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1H22 Earning Result
2022/07/27

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Agenda

1. 1H22 Operational Highlights
2. 1H22 Operational Overview
3. Research and Development
   - ONIVYDE®
   - PEP07 (SOL-578)
4. Vision for 2022
5. Q&A

Keep Deliver Sustainable Growth and Enhanced Value in 1H22

Commercial

ONIVYDE ® market and new indication expansion

1. ONIVYDE® 2L PDAC treatment got China NMPA approved.
2. ONIVYDE® EU/Asia Royalties with strong growth momentum.
3. ONIVYDE® 2L SCLC/1L PDAC phase III trial ongoing.

Pipeline

New project licensing and RD progress accelerated

1. PEP07 preclinical progress meets expectation
2. Early stage projects under evaluation

Operation

Operation with a sustainable growth

1. 1Q22 Cash and cash equivalents:
   - NTD$3.9 bn
2. Long-lasting dividend payout :
   - NTD$ 2.7/share (+8% YoY) 2021

1H22 Operational Overview

ONIVYDE® Revenue with Stable Growth

Sales and Royalties Drives Long-term Growth

NTD $(000)

Items / Year	2017	2018	2019	2020	2021	1H21/1H22 YoY (%)
Taiwan Sales	40,651	87,384	180,389	214,828	235,469	135,399 (20%)
Royalties from Europe and Asia	63,526	109,825	133,651	271,584	419,366	205,629 (27%)
Milestone	749,500	96,221	0	569,600	0	0
Total	853,677	293,430	314,040	1,056,012	654,835	341,028(25%)

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

1H22 Financial Results

NTD$ (000)	2022H1	2021H1	Amount Change	% Change
Operating revenue	341,028	273,908	67,120	25
Operating costs	23,948	19,238	4,710	24
Gross profit	317,080	254,670	62,410	25
Sales expenses	15,807	15,501	306	2
G&A expenses	45,405	39,944	5,461	14
R&D expenses	42,024	70,519	(28,495)	(40)
Total operating expenses	103,236	125,964	(22,728)	(18)
Operating income	213,844	128,706	85,138	66
Total non-operating income and expenses	12,557	174,554	(161,997)	(93)
Income before income tax	226,401	303,260	(76,859)	(25)
Income tax expense	48,697	61,913	(13,216)	(21)
Profit for the period	177,704	241,347	(63,643)	(26)
Common stock	1,455,968	1,465,968	(10,000)	(1)
EPS(NT$)	1.24	1.66	(0.42)	(25)

Research and Development

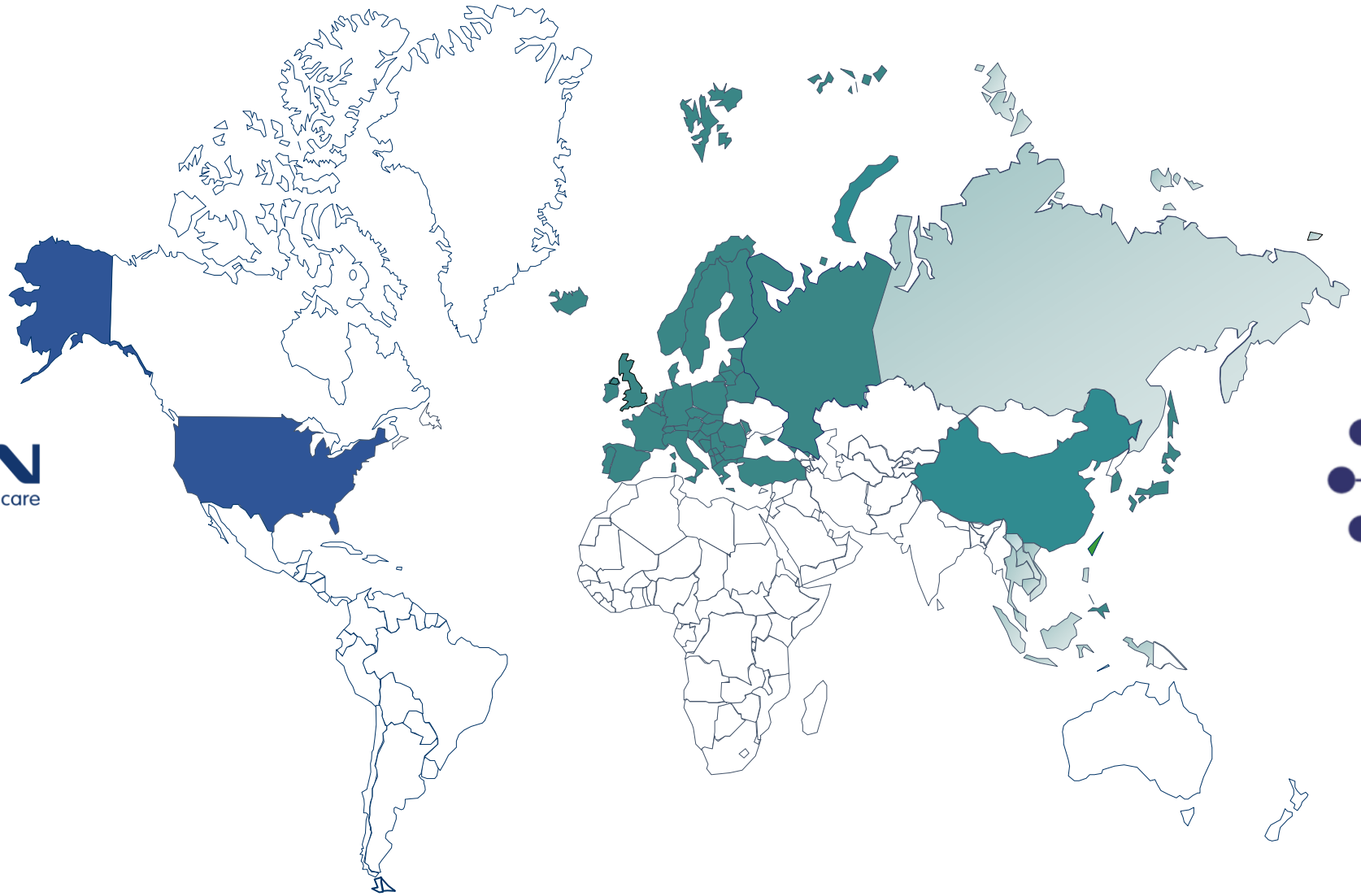
ONIVYDE® 2L SCLC Phase III Readout at 2H22

