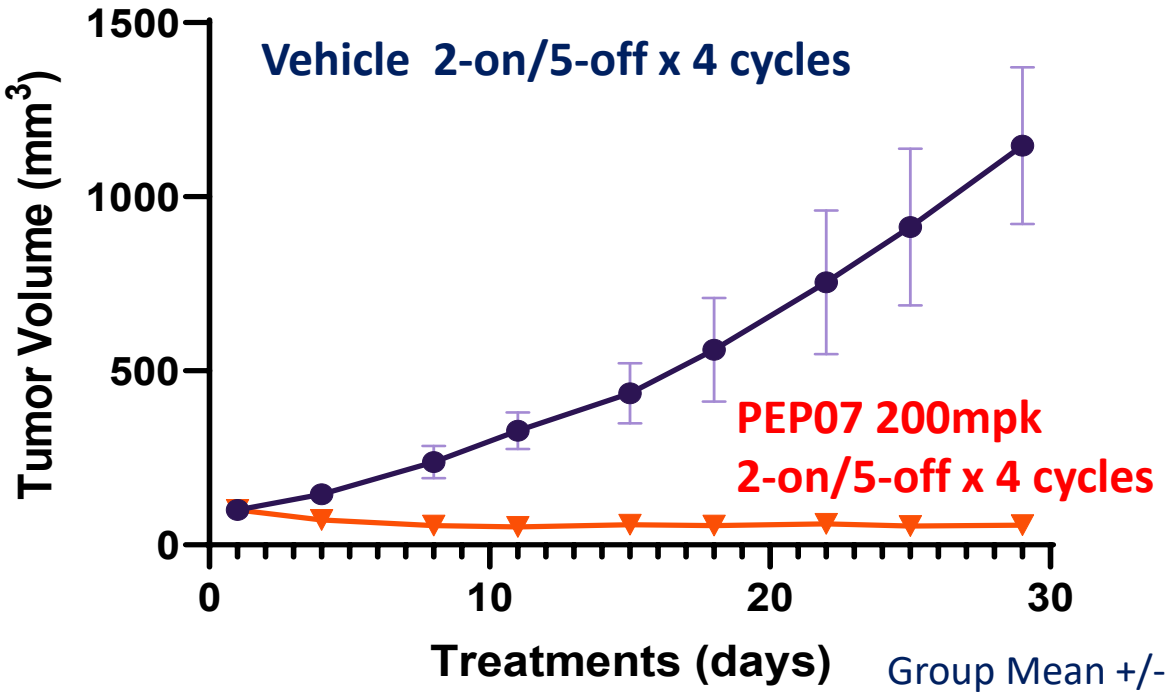
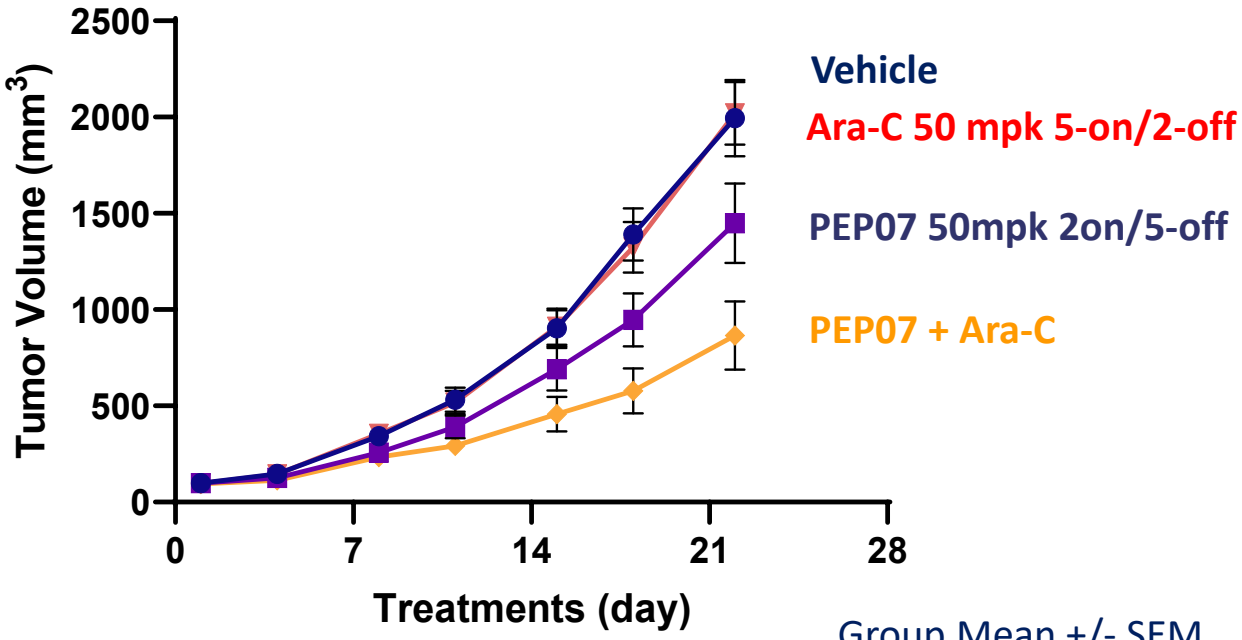
Acute Myeloid Leukemic (AML)

