PharmaEngine

智 擎 生 技 製 藥

1H22 Earning Result

2022/07/27

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議程

1. 2022年1H營運亮點
2. 2022年1H營運概況
3. 研發專案進度
   - ONIVYDE®
   - PEP07 (SOL-578)
4. 2022年營運展望
5. Q&A

2022年1H公司維持成長動能與創造價值

銷售端

ONIVYDE®市場擴展與新適應症延伸

1. 二線胰腺癌治療獲中國批准上市
2. 歐亞地區銷售權利金持續維持增長
3. 一線胰腺癌/二線小細胞肺癌全球三期試驗持續進行

研發端

新產品授權研發進程逐步加快

1. 本公司的PEP07相關前臨床試驗進度符合預期
2. 數項早期項目進入授權評估流程

營運端

公司營運穩健成長

1. 1H22在現金及約當現金暨按攤銷後成本衡量之金融資產
   - 達新台幣39億元
2. 穩定的股利配發策略
   - 2021年現金股利新台幣2.7元/股 (+8% YoY)

2022年1H營運概況

ONIVYDE®銷售持續成長

ONIVYDE®營收成長趨勢

單位: 新台幣仟元

項目 / 年份	2017年度	2018年度	2019年度	2020年度	2021年度	2022年度1H (較2021年同期成長率)
台灣銷貨收入	40,651	87,384	180,389	214,828	235,469	135,399 (20%)
歐亞銷貨權利收入	63,526	109,825	133,651	271,584	419,366	205,629 (27%)
里程碑金/授權金收入	749,500	96,221	0	569,600	0	0
合計	853,677	293,430	314,040	1,056,012	654,835	341,028(25%)

5 yr CAGR. 42% (ex. milestone)

2022年上半年營運概況

單位:新台幣仟元	2022H1	2021H1	Amount Change	% Change
營業收入	341,028	273,908	67,120	25
營業成本	23,948	19,238	4,710	24
營業毛利	317,080	254,670	62,410	25
推銷費用	15,807	15,501	306	2
管理費用	45,405	39,944	5,461	14
研究發展費用	42,024	70,519	(28,495)	(40)
營業費用	103,236	125,964	(22,728)	(18)
營業利益	213,844	128,706	85,138	66
營業外收入(支出)	12,557	174,554	(161,997)	(93)
稅前淨利	226,401	303,260	(76,859)	(25)
所得稅費用	48,697	61,913	(13,216)	(21)
本期淨利	177,704	241,347	(63,643)	(26)
股本	1,455,968	1,465,968	(10,000)	(1)
基本每股盈餘(元)	1.24	1.66	(0.42)	(25)

