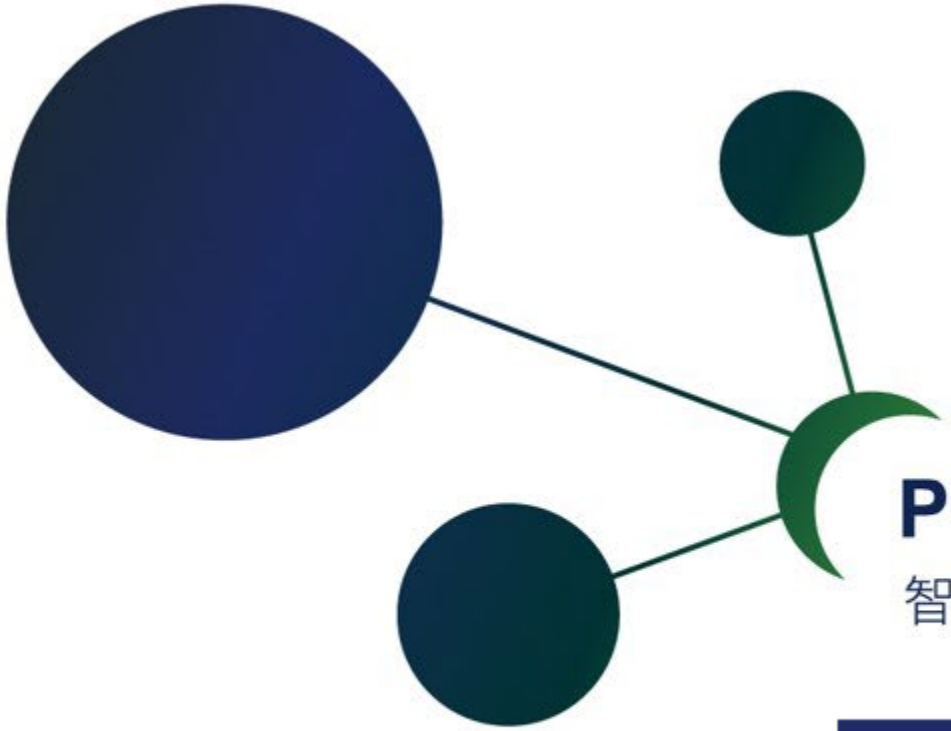


PharmaEngine

智 擎 生 技 製 藥

投資人說明會4162.TWO

2022/10/28

張麒星 發言人

童力威 投資人關係

免責聲明

- 本簡報中所提及之預測性資訊包括營運展望、財務狀況以及業務預測等內容，乃是建立在本公司從內部與外部來源所取得的資訊基礎。
- 本公司未來實際所可能發生的營運結果、財務狀況以及業務成果，可能與這些明示或暗示的預測性資訊有所差異。其原因可能來自於各種因素，包括市場風險、市場需求，以及本公司持續推出新藥產品專案等因素。
- 本簡報中對未來的展望，反應本公司截至目前為止對於未來的看法。對於這些看法，未來若有任何變更或調整時，本公司將盡力隨時再度提醒或更新。

議程

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

公司維持營收穩定與價值創造

銷售端

ONIVYDE®市場擴展與新適應症延伸

1. 二線胰腺癌治療將於中國市場開賣
2. 歐亞地區銷售量持續維持增長
3. 一線胰腺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. 正式授權引進PEP07
3. 與外部新藥研發平台合作開展數項早期研發項目
4. 數項研發專案進入授權評估流程

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35億元

2022年YTD營運概況

- ONIVYDE®銷售量持續成長

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YTD (較2021年同期成長率)
台灣銷貨收入	40,651	87,384	180,389	214,828	235,469	211,942 (22.5%)
歐亞銷貨權利收入	63,526	109,825	133,651	271,584	419,366	283,968 (2.2%)
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	495,910 (9.9%)