PEP07 (SOL-578) File IND at 2H22

Multiple Projects Under Evaluation with

External AI/CADD collaboration

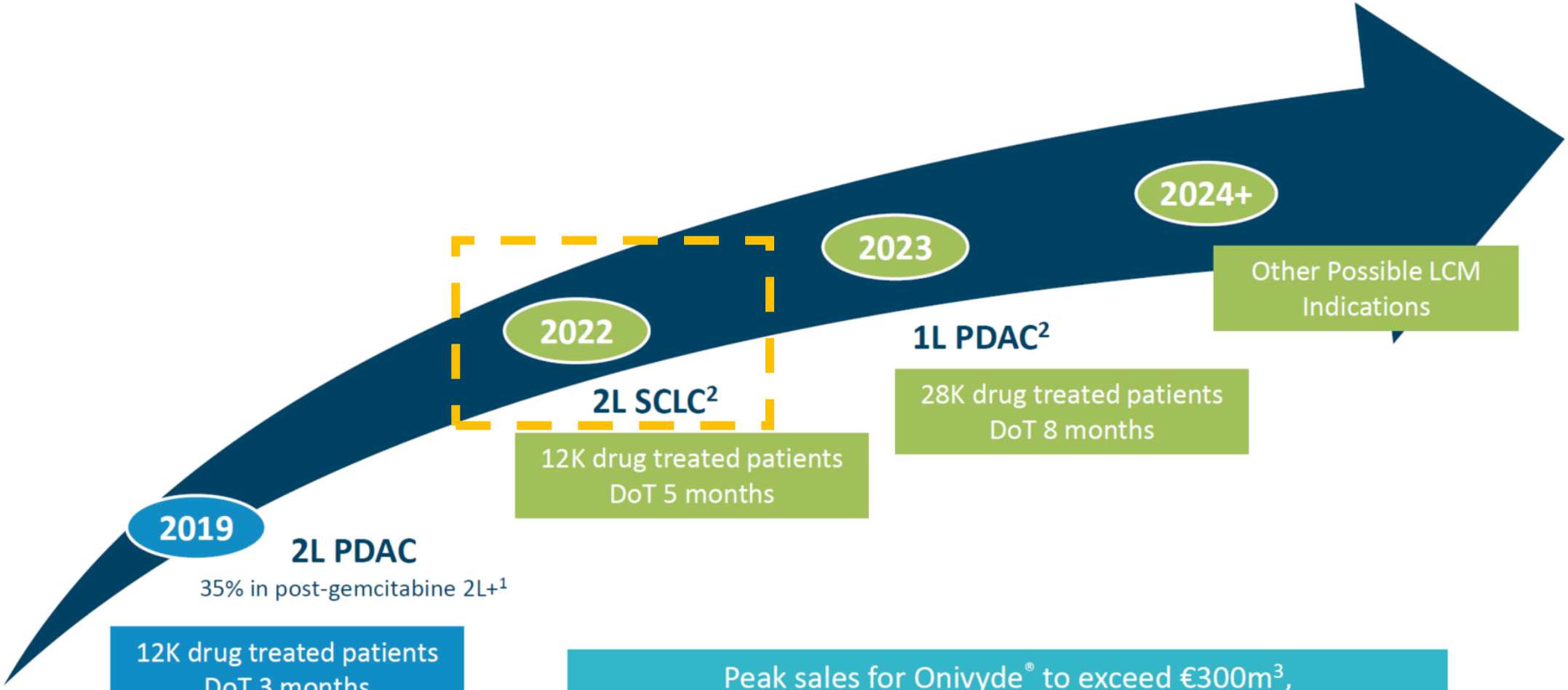
ONIVYDE® Keep Global Market Expansion at 2L PDAC



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

Small Cell Lung Cancer (SCLC)

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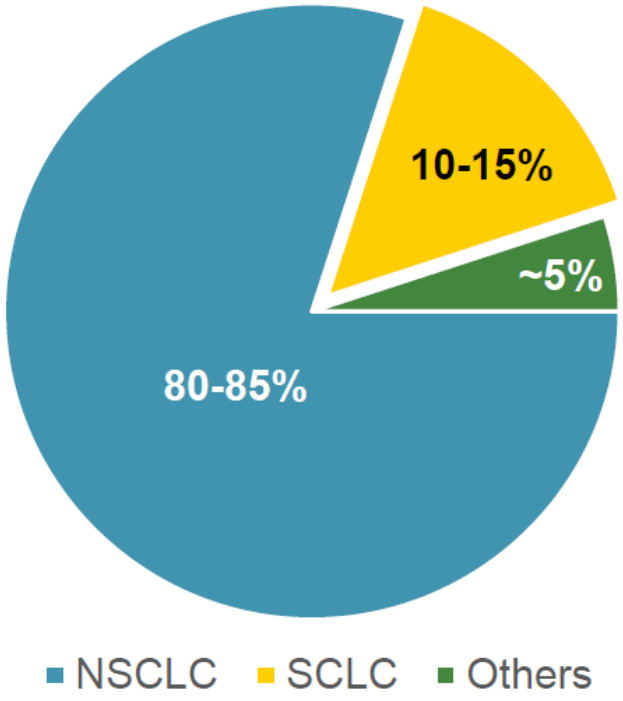
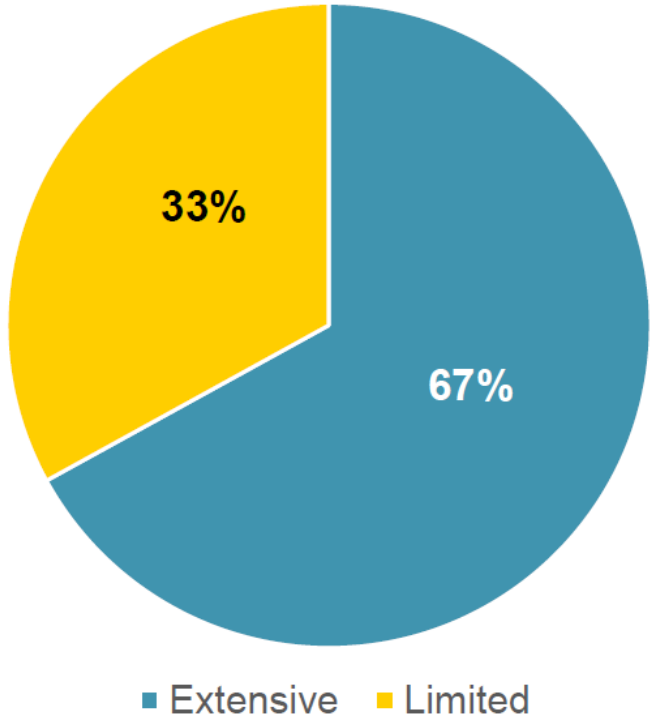
Types of lung cancer[1]



Characteristics of SCLC[2]

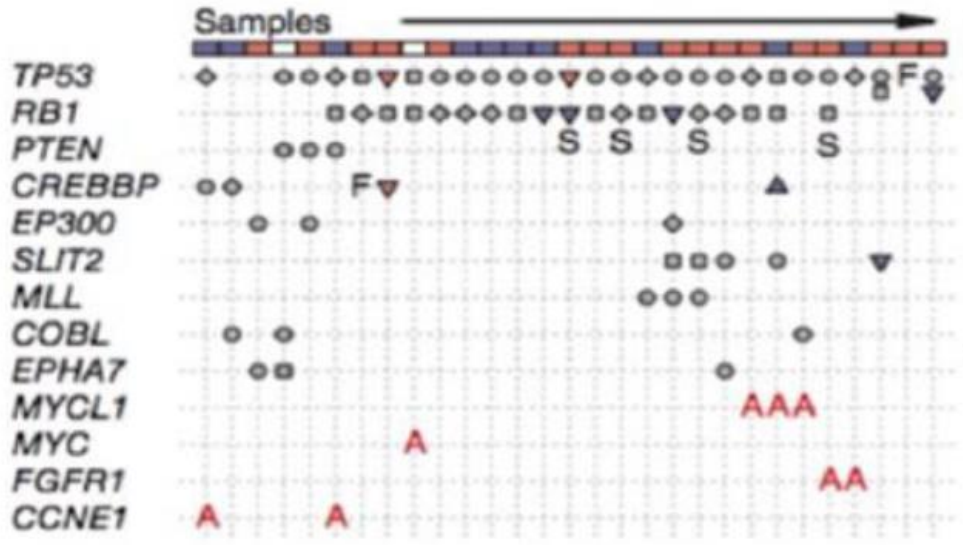
- Rapid doubling time
- High growth fraction
- Paraneoplastic syndromes
- Early development of widespread metastases
- SCLC is a very aggressive cancer that is usually diagnosed at the extensive stage[3]
- 5yr survival
  - Limited stage ranges from 20 40% [4]
  - Extensive stage <5% [4]

SCLC Stage at Diagnosis[1]