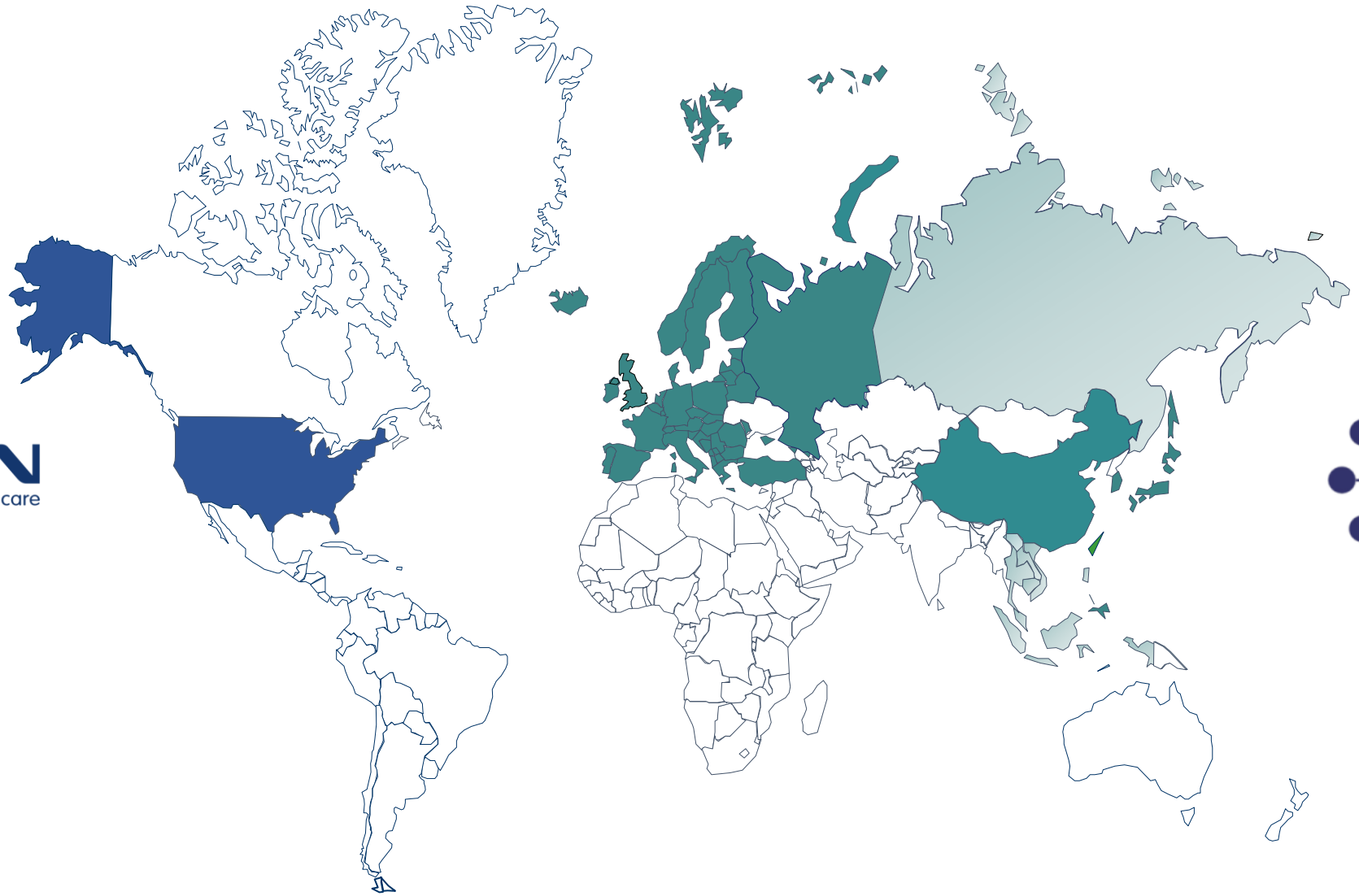
產品專案進度

ONIVYDE®2線小細胞肺癌預計2H22解盲

PEP07 (SOL-578) 預計2H22申請IND

偕同外部AI/CADD技術啟動數項新專案

ONIVYDE®持續拓展全球銷售市場



Approved

Yet approved

ONIVYDE®不斷拓展新的治療機會

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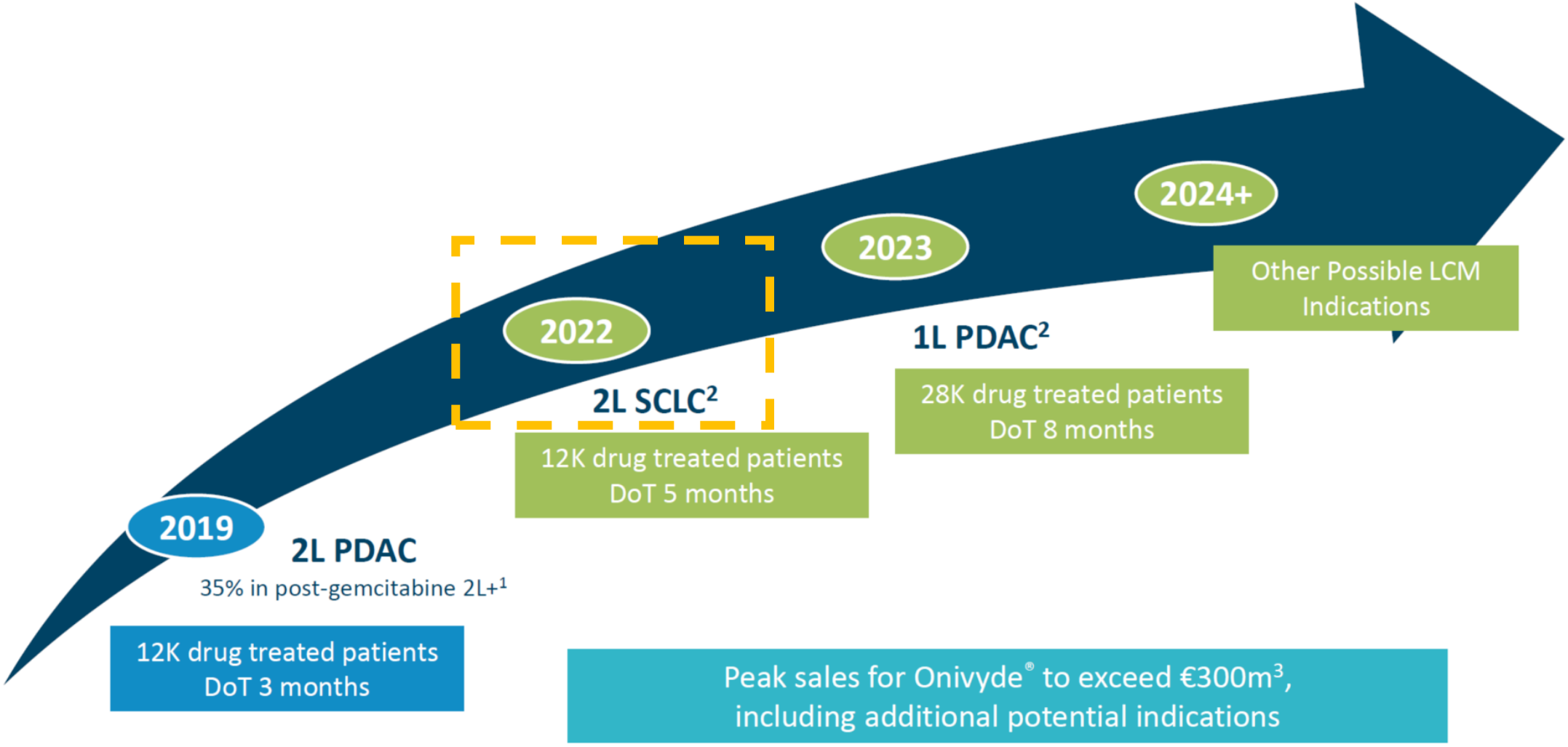

LCM: Life cycle management; PDAC: Pancreatic ductal adenocarcinoma; SCLC: Small cell lung cancer; DoT: Duration of treatment; 1L: First line; 2L: Second line; 1. IQVIA APLD claims, September 2020 ; 2. Expected submission dates ; 3. Risk adjusted; IPSEN Capital Market Day 2020

何謂小細胞肺癌(SCLC)

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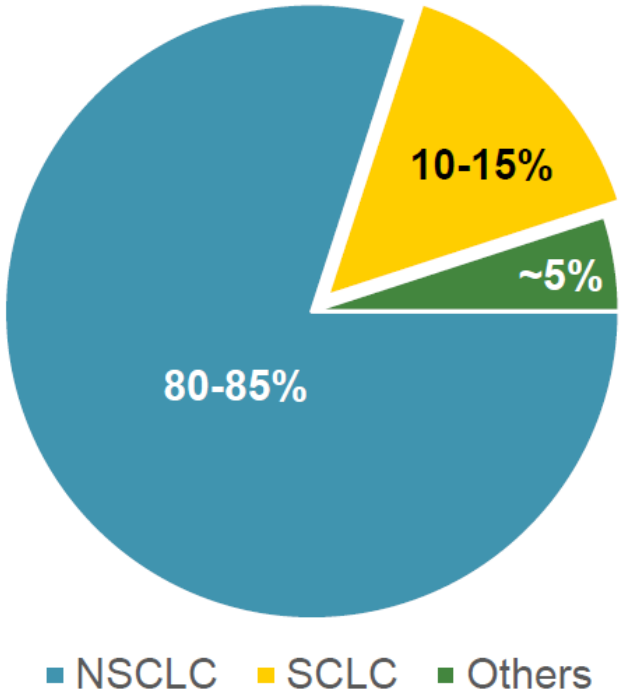
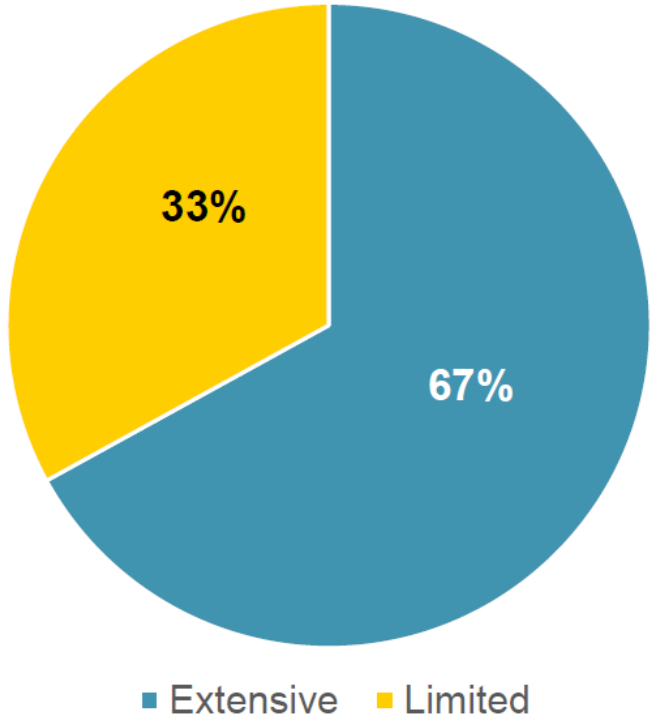
Types of lung cancer[1]



Characteristics of SCLC[2]