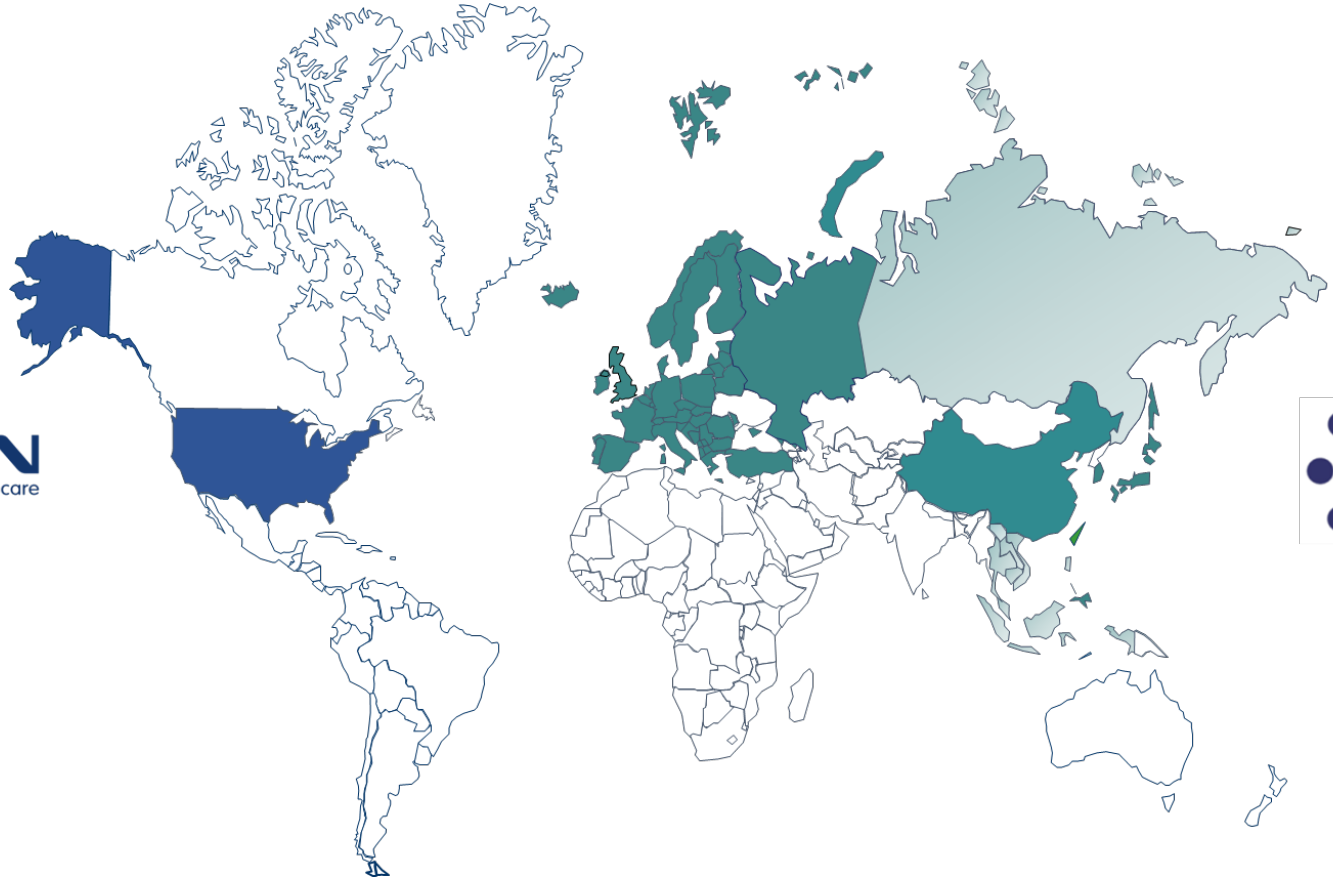
2022年YTD營運概況

單位:新台幣仟元	2022 YTD	2021 YTD	Amount Change	% Change
營業收入	495,910	451,034	44,876	10%
營業成本	37,416	29,472	7,944	27%
營業毛利	458,494	421,562	36,932	9%
推銷費用	29,111	23,765	5,346	22%
管理費用	74,226	62,820	11,406	18%
研究發展費用	122,037	107,504	14,533	14%
營業費用	225,374	194,089	31,285	16%
營業利益	233,120	227,473	5,647	2%
營業外收入(支出)	94,987	178,659	(83,672)	(47%)
稅前淨利	328,107	406,132	(78,025)	(19%)
所得稅費用	62,941	91,631	(28,690)	(31%)
本期淨利	265,166	314,501	(49,335)	(16%)
基本每股盈餘(元)	1.85	2.17	(0.32)	(15%)

產品專案進度

- ONIVYDE®一線胰臟癌癌預計YE22解盲
- PEP07 正式授權引進
- 預計YE22申請PEP07 海外IND
- 偕同外部AI/CADD技術啟動數項新專案