Ara-C Sensitive



Group Mean +/- SEM
n=8/group

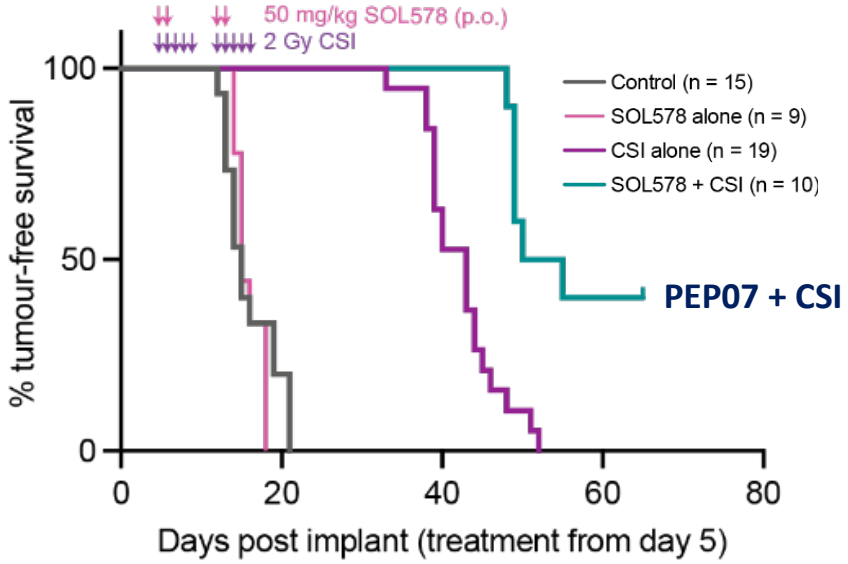
Ara-C Resistant



Group Mean +/- SEM
n=8/group

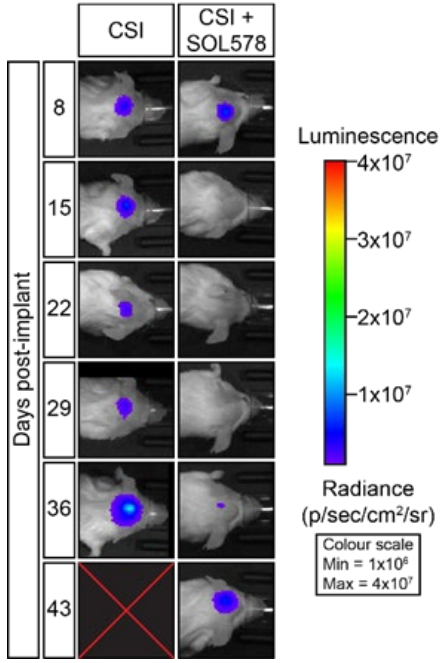
PEP07 (*p.o.*) Combined with Radiation Shows Tumor Reduction and Survival Benefit in Medulloblastoma Orthotopic Model