1 American Cancer Society. What is Lung Cancer? https://www.cancer.org/cancer/lung cancer/about/what is.html , 2 Dowell JE, et al. In: Grippi MA, et al. eds. Fishman's Pulmonary Diseases and Disorders , Fifth Edition. New York, NY: McGraw Hill; 2015, 3 American Cancer Society, https://www.cancer.org/cancer/small cell lung cancer/about/what is small cell lung cancer.html , 4 Nat Rev Clin Oncol . 2017 Sep 14(9) 549 561 3 von Pawel et al. J Clin Oncol 32:4012 4019, 5 National Cancer Institute. Small cell lung cancer treatment (PDQ®) health professional version. https://www.cancer.gov/types/lung/hp/small cell lung treatment pdq

SCLC New Drug Development with High Entry Barrier



- Most common genomic alterations are in tumor suppressor genes
  - Turning off an "off switch" is a real challenge

Source: Peifer et al Nature Genetics 2012

Drug class failures 2L SCLC:

- Aurora Kinase
- BCL2
- C-Kit
- DLL-3
- EGFR
- FLT3
- HDAC
- IGF
- mTOR
- PD1
- Proteosome inhibitor
- VEGF

Drug	Company	Target or mechanism of action	Status
Lurbinectedin	PharmaMar/Jazz Pharmaceuticals	RNA polymerase II	APPROVED
Trilaciclib	G1 Therapeutics	CDK4/6	PR
Tiragolumab	Roche/Chugai	TIGIT	Phase III
Tremelimumab	AstraZeneca	CTLA4	Phase III
Nanoliposomal pegylated irinotecan (Onyvide)[a]	Ipsen	Topoisomerase I	Phase III
RRx-001	EpicentRx	Nitric oxide prodrug	Phase III
Etirinotecan pegol	Nektar Therapeutics	Topoisomerase I	Phase II
Abemaciclib (Verzenio and Verzenios)[a]	Eli Lilly	CDK4/6	Phase II
Guadecitabine	Astex Pharmaceuticals	DNMT	Phase II
Olaparib (Lynparza)[a]	AstraZeneca	PARP	Phase I/II
CC-90011	Bristol-Myers Squibb	LSD1	Phase I/II
LY3295668	Eli Lilly	Aurora kinase A	Phase I/II
AMG757	Amgen	DLL3 and CD3	Phase I

"SCLC is difficult to treat in part because you can't target an absent protein the way you can target a mutant protein–there's nothing against which a drug can be directed"

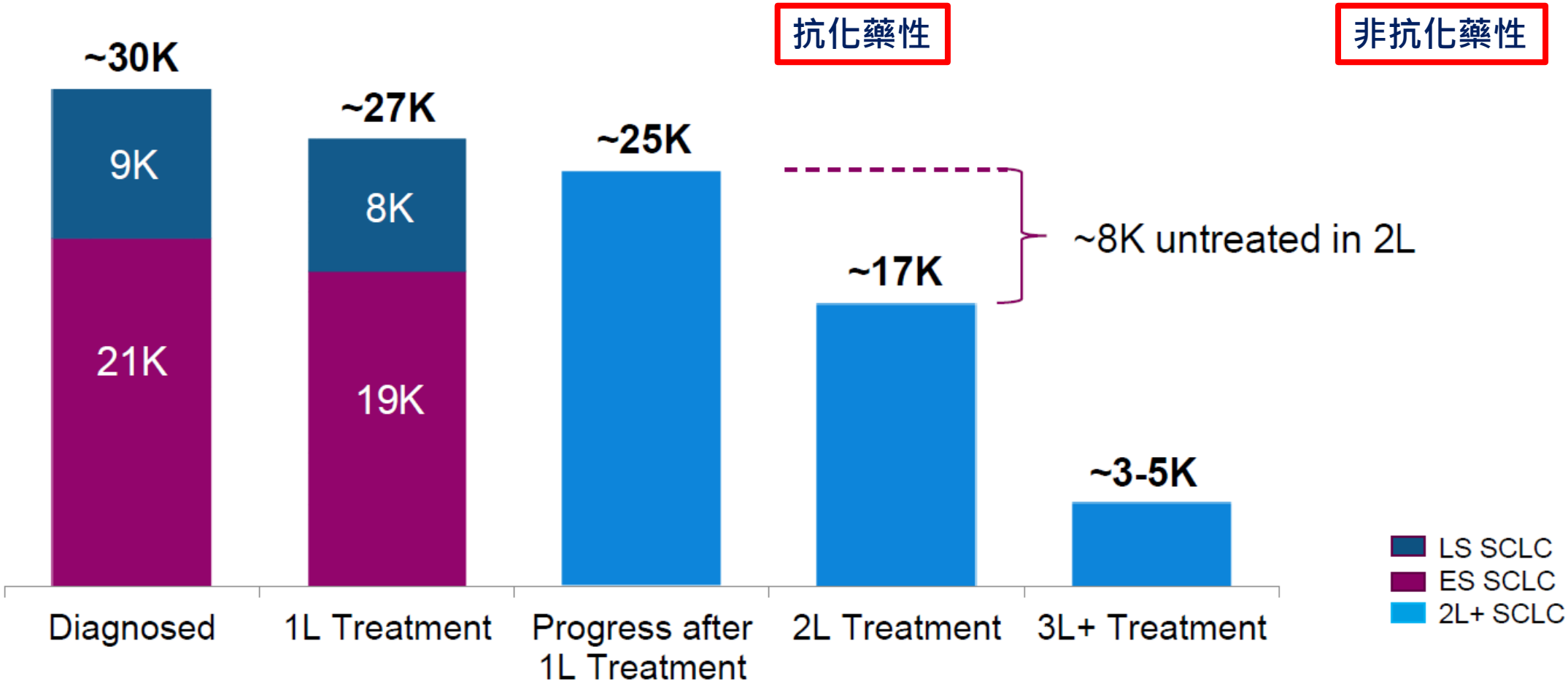
Source: Rudin C. Looking Ahead to New Therapies in Small Cell Lung Cancer. Clinical Advances to Hematology & Oncology 2018:16 (4): 269-272

2L SCLC Treatment is Urgent Unmet Medical Need

	Extensive Stage, 1L	Limited Stage, 1L	2L+
FDA Approved	Platinum + Etoposide + Atezolizumab or Durvalumab		Lurbinectedin (2021) Topotecan (2007)
NCCN Guideline ***Preferred regimens***	Platinum + Etoposide + Atezolizumab or Durvalumab	Cisplatin + Etoposide +/- RT	Relapse ≤ 6 months: topotecan or Clinical trial
NCCN Guidelines ***Other recommended regimens***	Platinum + etoposide or cisplatin+ irinotecan		Relapse ≤ 6 months: multiple other chemo or Relapse > 6 months: original regimen (W/O IO)