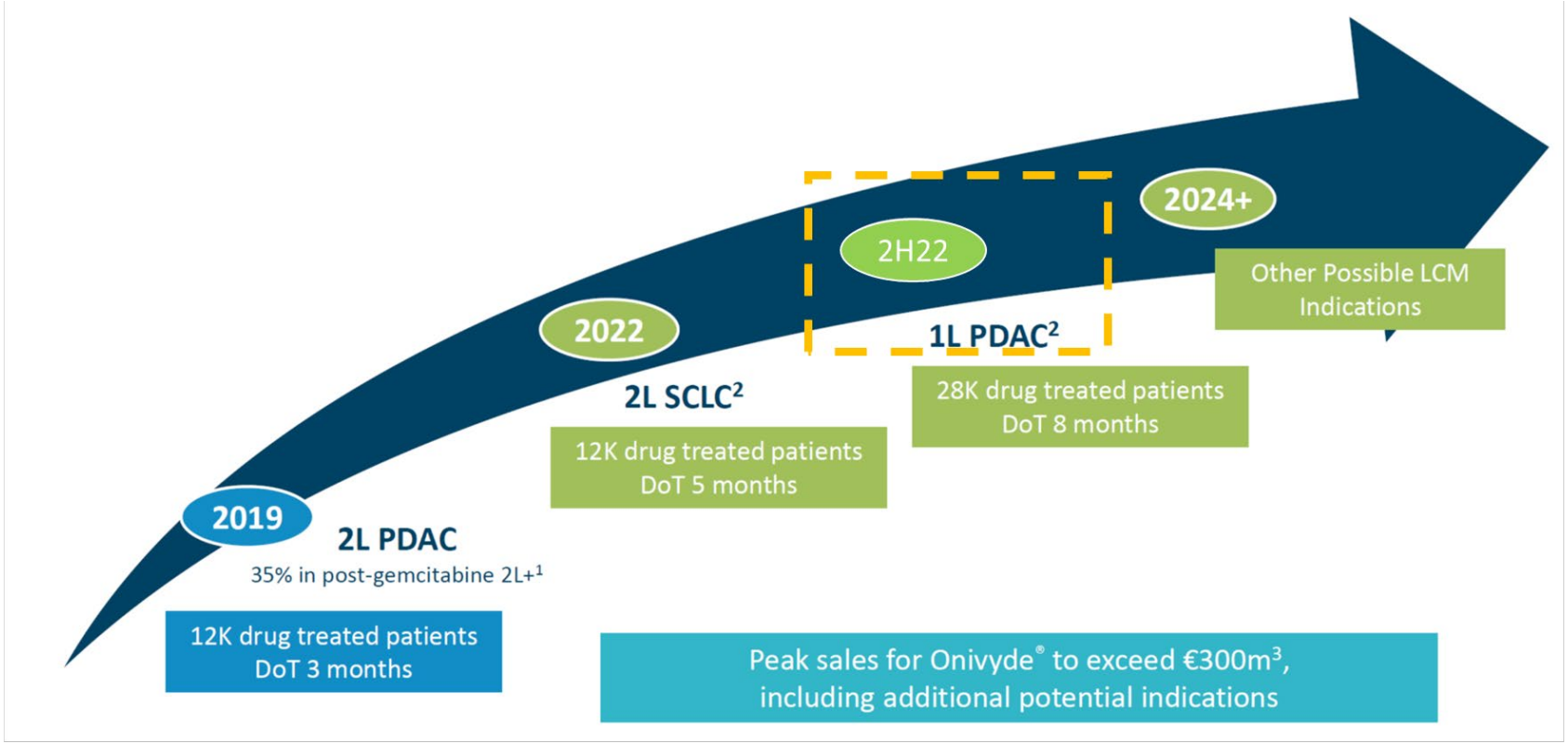
ONIVYDE®持續拓展全球銷售市場



Approved

Yet approved

ONIVYDE®不斷拓展新的治療機會

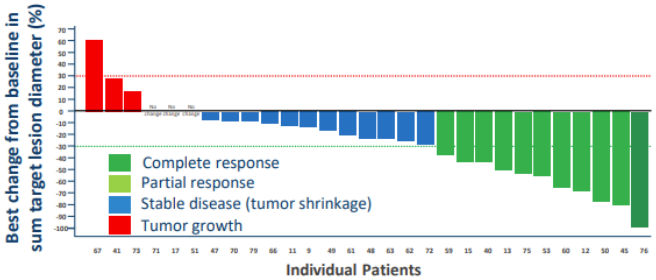


LCM: Life cycle management; PDAC: Pancreatic ductal adenocarcinoma; SCLC: Small cell lung cancer; DoT: Duration of treatment; 1L: First line; 2L: Second line; 1. IQVIA APLD claims, September 2020 ; 2. Expected submission dates ; 3. Risk adjusted; IPSEN Capital Market Day 2020

ONIVYDE®: 1L pancreatic ductal adenocarcinoma (PDAC)

PharmaEngine 智擎生技製藥

Phase 2 results

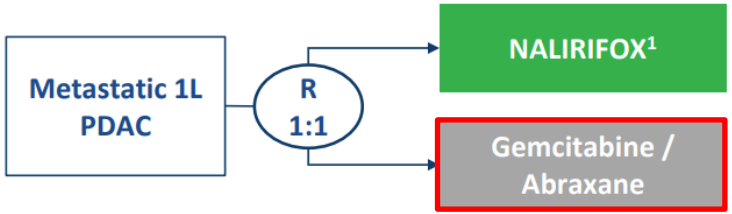


Among 29 evaluable patients who received selected dose, 23 **(79%) had tumor shrinkage**

	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)

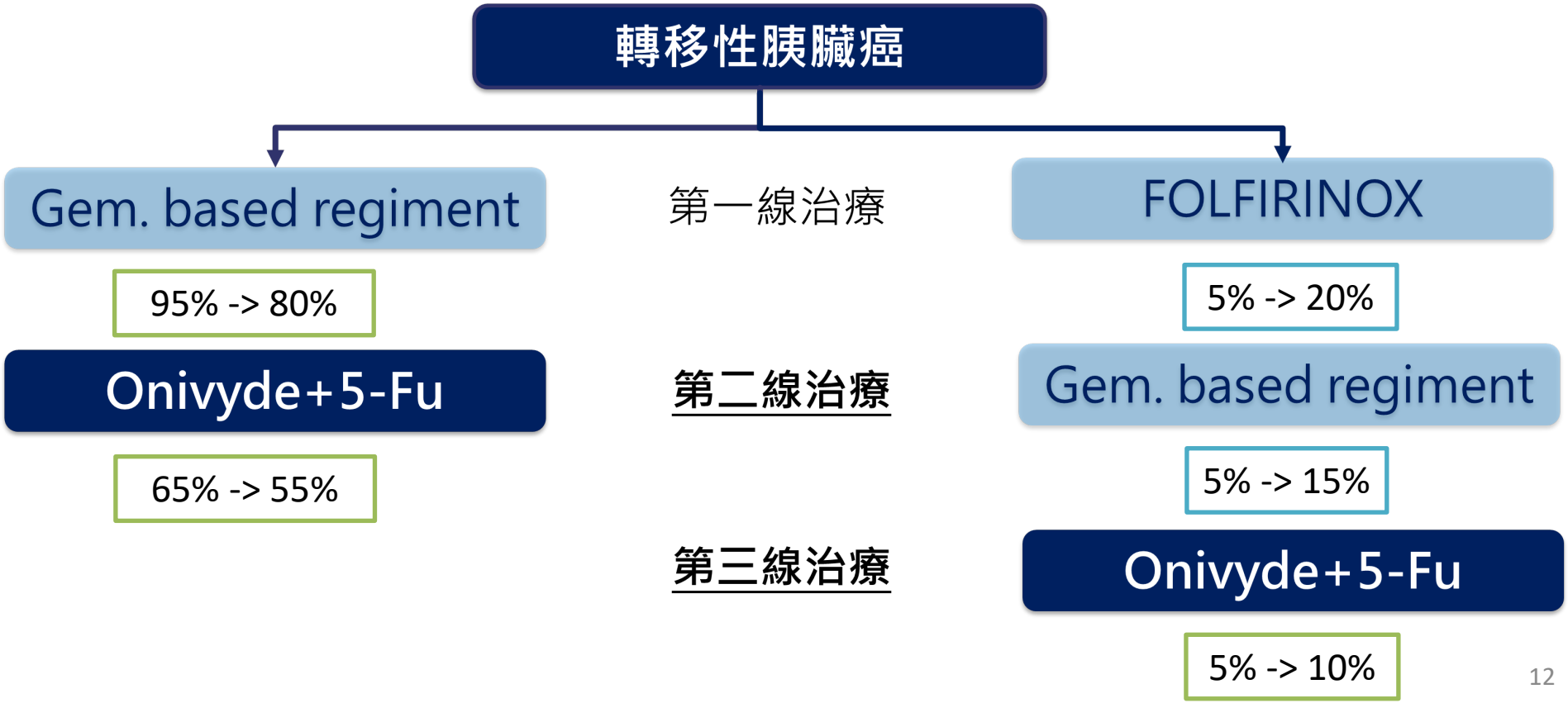
Source: ESMO World Congress on Gastrointestinal Cancer 2020 Oral Presentation. Abstract LBA 1 ; IPSEN Capital Market Day 2020