PEP07 (*p.o.*) + CSI increase tumor free survival



Treatment schedule	Number of mice (n)	Median survival (d)
Week 1: Su M Tu W Th F Sa; Week 2: Su M Tu W Th F Sa		
Control	15	15
50 mg/kg SOL578 (p.o.)	9	15
2 Gy CSI	19	43
50 mg/kg SOL578 (p.o.) 2h **before** CSI	10	52.5

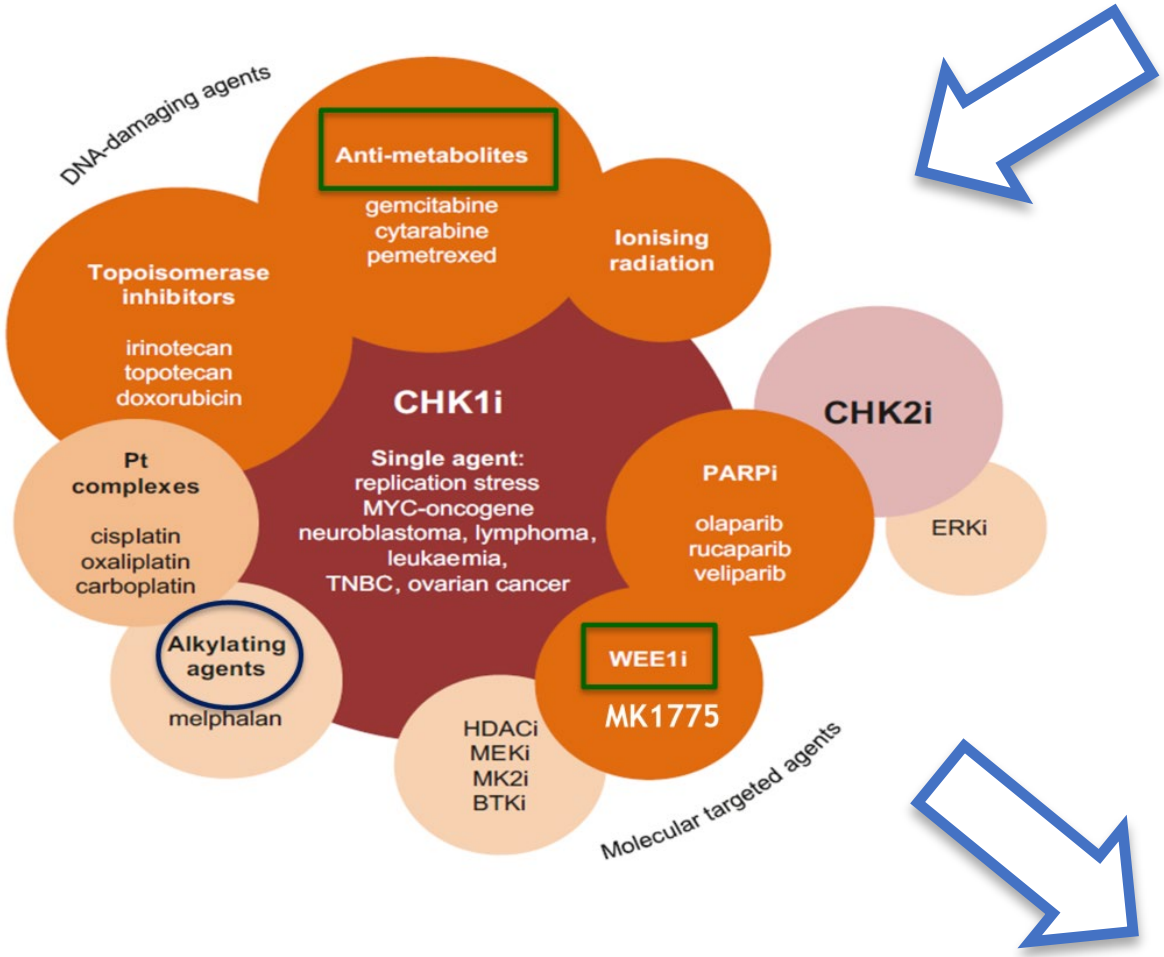
PEP07 (*p.o.*) + CSI show Intracranial tumors regression