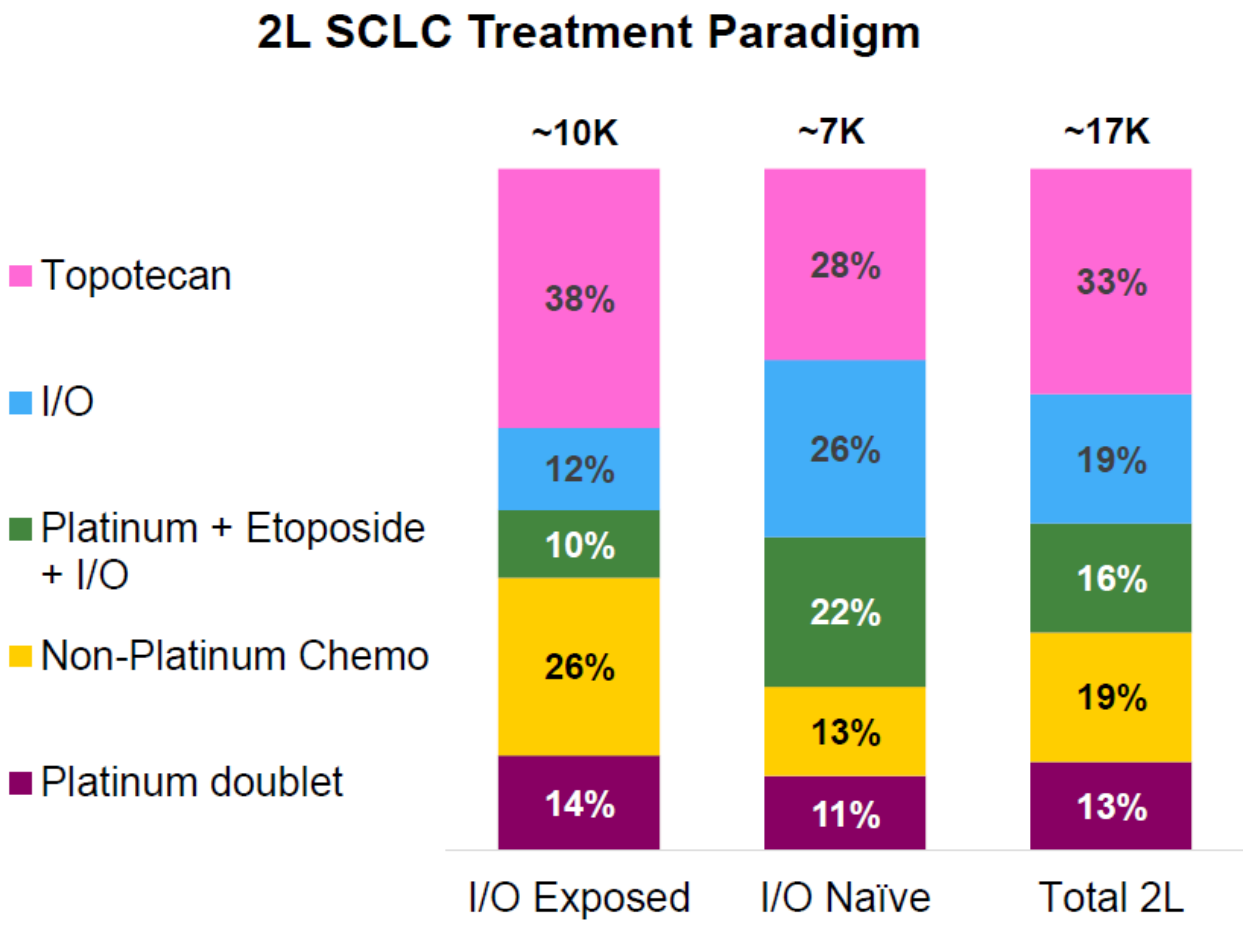
2L SCLC U.S. Market Opportunity

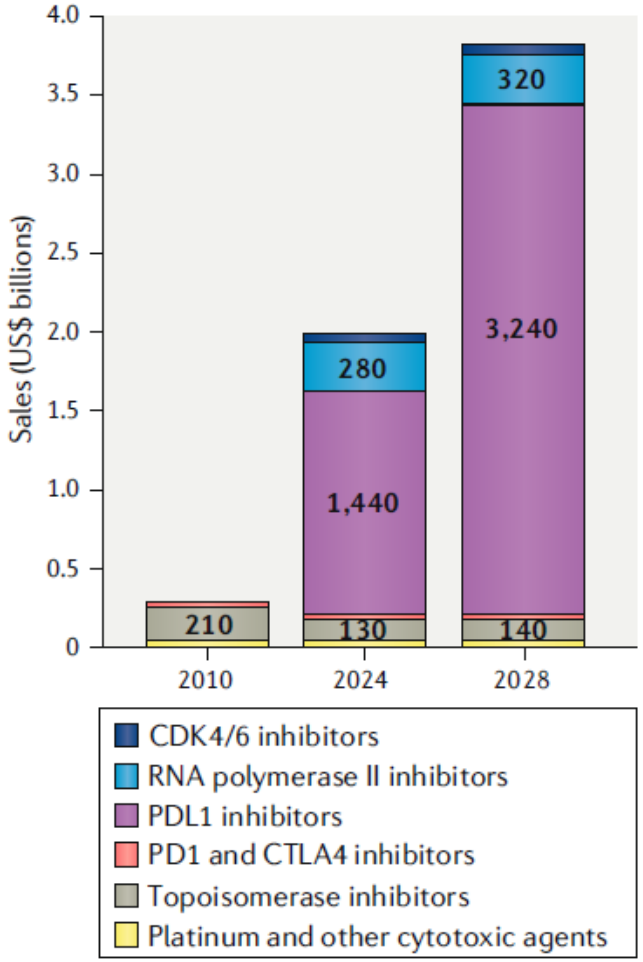
Of the ~17K 2L SCLC Patients, ~30% have CTFI < 90 days and ~70% have CTFI ≥ 90 days[1]



1 Jazz market research, SHS claims data; Other sources: SEER Cancer Stat Facts https://seer.cancer.gov/statfacts/html/lungb.html, accessed April 19, 2019; American Cancer Society, https://www.cancer.org/cancer/small cell lung cancer/about/what is small cell lung cancer.html, acces sed April 12, 2019; Kantar Health Treatment Architecture SCLC July 2018

Estimated major-market sales of key therapies for small-cell lung cancer, by drug class





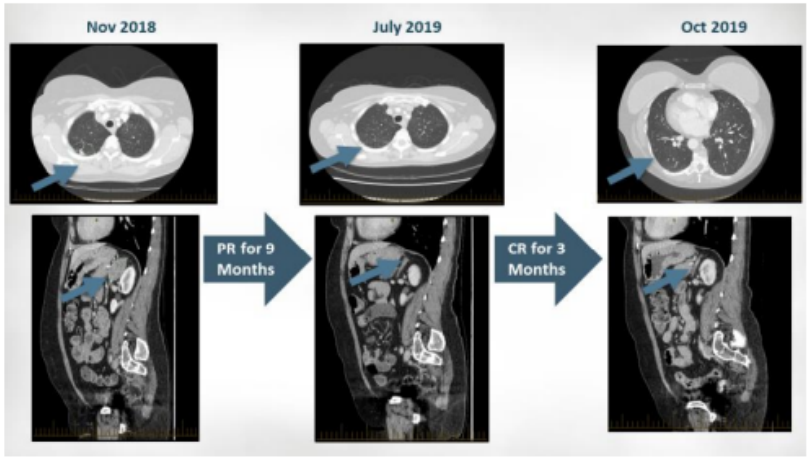
The figure shows the 2018–2028 forecast for the seven major markets: the USA , France, Germany , Italy , Spain, UK and Japan. CDK4/6, cyclin- dependent kinase 4/6.

Source: Jazz market research. Other treatments include non-platinum based therapies reflecting divergence in opinions of standard of care. Chemo includes both platinum and non-platinum regimens. IO includes IO alone and Platinum doublet + IO.