Frontline Regimens for Patients With Metastatic Pancreatic Cancer

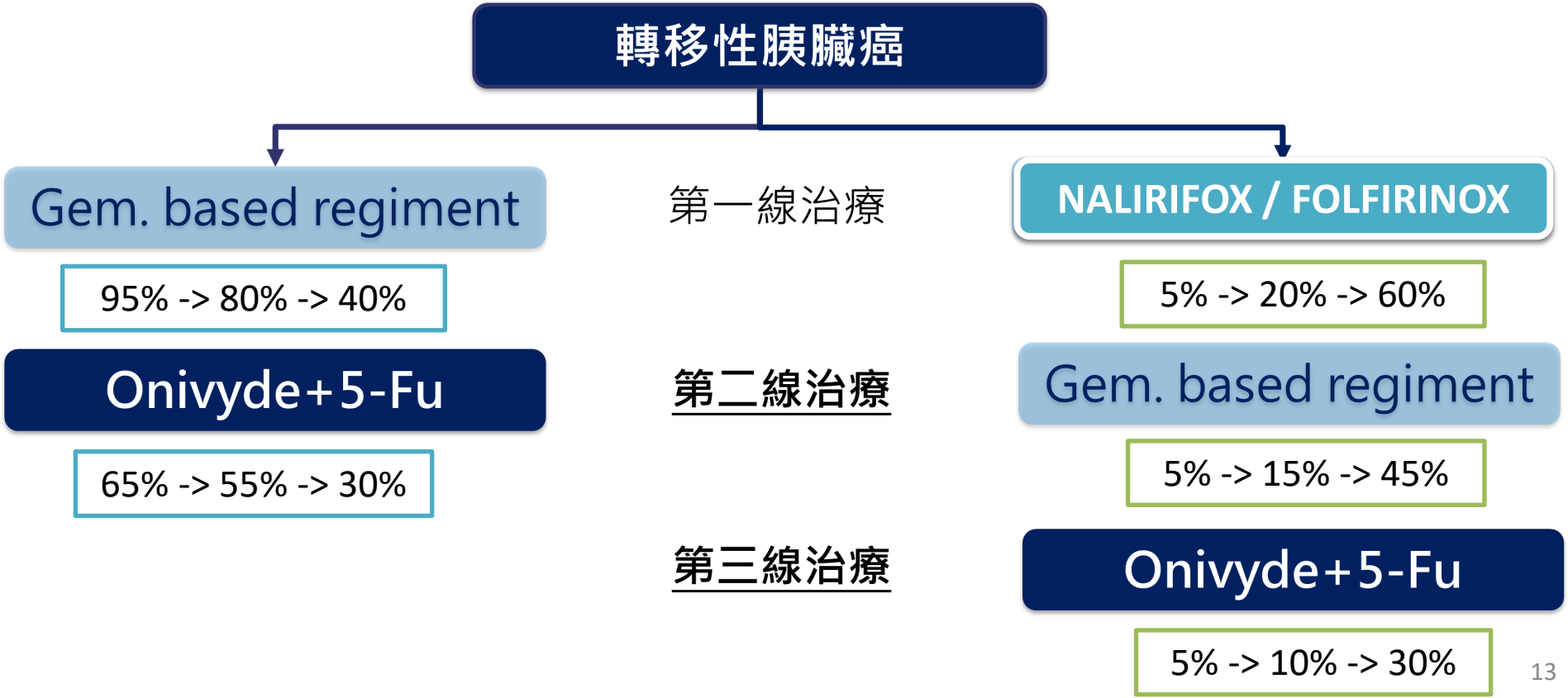
Trial Characteristics and Outcomes	FOLFIRINOX vs Gem (N = 342)[1]	nab-Pac + Gem vs Gem (N = 861)[2]
Median age, yrs (range)	61 (25-76)	62 (27-86)
Male, %	62	57
Region (NA/WE/EE/A), %	0/100 (France)/0/0	62/9/15/14
ECOG PS/KPS (0/100, 1/80-90, 2/60-70), %	37/62/1	16/76/8
Tumor location (H/B/T), %	39/31/26	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.