PEP07 is a potent brain penetrating oral inhibitor which has potential to intensify the effectiveness of CSI on brain cancer

D425 Medulloblastoma orthotopic model ; CSI: CranioSpinal Irradiation

PEP07 for Potential Combination Therapies



In vitro Combo treatment

SoC agents	Indication	Cell line
Ara-C	AML	MV4-11 / THP-1
Gemcitabine	NSCLC	NCI-H1703
5-Fu	Esophagus	KYSE-270
5-Fu	Stomach	MKN-45, SNU-16, SNU-5,
5-Fu	CRC	DLD-1, HT-29, SW480
TMZ	Brain	IMR-32
Sorafenib	RCC	A498

Green: Synergism ; Blue: Additivity

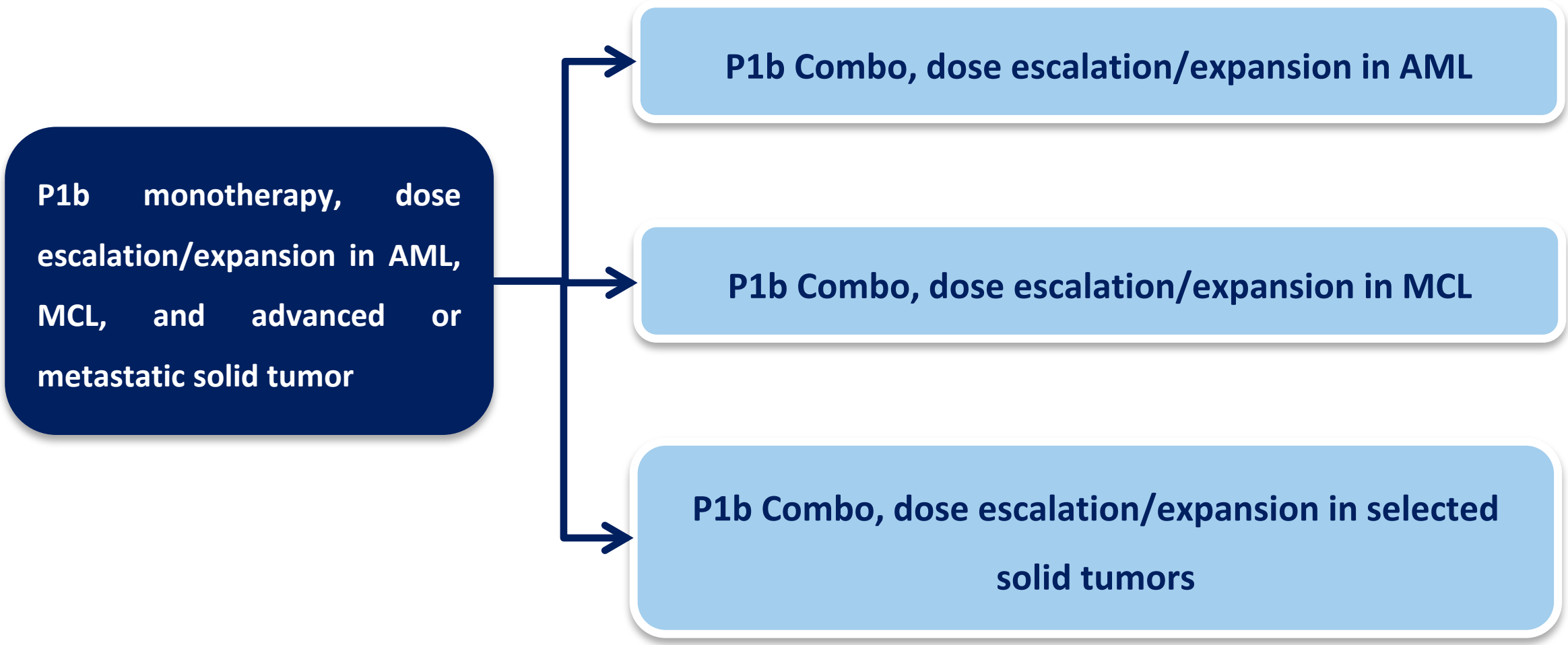
Clinical Trial Designs and Indications Guidance