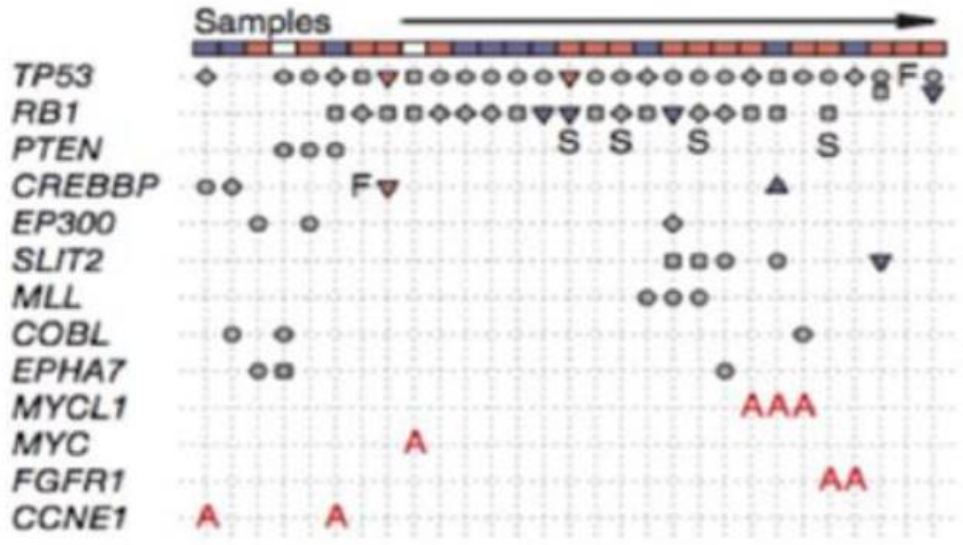
- Rapid doubling time
- High growth fraction
- Paraneoplastic syndromes
- Early development of widespread metastases
- SCLC is a very aggressive cancer that is usually diagnosed at the extensive stage[3]
- 5yr survival
  - Limited stage ranges from 20 40% [4]
  - Extensive stage <5% [4]

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

小細胞肺癌新藥研發門檻較高



- 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

二線小細胞肺癌治療選項較少

	Extensive Stage, 1L	Limited Stage, 1L	2L+
FDA Approved	Platinum + Etoposide + Atezolizumab or Durvalumab		Lurbinectedin (2020) 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)

二線小細胞肺癌治療市場具發展潛力

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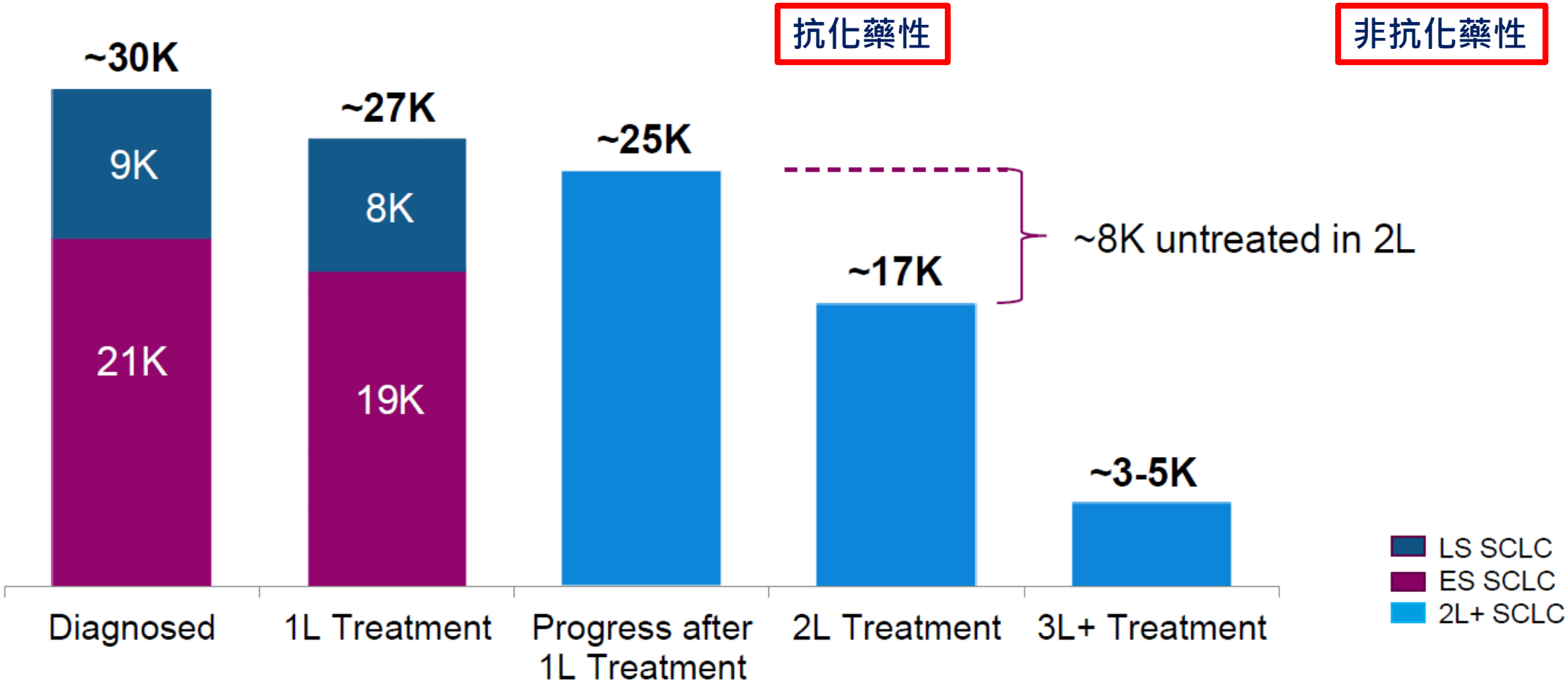
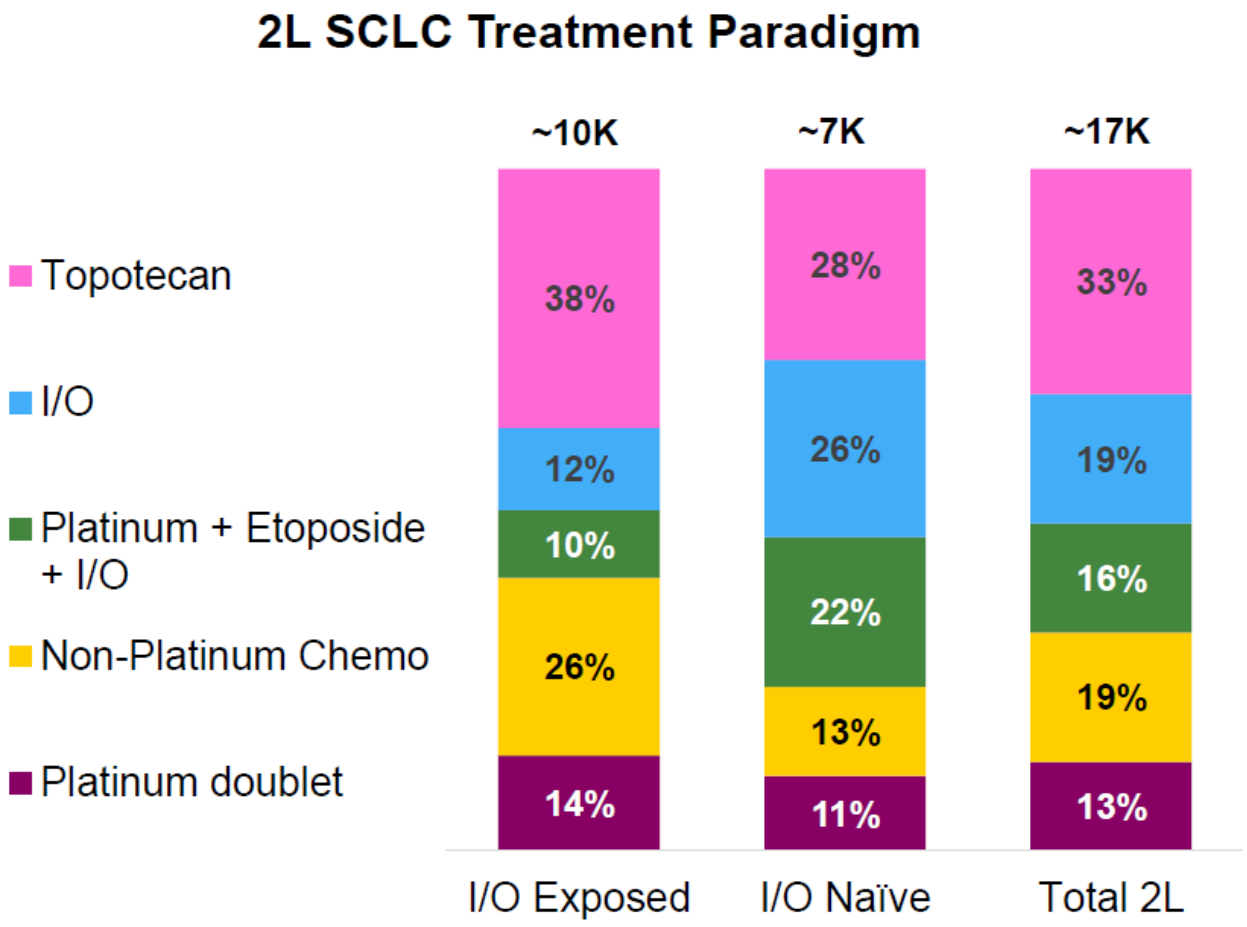
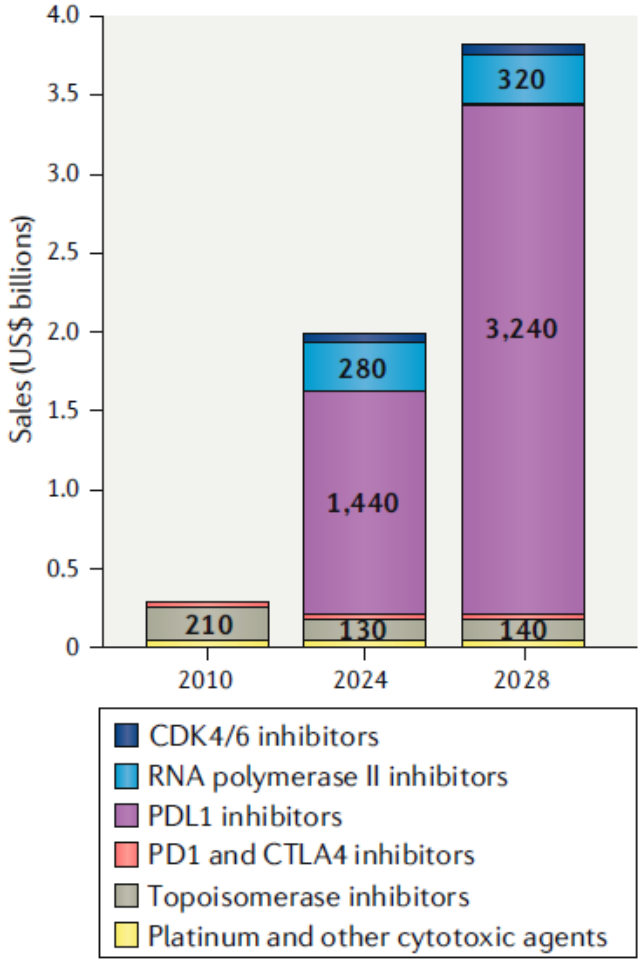
Of the ~17K 2L SCLC Patients, ~30% have CTFI < 90 days and ~70% have CTFI ≥ 90 days[1]