轉移性胰臟癌治療市場分析 (I)

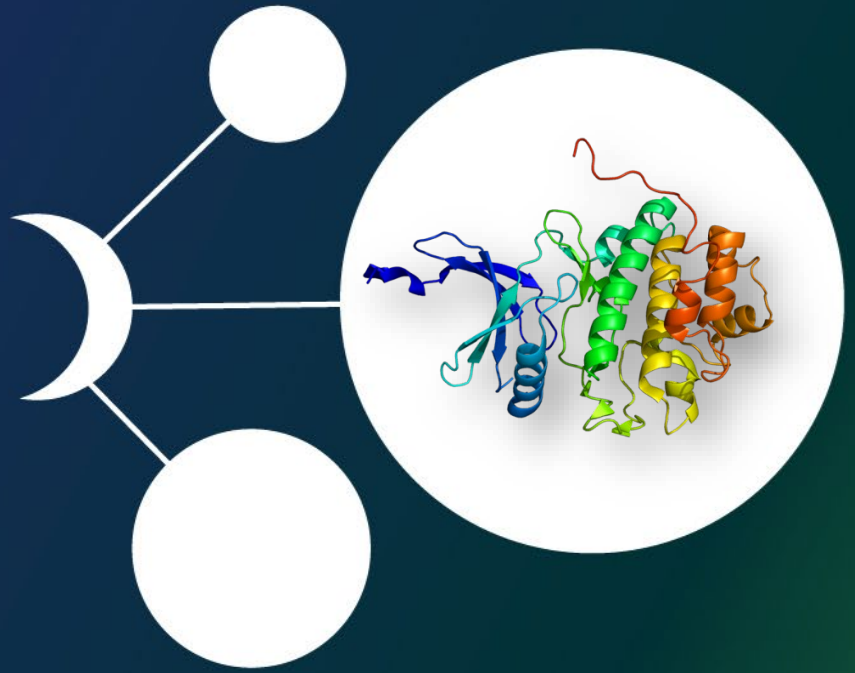


轉移性胰臟癌治療市場分析 (II)

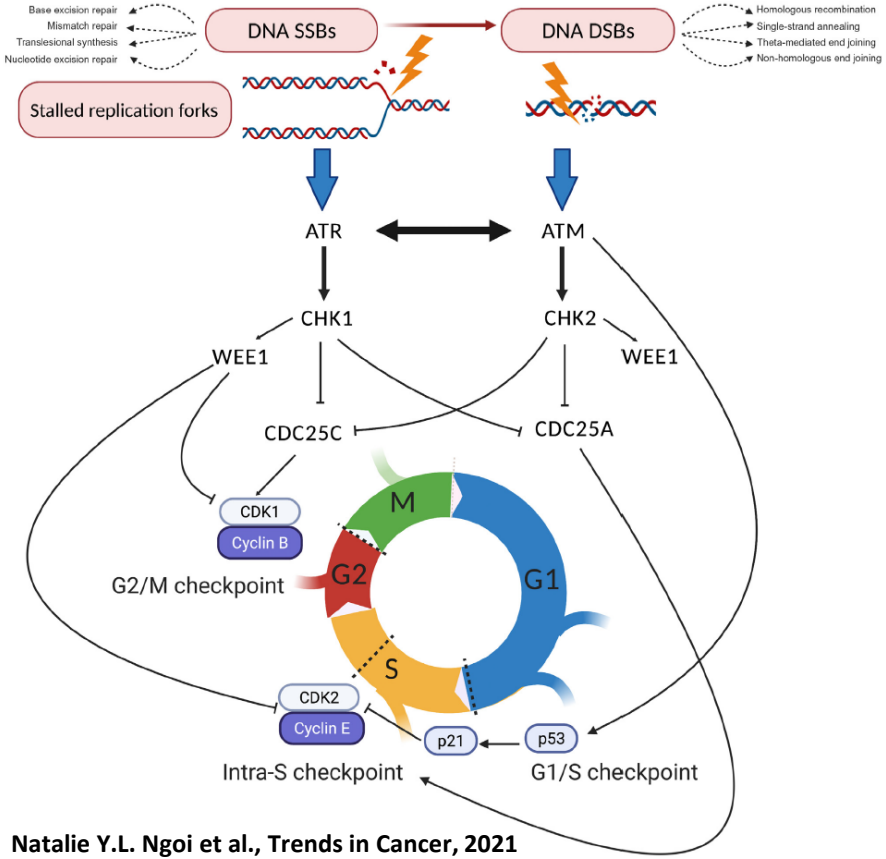


PEP07 (CHK1 抑制劑)

- 正式向Sentinel Oncology授權引進
- 早期同類型開發項目的國際授權案熱度增加
- YE22前申請海外一期臨床試驗



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

PharmaEngine 智擎生技製藥

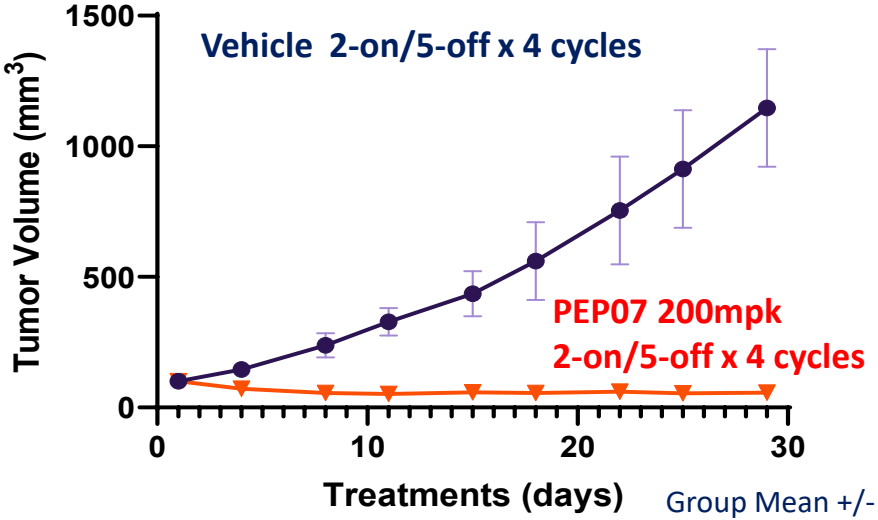
PEP07 is a brain penetrating oral inhibitor which is more potent, selective, specific than the competitors.