Nature Reviews | Drug Discovery NEWS & ANALYSIS volume 19 | August 2020

ONIVYDE® : Potential to Establish Standard of Care in 2L SCLC

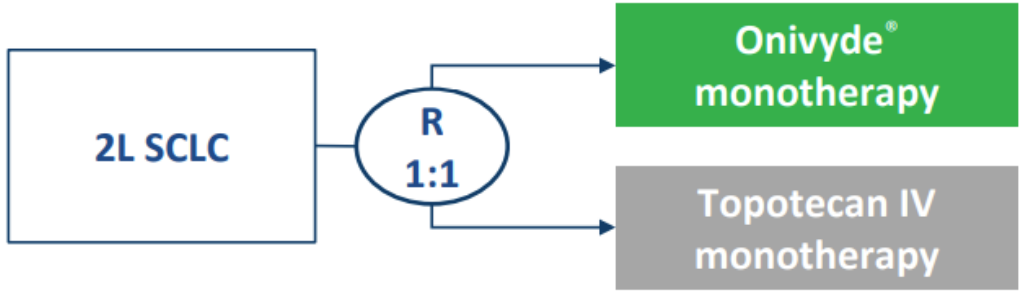
Phase 2 results



	Resilient Study Part 1 – 70 mg/m² Cohort
N	25
Complete Response	1 (4%)
Partial Response	10 (40%)
Stable Disease	7 (28%)
ORR; % (95%)	11 (44%)
DCR; % (95%)	18 (72%)

Phase 3 RESILIENT study status & design

- Phase 3 study ongoing
- Expected topline readout 2022
- **Potential for accelerated regulatory review**



2L SCLC (N=450)

- Histologically/cytologically confirmed SCLC with evaluable disease per RECIST v1.1
- Progression after 1L platinum-based therapy
- Prior immunotherapy is allowed
- ECOG performance status of 0 or 1

Primary endpoint

- OS

Secondary endpoints

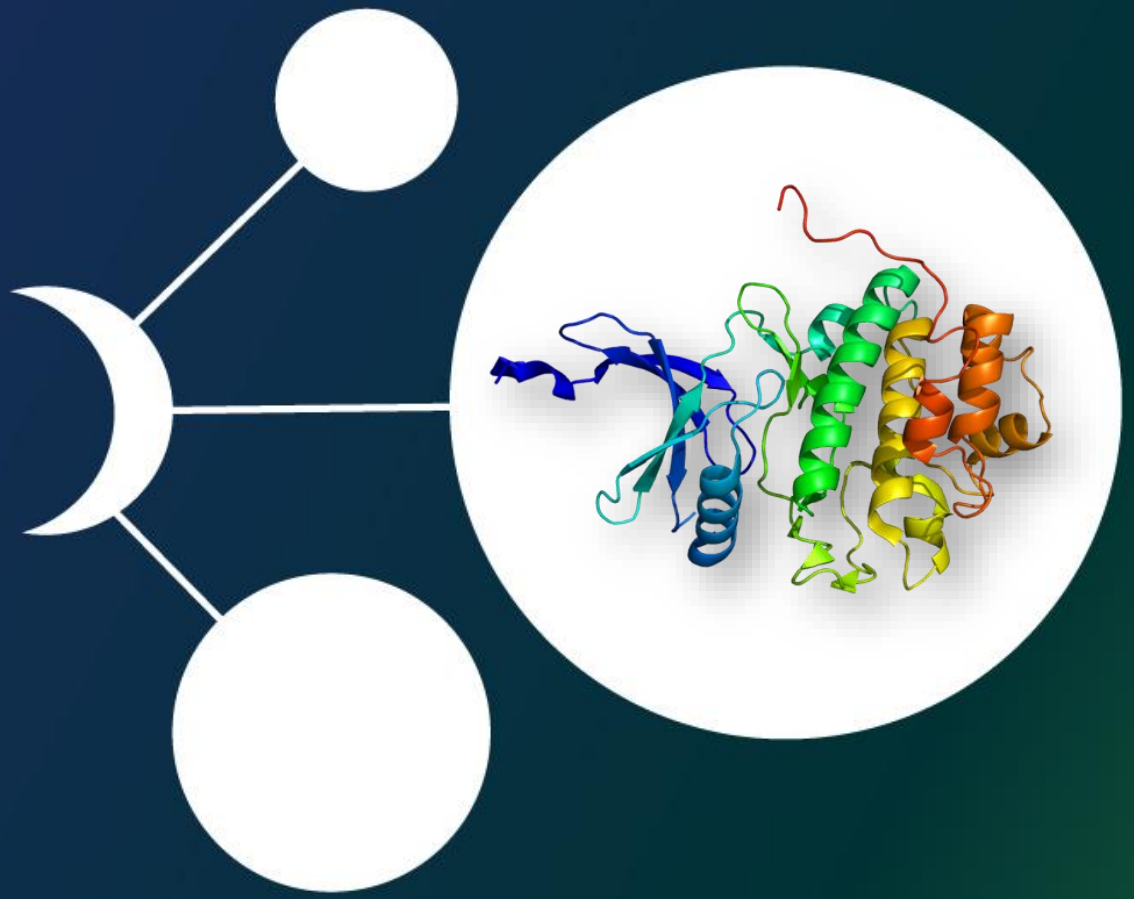
- PFS
- ORR
- Safety

SCLC: small cell lung cancer; ORR: Overall response rate; DCR: Disease control rate; RECIST: Response evaluation criteria in solid tumors; PFS: Progression free survival; ECOG: Eastern cooperative oncology group functional status measure; 2L: Second line Source: IASLC World Congress on Lung Cancer 2019 Oral Presentation, OA03.03. ; IPSEN Capital Market Day 2020

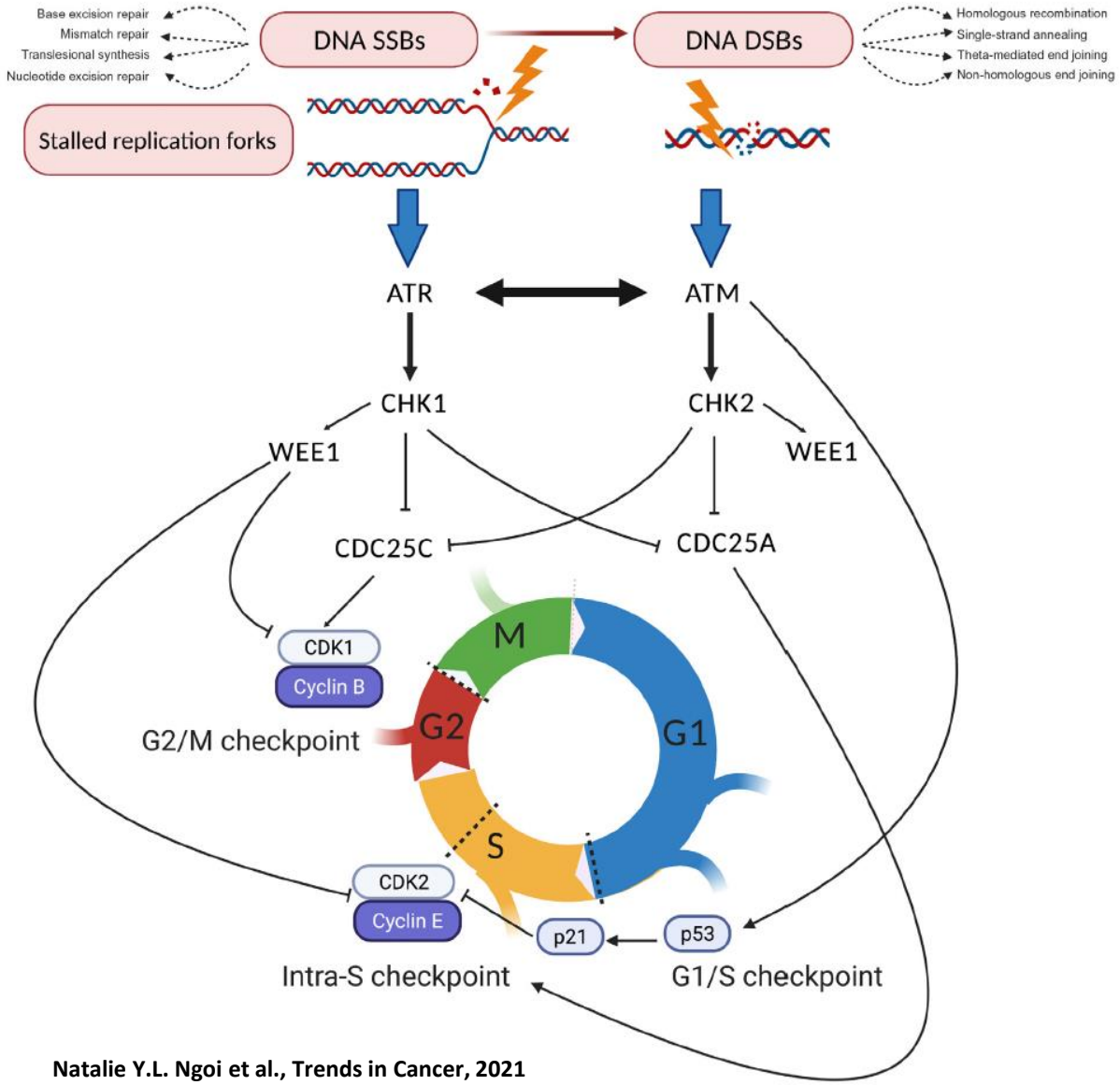
PEP07 (SOL-578)