：Synergistic effect verified in PEP07

：Additive effect observed in PEP07

Targeting the DNA Damage Response for Anti-Cancer Therapy 241-276, 2018

PEP07 Early-Stage Clinical Development Strategy



Preclinical biomarker study is ongoing for further design of clinical trials

PEP07 Keep Moving Forward to Phase I

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Development Plan	2021												2022											
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
Preclinical Development																								
CMC Development																								
Toxicology Development																								
IND Preparation/ Submission																								

Preclinical

Additional Efficacy studies in animal models ongoing.
Biomarker evaluation ongoing.

CMC

1 kg of GMP DS production completed.
GMP DP development and production 1st strength completed.

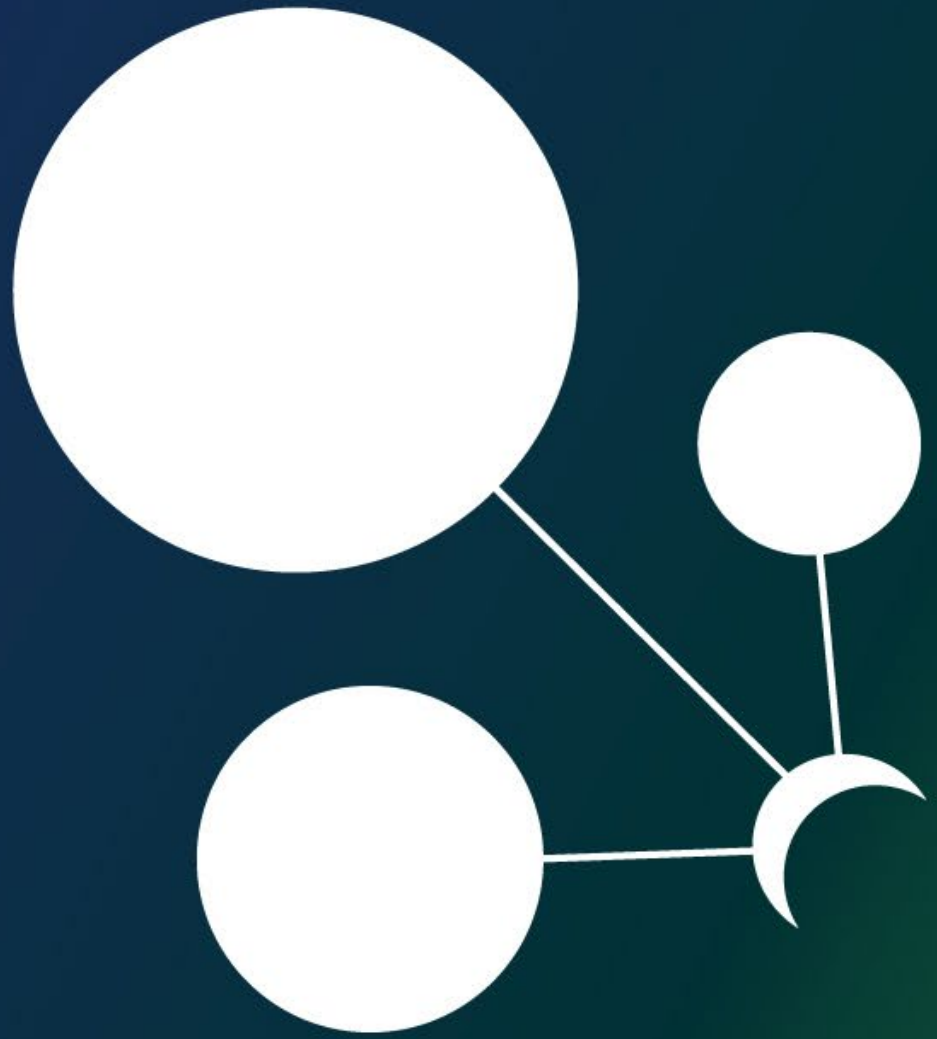
Toxicology

GLP study completed.

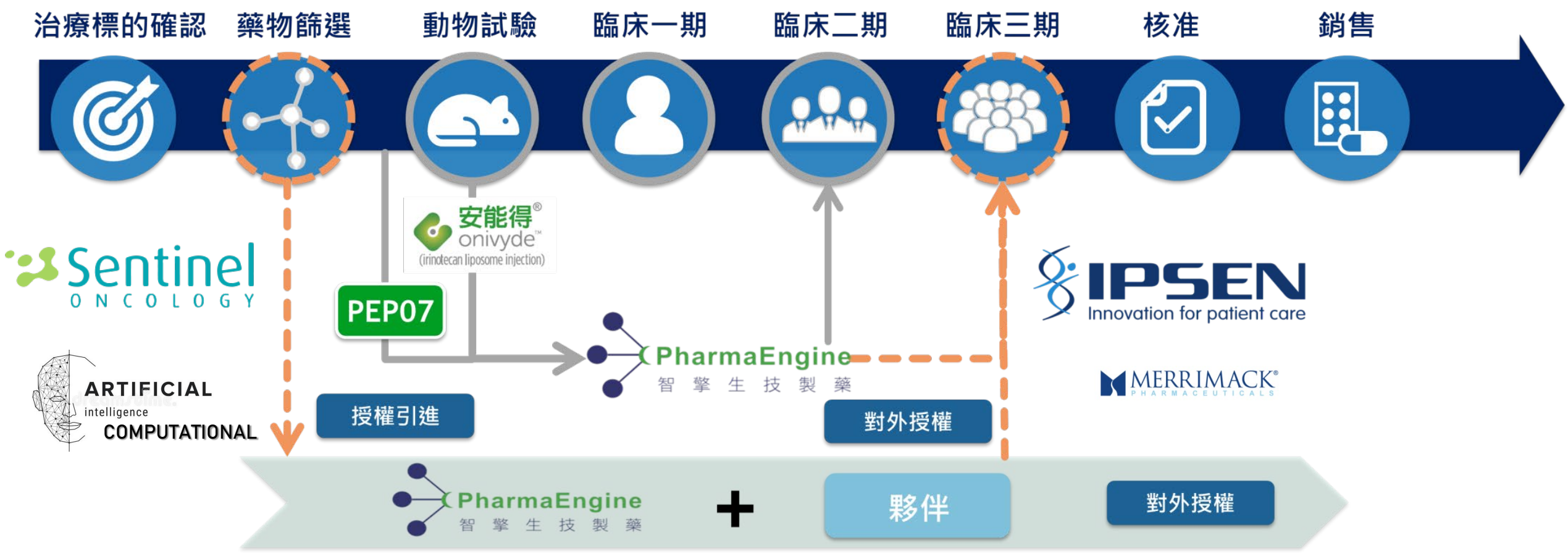
IND Prep. & Sub.