	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				

PEP07 臨床前證據顯示單獨或合併使用於血液腫瘤具有顯著療效

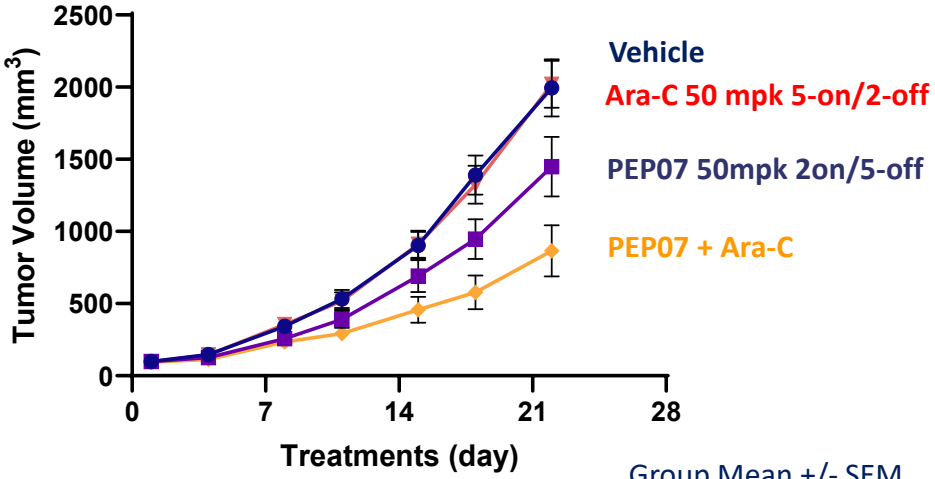
Acute Myeloid Leukemic (AML)

Ara-C Sensitive



Group Mean +/- SEM
n=8/group

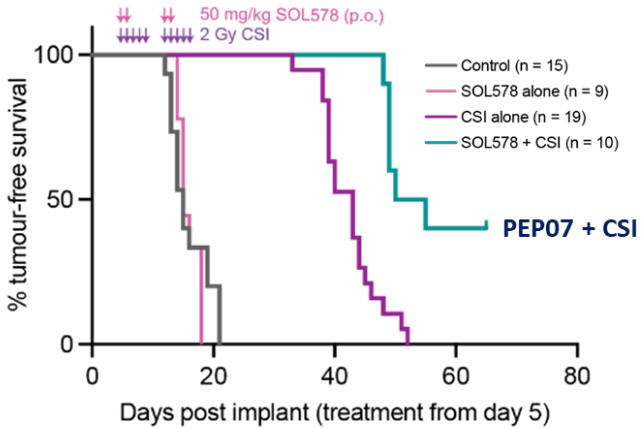
Ara-C Resistant



Group Mean +/- SEM
n=8/group

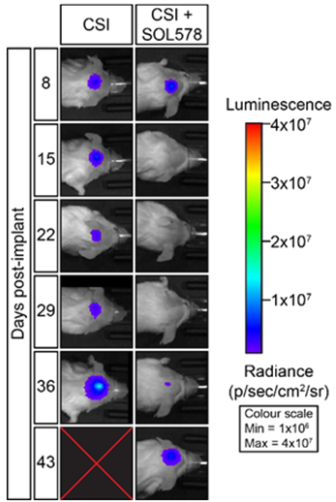
臨床前證據顯示口服PEP07合併放射線療法使用於腦瘤具有顯著療效

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



Treatment schedule (Week 1: Su M Tu W Th F Sa; Week 2: Su M Tu W Th F Sa)	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

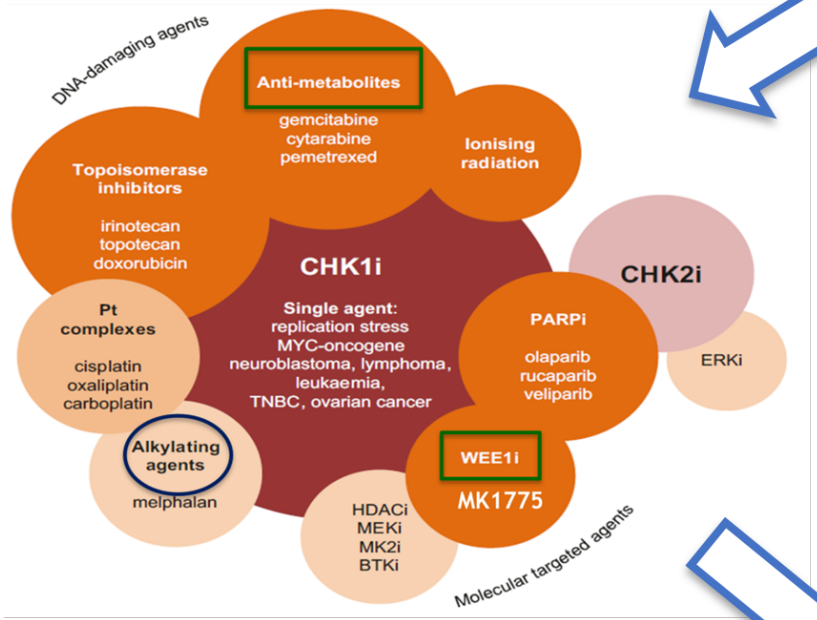
PEP07 (*p.o.*) + CSI show Intracranial tumors regression



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 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