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.	Biotech	Pharma	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

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

PEP07 (SOL-578) – Potential Best in Class CHK1 Inhibitor

PEP07 (SOL-578) is a brain penetrating oral inhibitor which is more potent, selective, specific than the competitors.

	Drug	Potency	Selectivity	Specificity	Oral Bioavailability
Eli Lilly	LY2606368				
Genetech	GDC-0575				
Sierra Oncology	SRA-737				
Esperas Pharma	LY2880070				
PEI/Sentinel	PEP07/SOL-578				

Excellent Good Fair Poor Unknown

PEP07 (SOL-578) : Significant Efficacy in Hematologic Malignancies as Monotherapy and Combination Therapy

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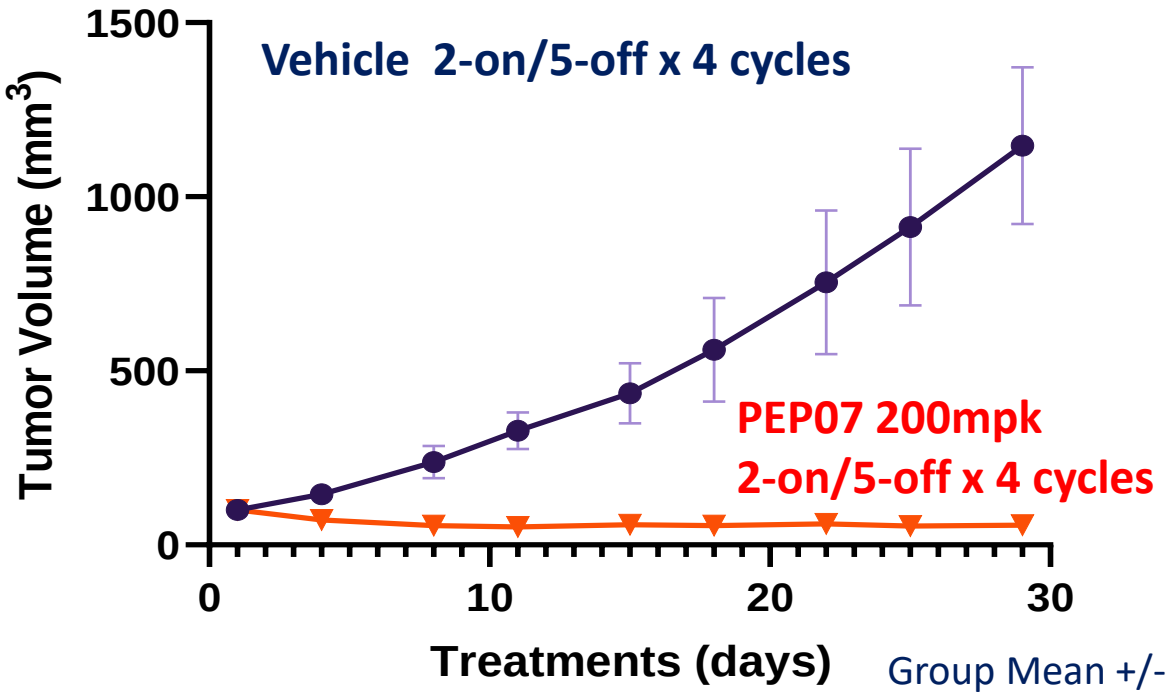
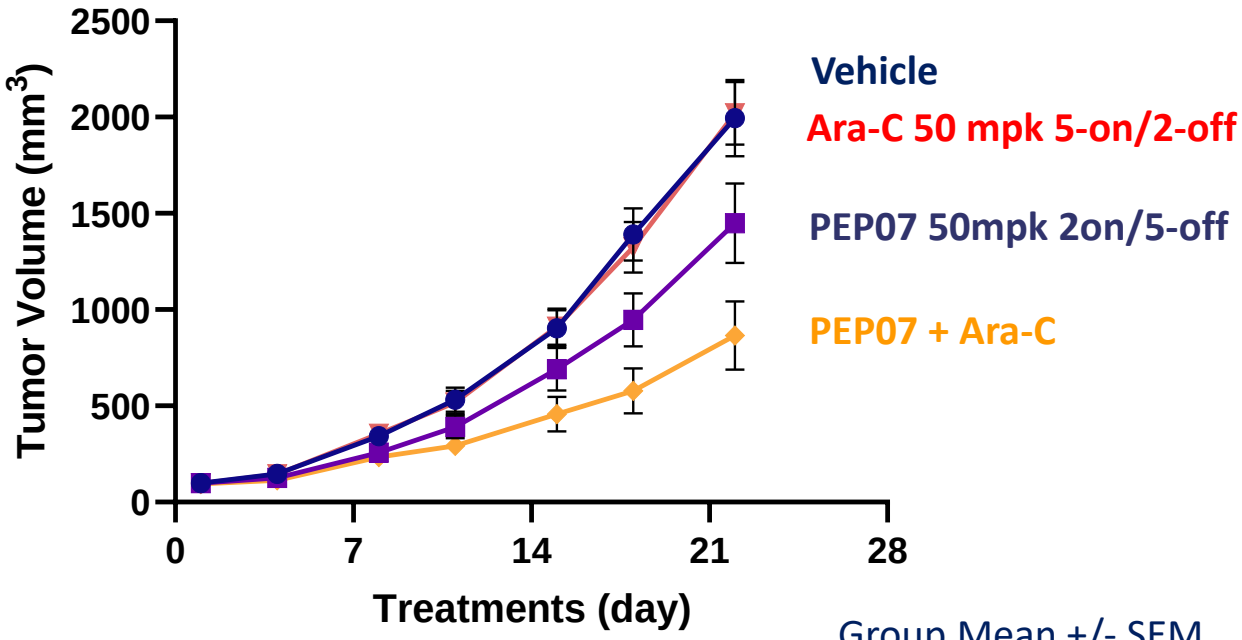
Acute Myeloid Leukemic (AML)