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





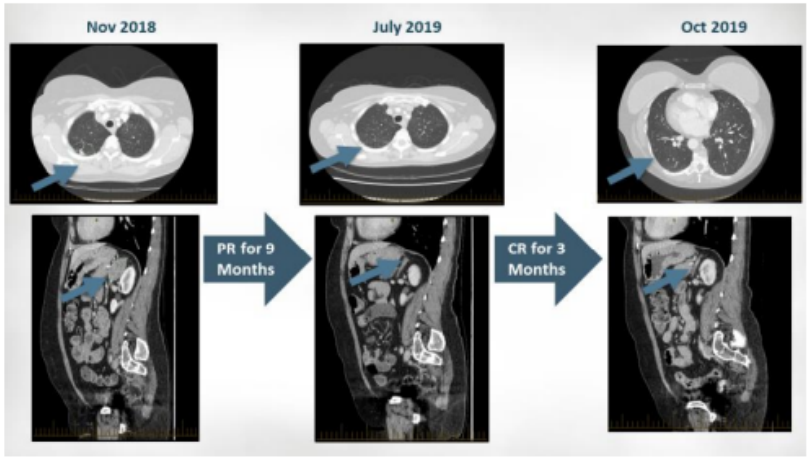
The figure shows the 2018–2028 forecast for the seven major markets: the USA , France, Germany , Italy , Spain, UK and Japan. CDK4/6, cyclin- dependent kinase 4/6.