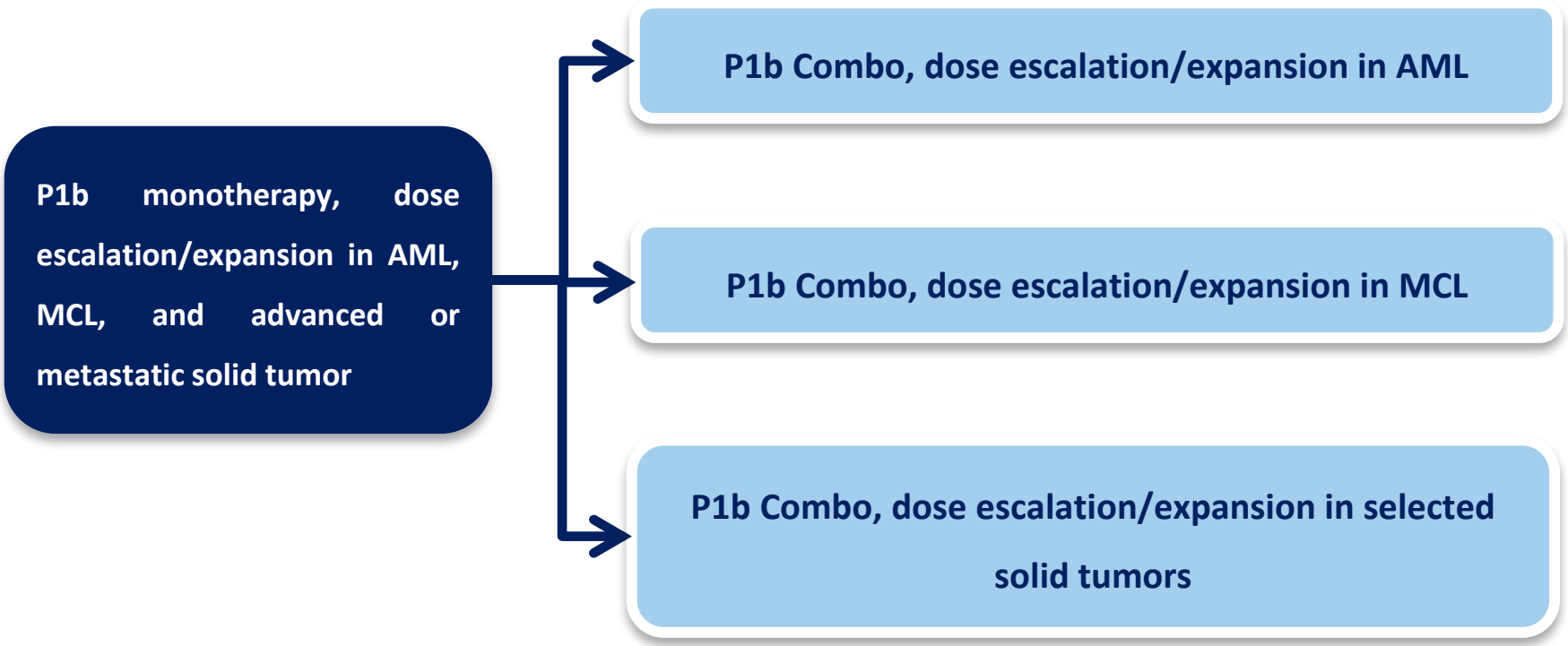
Clinical Trial Designs and Indications Guidance

：Synergistic effect verified in PEP07

：Additive effect observed in PEP07

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

PEP07 早期臨床試驗規劃



Preclinical biomarker study is ongoing for further design of clinical trials

PEP07 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 1st strength completed.

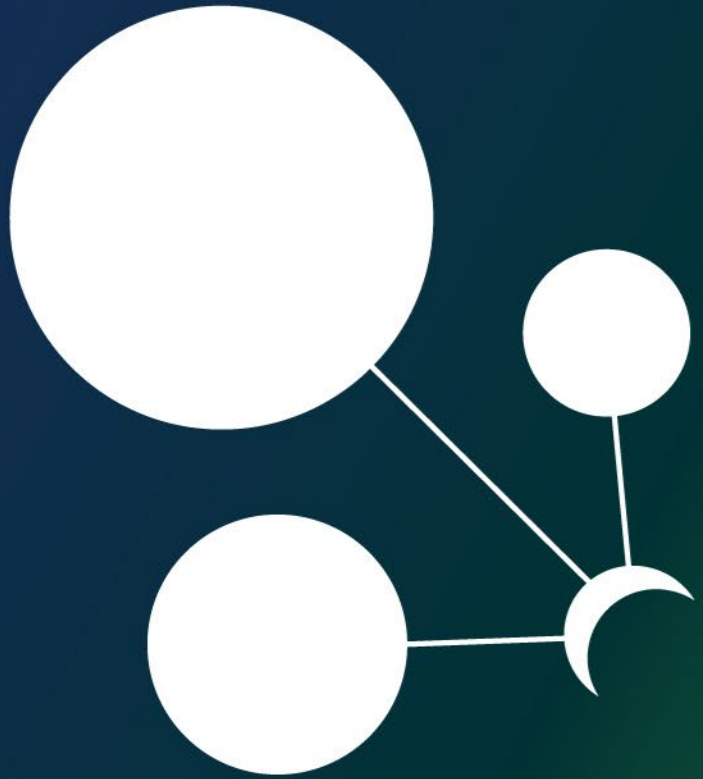
Toxicology

GLP study completed.