Ara-C Sensitive



Group Mean +/- SEM
n=8/group

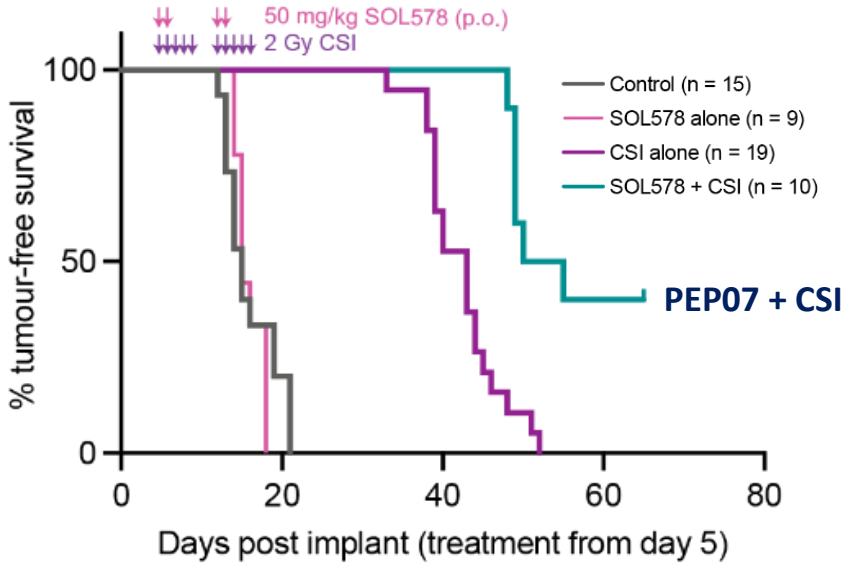
Ara-C Resistant



Group Mean +/- SEM
n=8/group

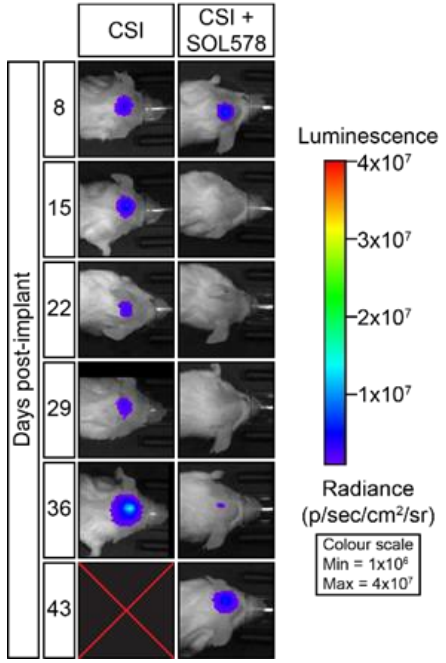
PEP07 (*p.o.*) Combined with Radiation Shows Tumor Reduction and Survival Benefit in Medulloblastoma Orthotopic Model

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

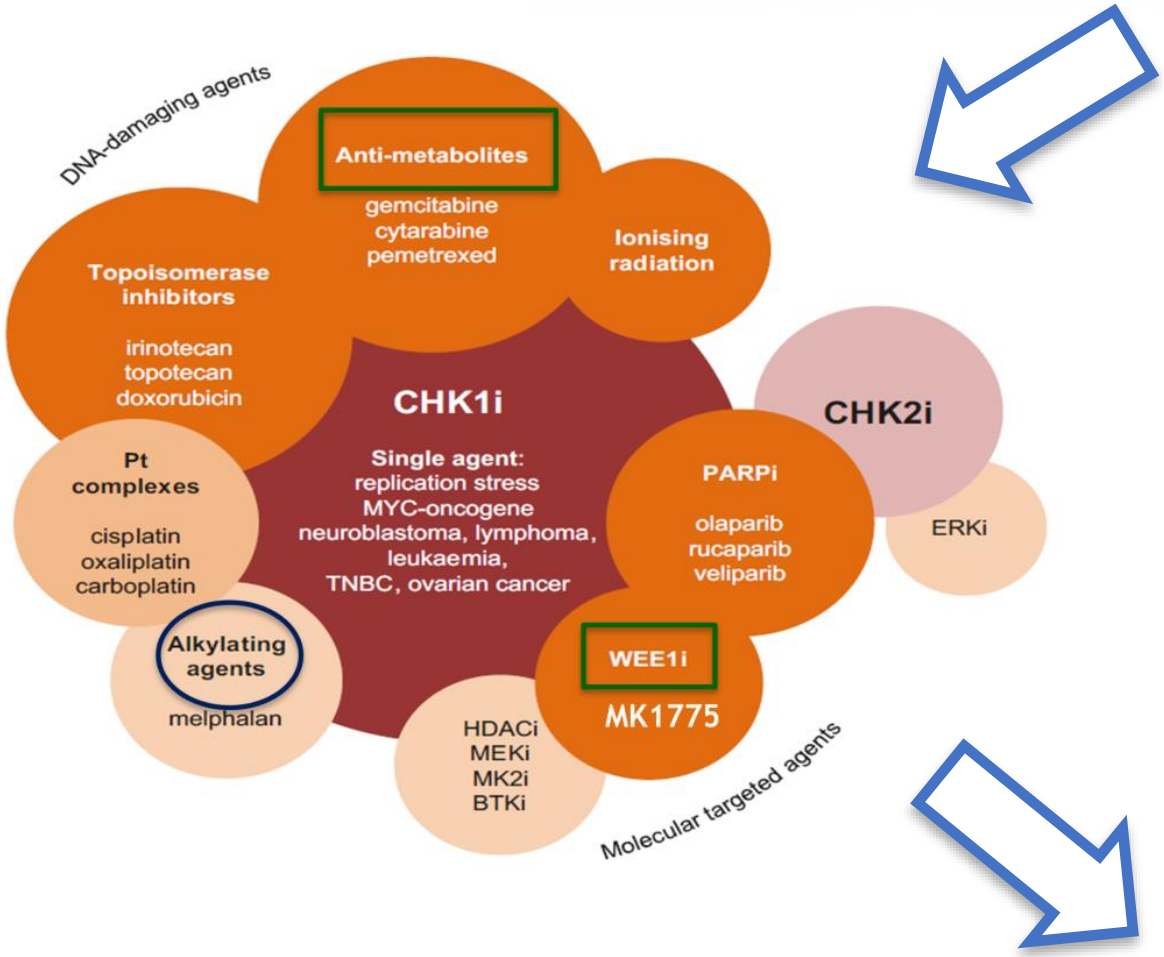
PEP07 (*p.o.*) + CSI show Intracranial tumors regression



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 (SOL-578) 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 (SOL-578) Keep Moving Forward to Phase I