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

安能得®具有治療二線小細胞肺癌的潛力與價值

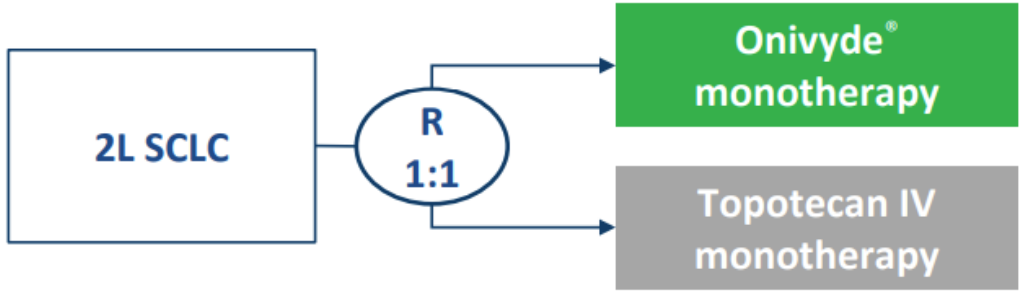
Phase 2 results



	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

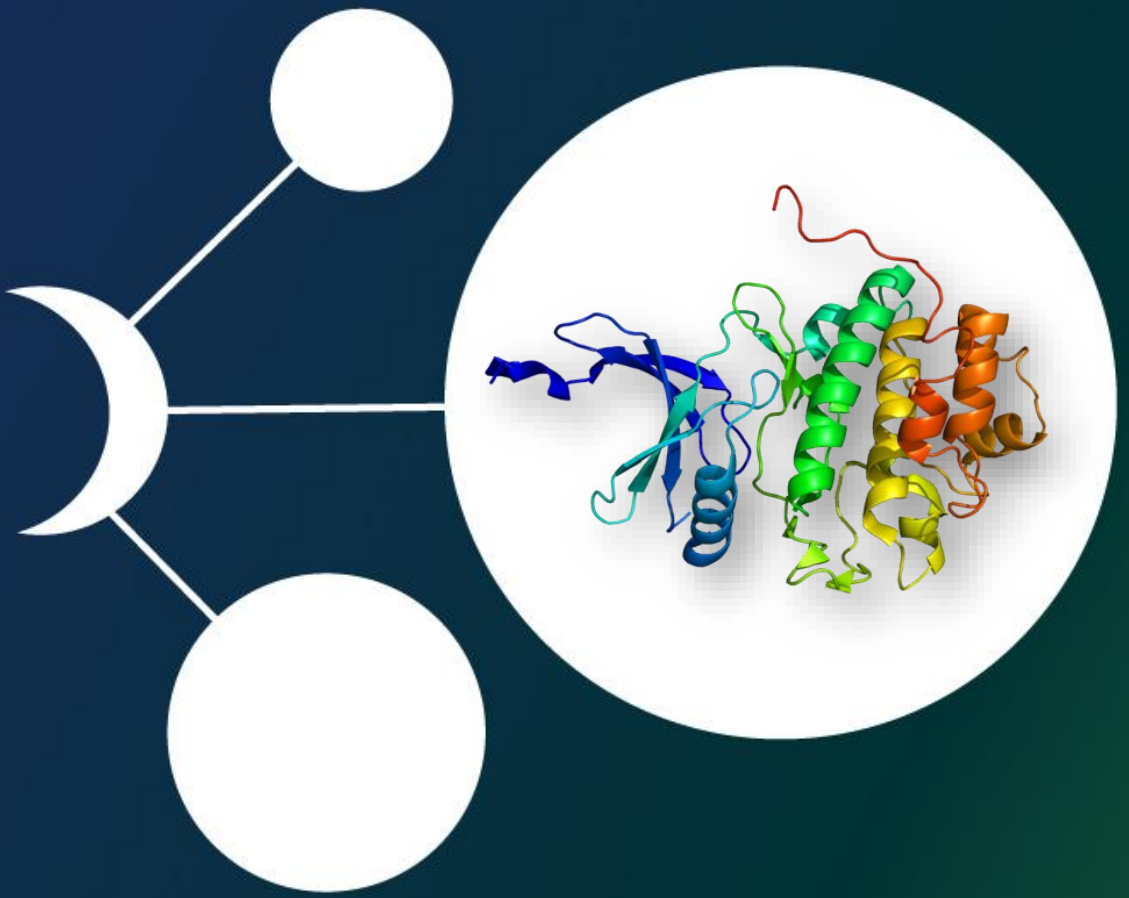
- PFS
- ORR
- Safety

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

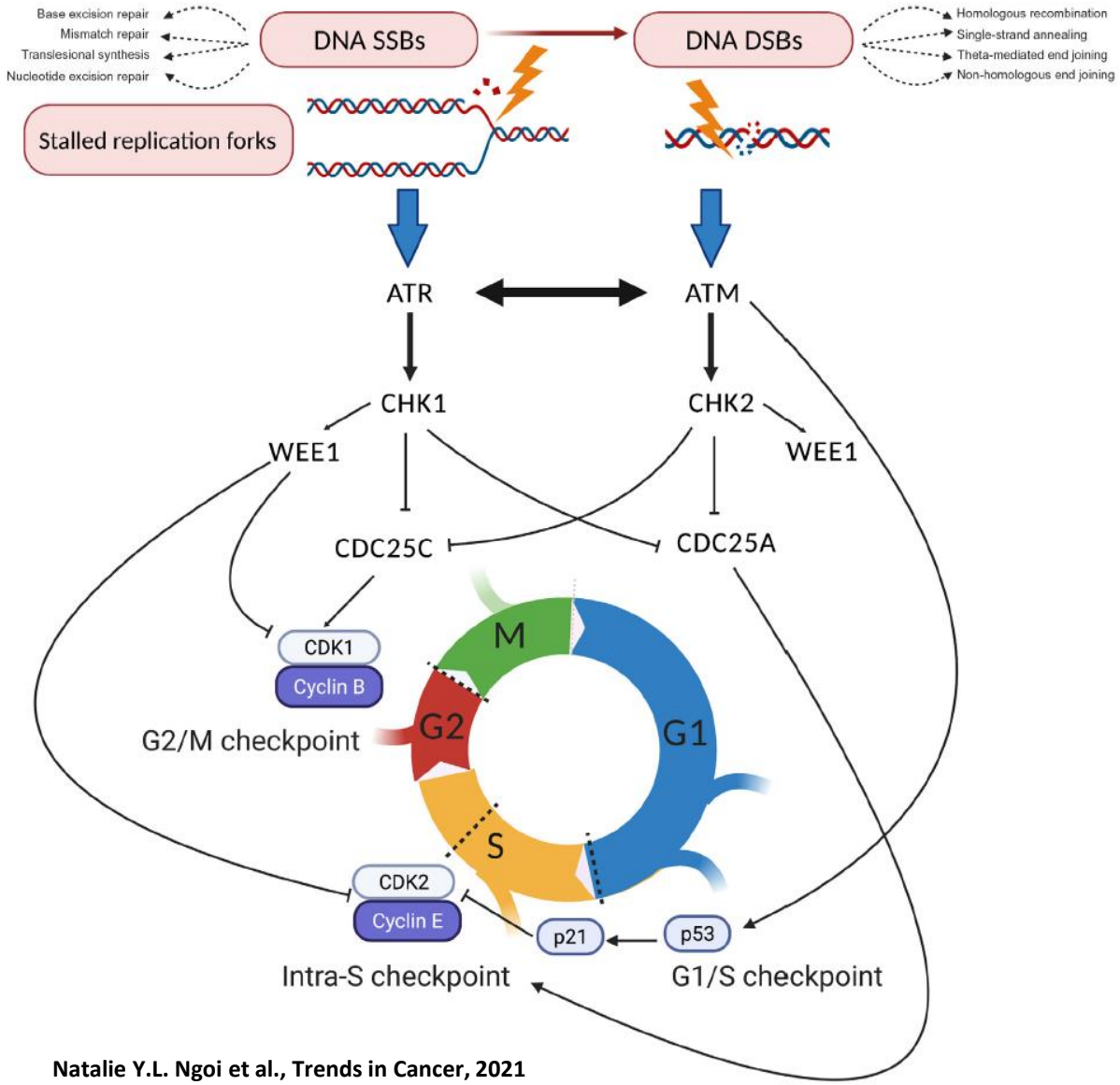
PEP07 (SOL-578)

早期同類型開發項目的國際授權案熱度增加

持續往一期臨床推進



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.