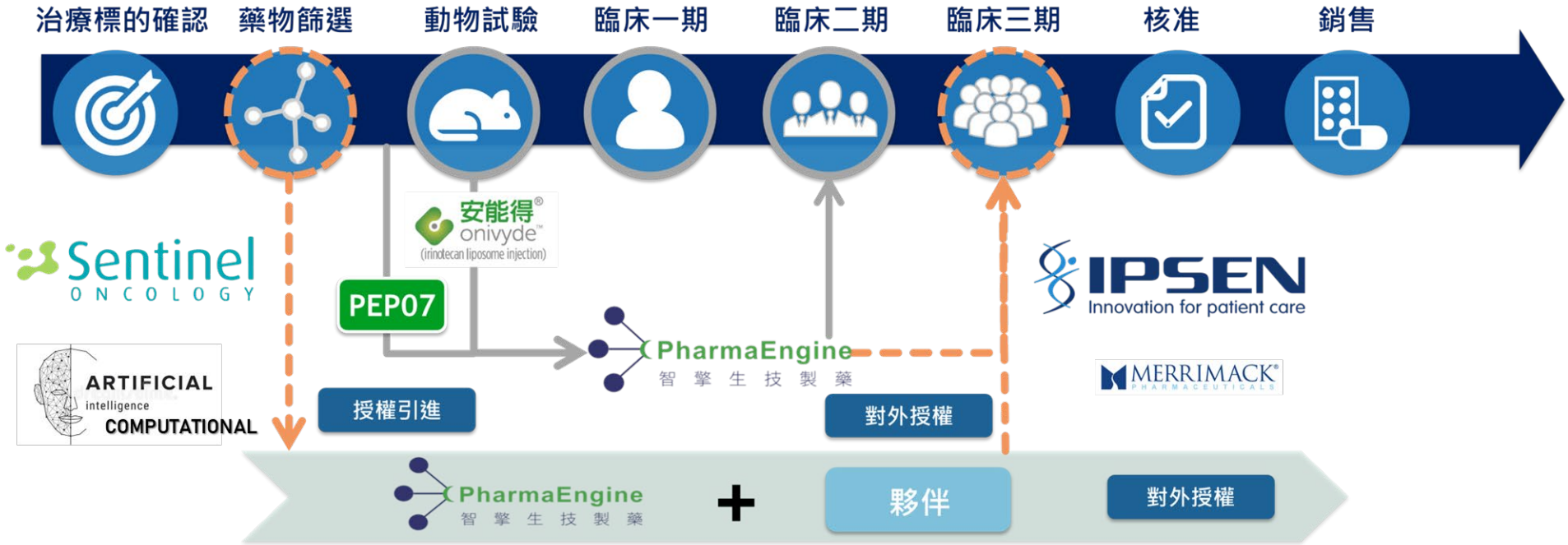
IND Prep. & Sub.

IND submission before YE22.

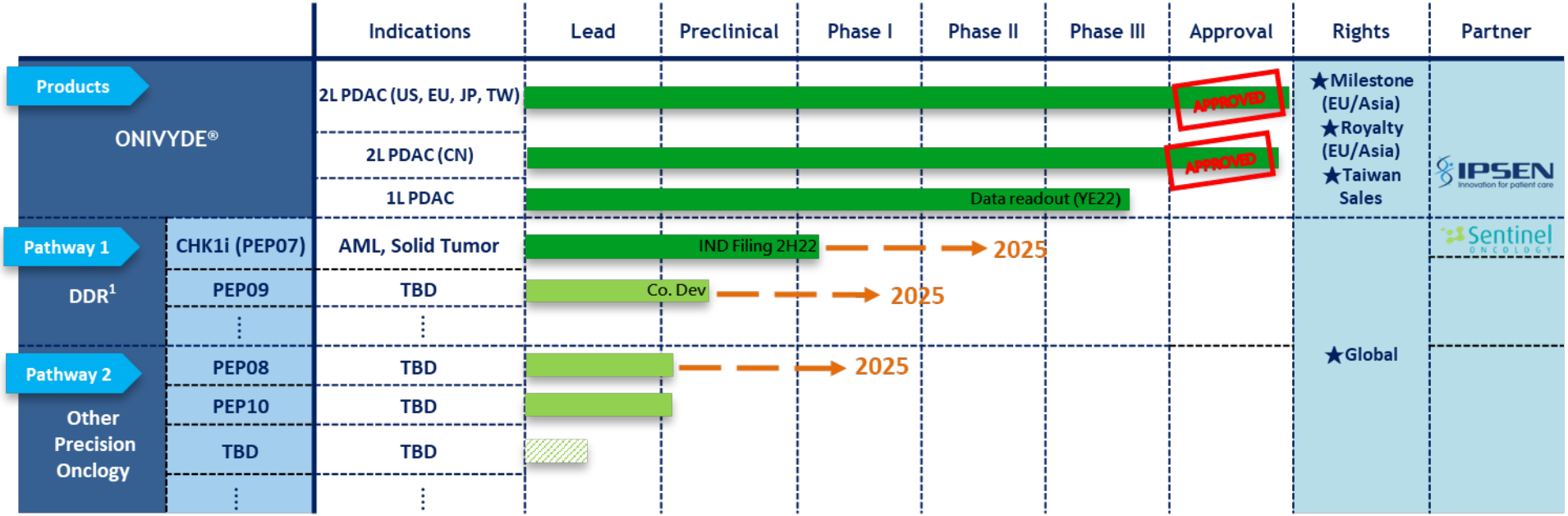
2022年
營運展望



Virtual Pharmaceutical Company 營運模式



產品組合聚焦在癌症精準醫療



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. 一線胰腺癌三期臨床數據公告(YE22)

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. DDR標靶新藥PEP09合作研發
3. 癌症精準靶位新藥PEP08, PEP10研發
4. 啟動其他癌症精準靶位新藥研發


PharmaEngine
智 擎 生 技 製 藥