IND submission before YE22.

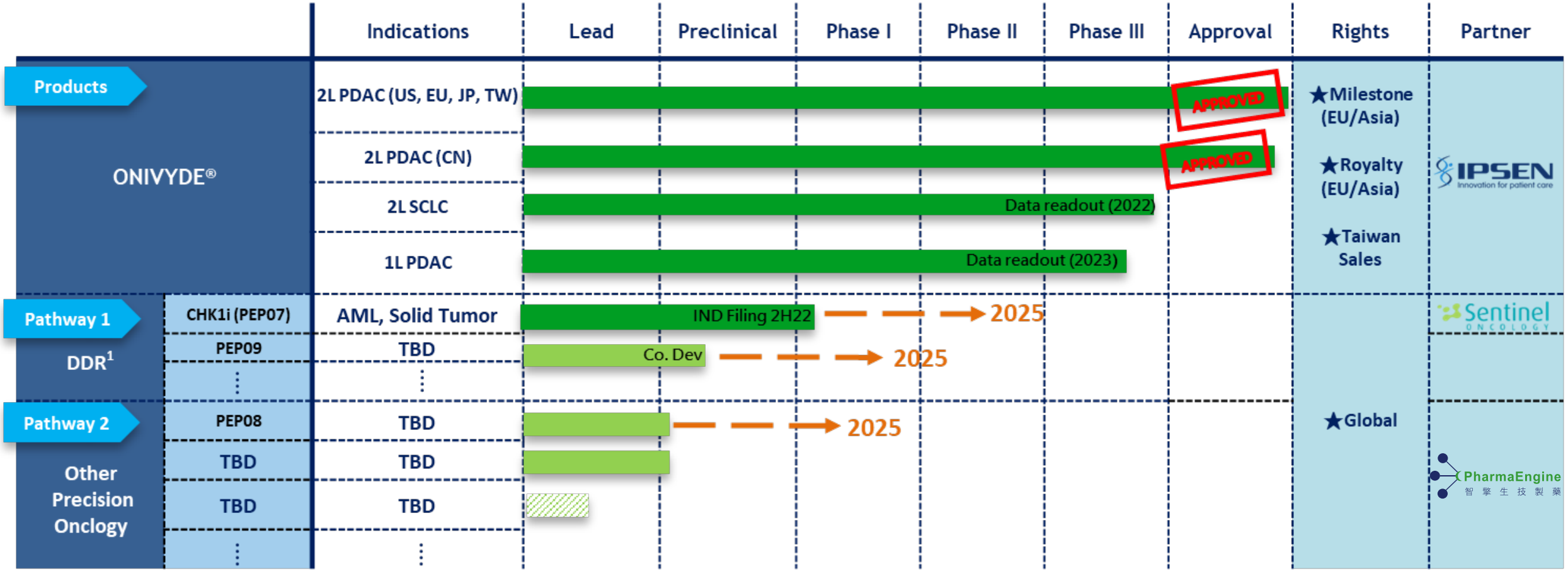
Vision for 2022



Virtual Pharmaceutical Company Business Model



Pipeline Portfolio Focus on Precision Oncology



1. DDR: DNA Damage Response (BRCA1/2, CHK1/2, WEE1, etc…)

2022: Year of Revitalization and Marching Forward

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Growth through ONIVYDE® life cycle management

1. 2L PDAC get approval and reimbursement in additional countries
2. 1L PDAC Phase III data readout (YE22)

Advancement and growth of early-stage pipeline

1. PEP07 IND/CTA submission
2. Co-develop 2nd DDR PEP09 project
3. Develop next generation target therapy PEP08 and PEP10
4. Initiate other precision oncology projects development

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