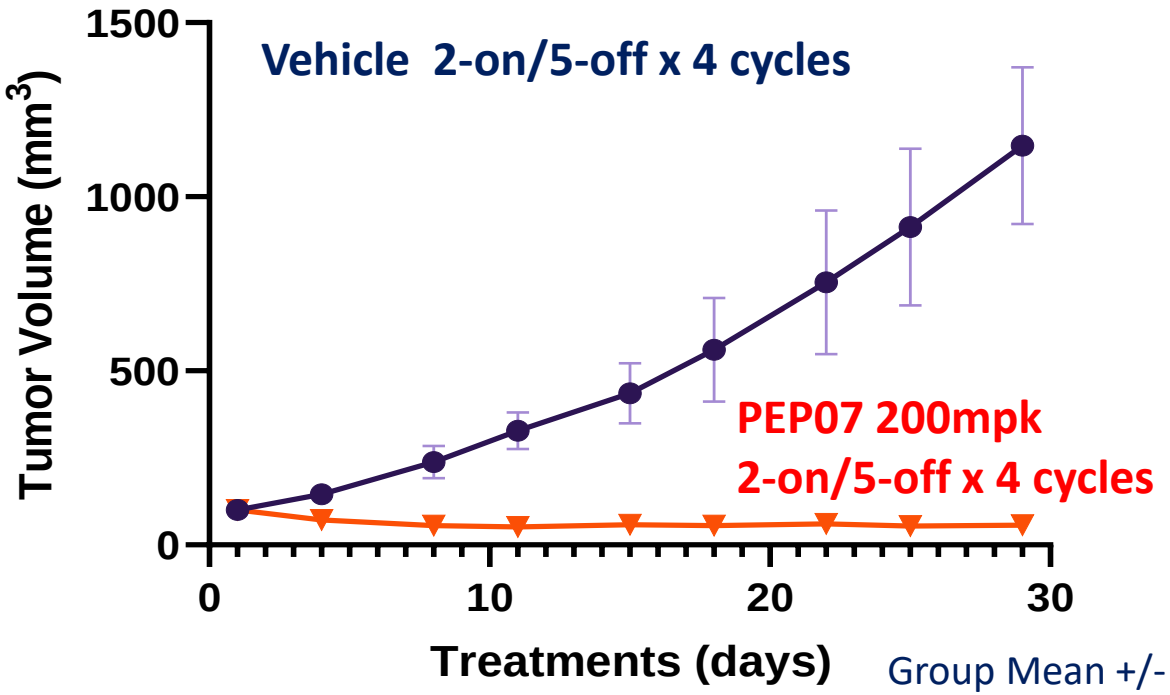
	Drug	Potency	Selectivity	Specificity	Oral Bioavailability
Eli Lilly	LY2606368				
Genetech	GDC-0575				
Sierra Oncology	SRA-737				
Esperas Pharma	LY2880070				
PEI/Sentinel	PEP07/SOL-578				

Excellent Good Fair Poor Unknown

臨床前證據顯示PEP07 (SOL-578)單獨或合併使用於血液腫瘤具有顯著療效

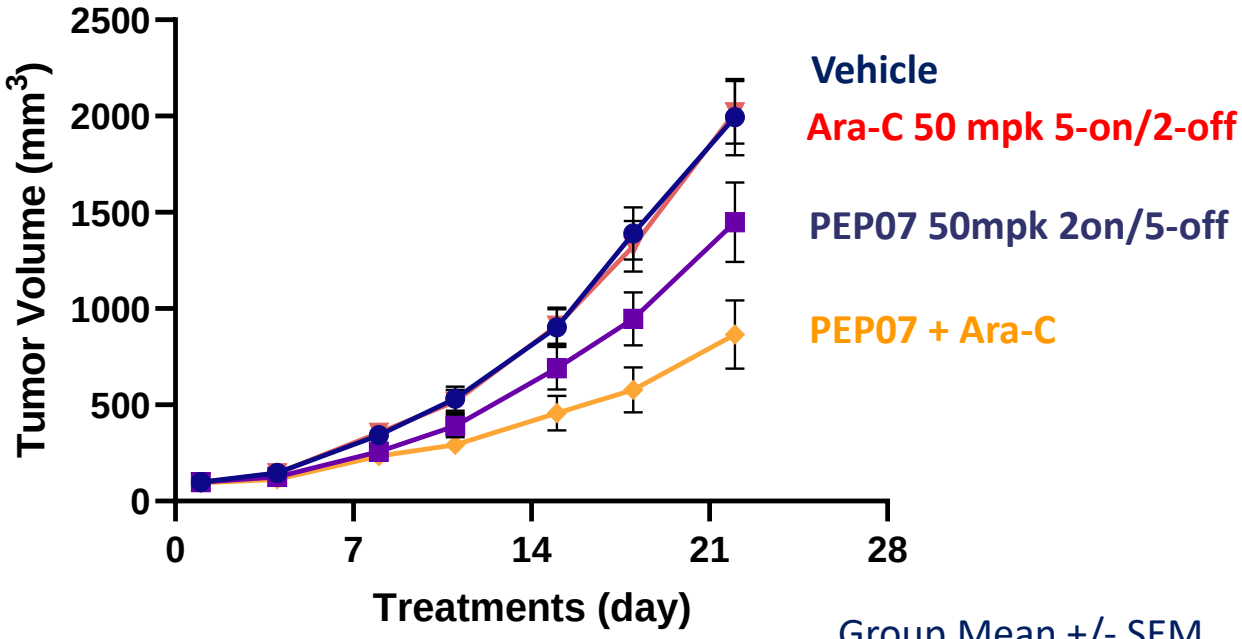
Acute Myeloid Leukemic (AML)

Ara-C Sensitive



Group Mean +/- SEM
n=8/group

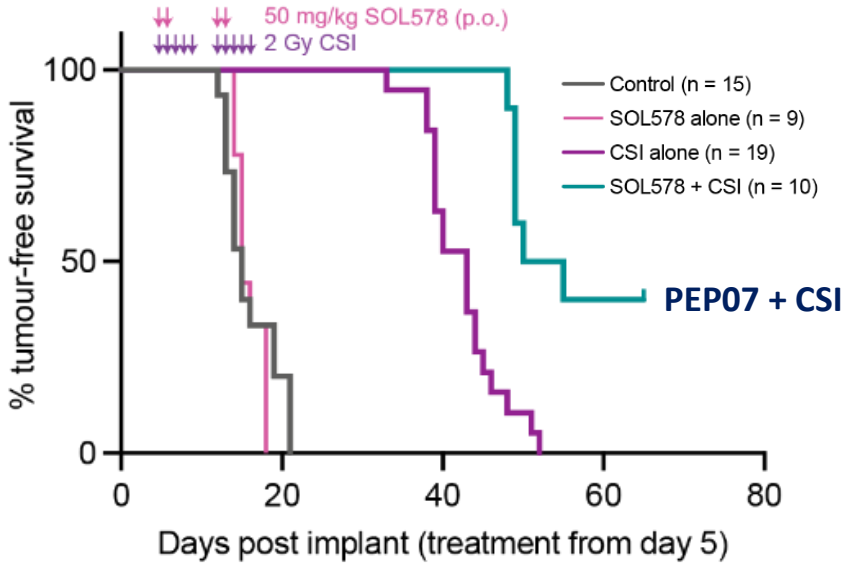
Ara-C Resistant



Group Mean +/- SEM
n=8/group

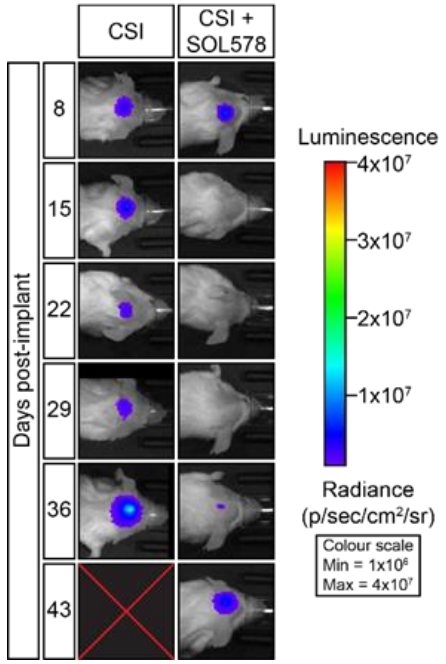
臨床前證據顯示口服PEP07 (SOL-578)合併放射線療法使用於腦瘤具有顯著療效