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 ongoing

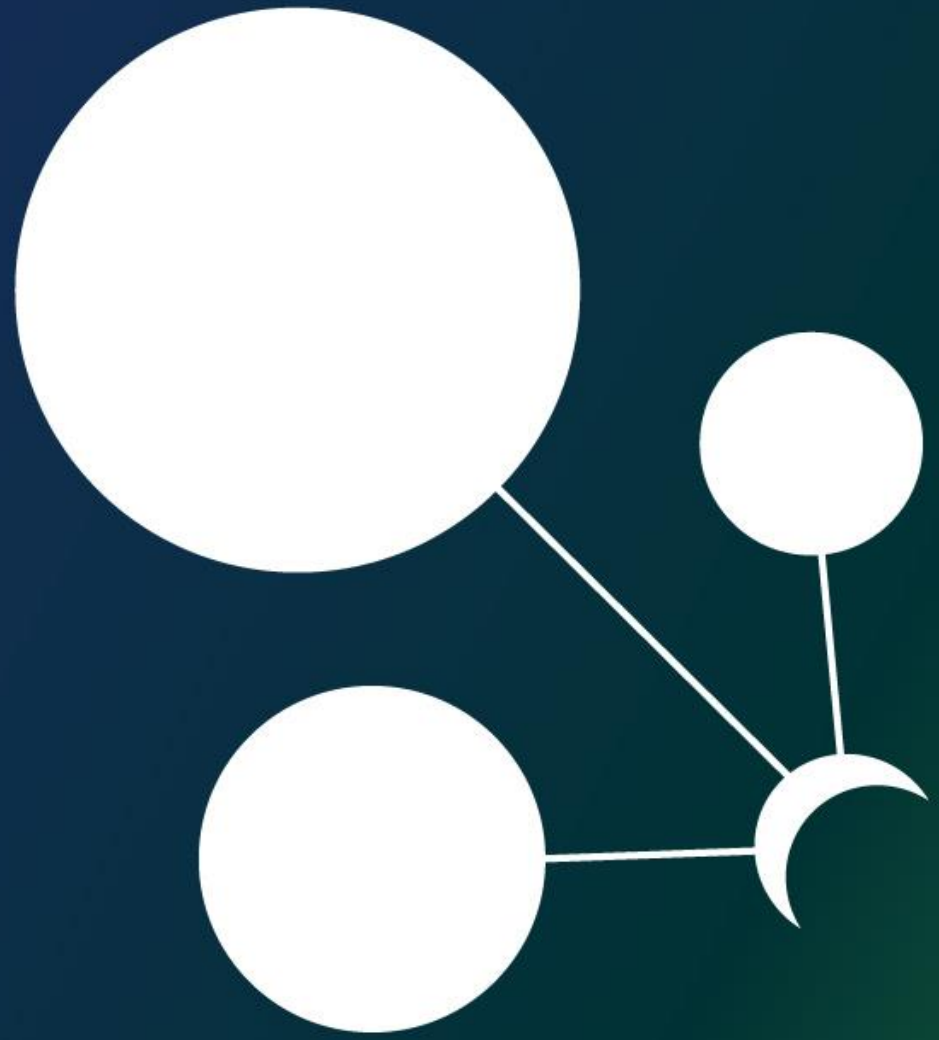
Toxicology

GLP study ongoing

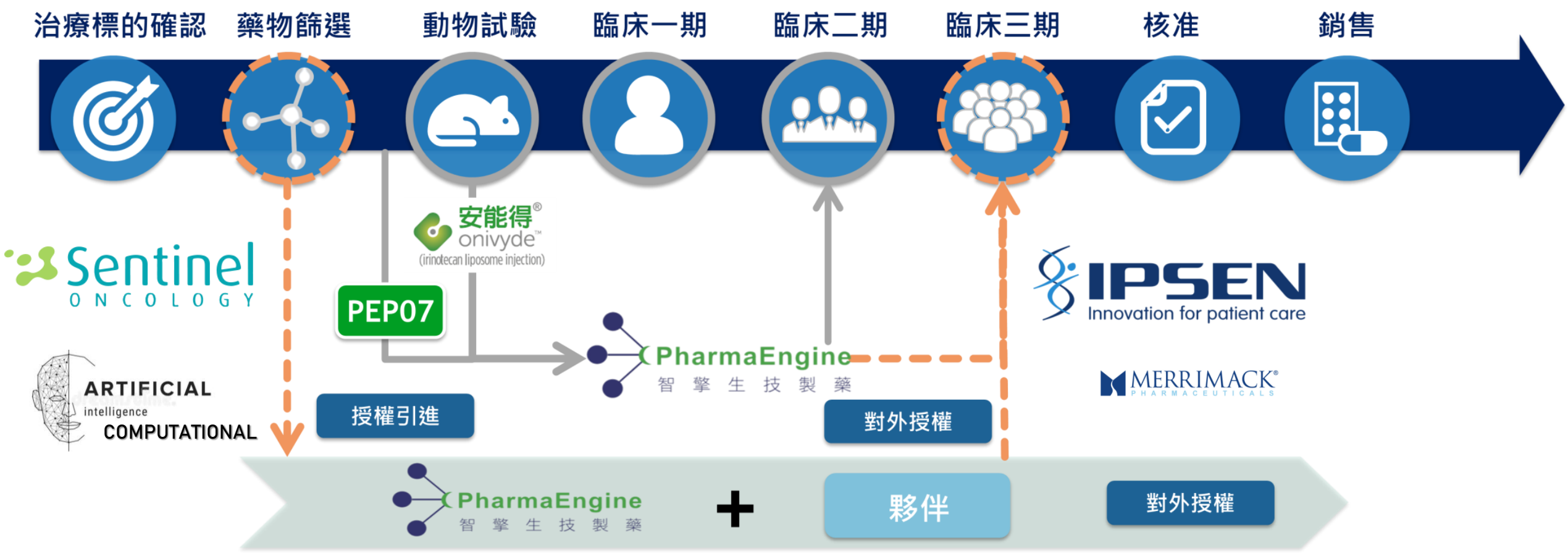
IND Prep. & Sub.

Target submission on 2022Q3

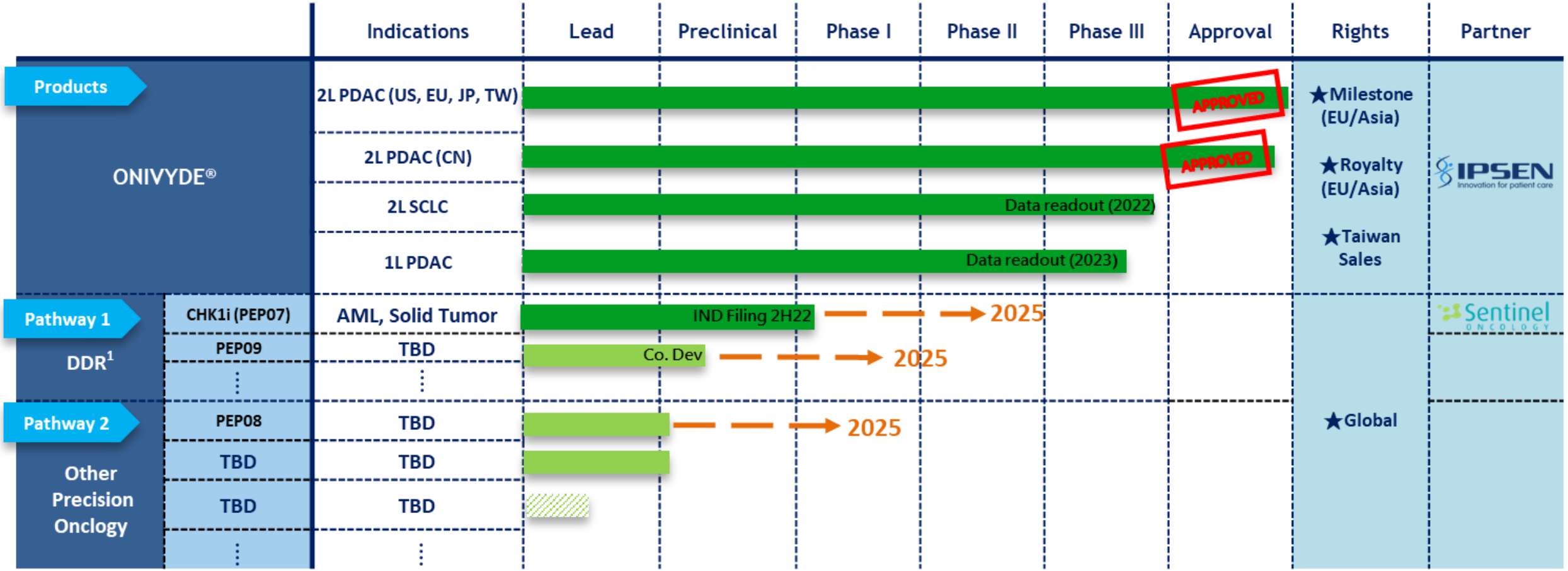
Vision for 2022



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. 2L SCLC Phase III data readout
3. 1L PDAC Phase III data readout (2023)

Advancement and growth of early-stage pipeline

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

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