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



Treatment schedule	Number of mice (n)	Median survival (d)
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

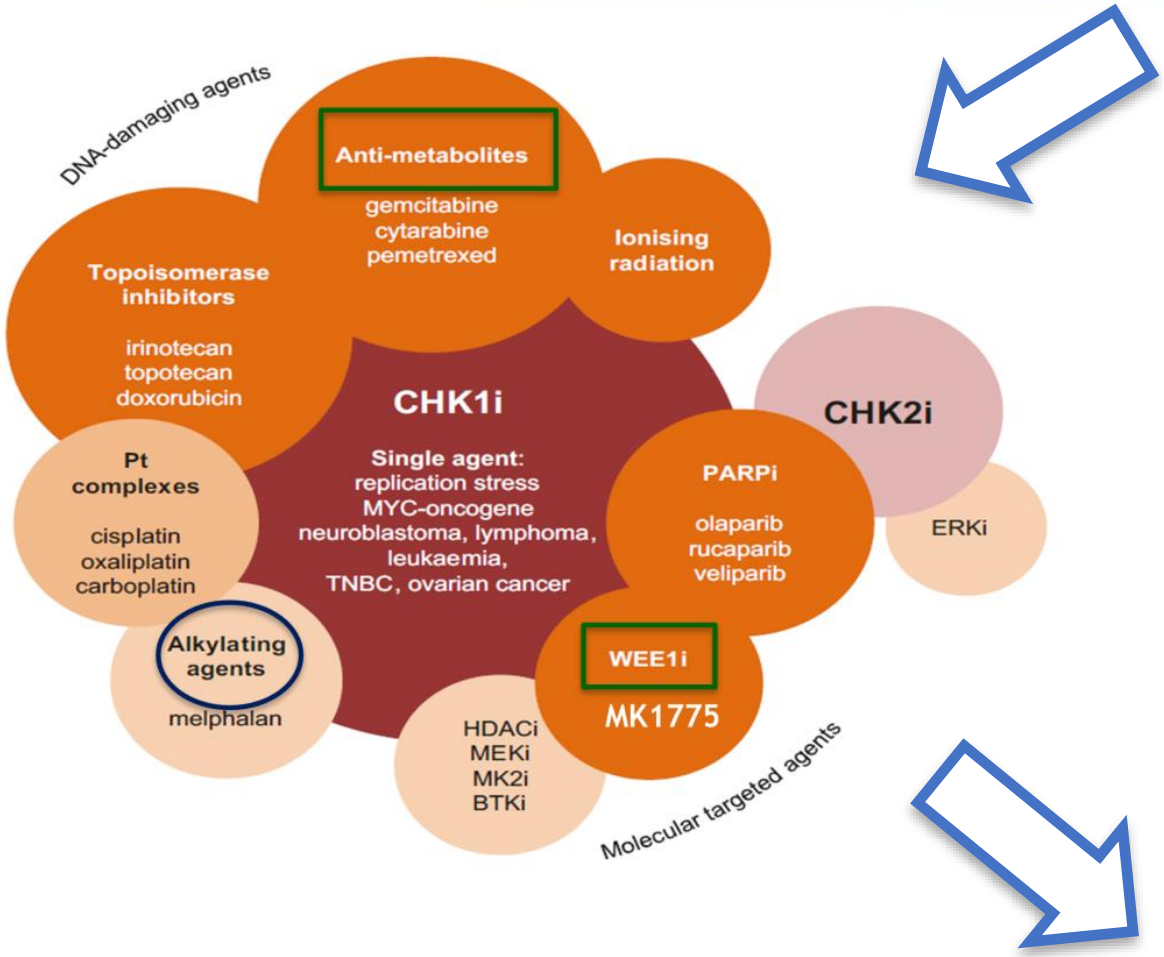
PEP07 (*p.o.*) + CSI show Intracranial tumors regression



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) 具有多項組合療法的潛力



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) 持續往一期臨床推進

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

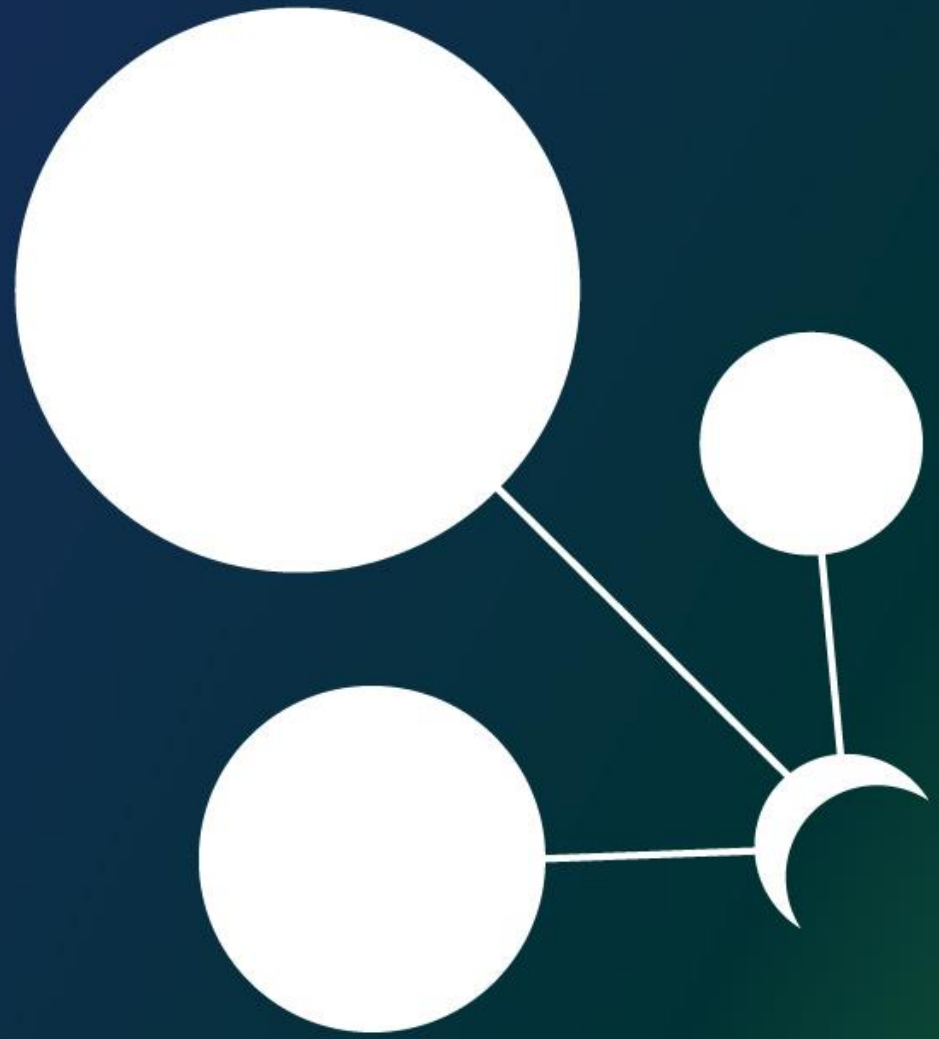
Toxicology

GLP study ongoing

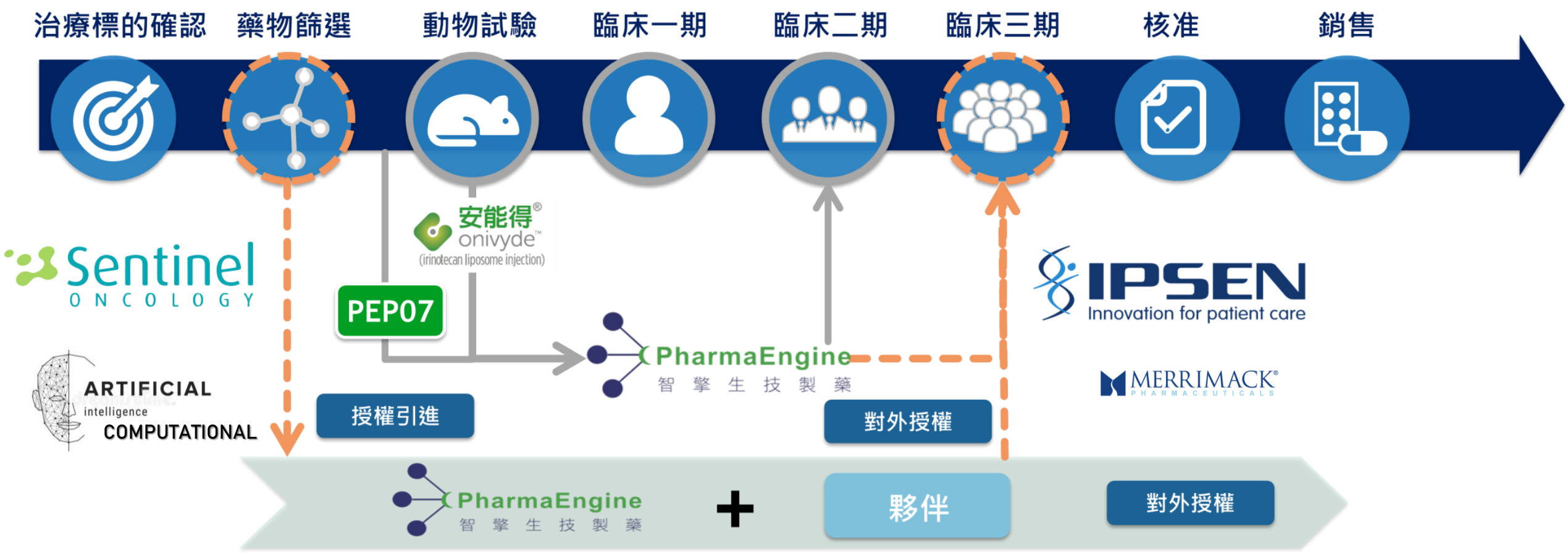
IND Prep. & Sub.

Target submission on 2022Q3

2022年
營運展望



Virtual Pharmaceutical Company 營運模式



產品組合專注在癌症精準醫療

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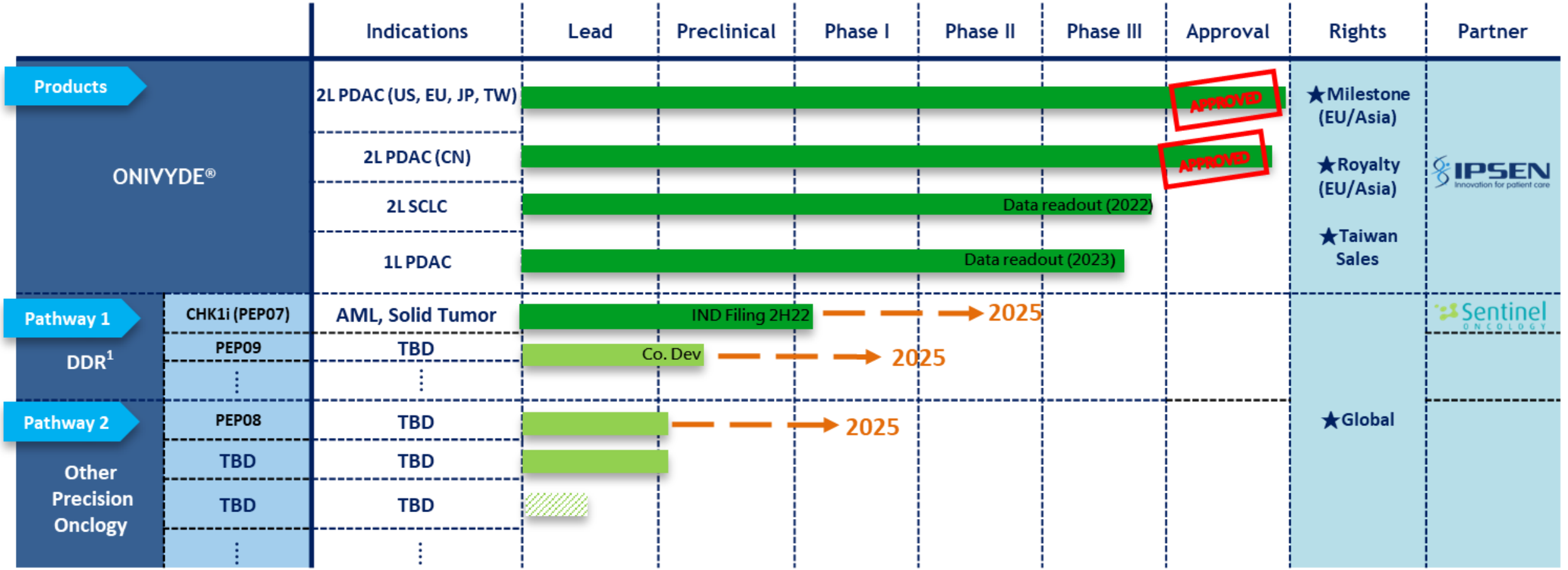

1. DDR: DNA Damage Response (BRCA1/2, CHK1/2, WEE1, etc…)

2022: Year of Revitalization and Marching Forward

ONIVYDE®產品生命週期的延展

1.二線胰腺癌陸續取得歐亞多國藥證與醫保

2.二線小細胞肺癌(SCLC)三期臨床數據公告

3.一線胰腺癌三期臨床數據公告(2023)

早期在研產品的推動與擴增

1.PEP07申請一期臨床試驗(IND/CTA)

2.癌症精準靶位新藥PEP08研發

3.DDR標靶新藥PEP09合作研發

4.啟動其他癌症精準靶位新藥研發

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