PharmaEngine

智 擎 生 技 製 藥

投資法人說明會4162.TWO

2022/03/10

總經理

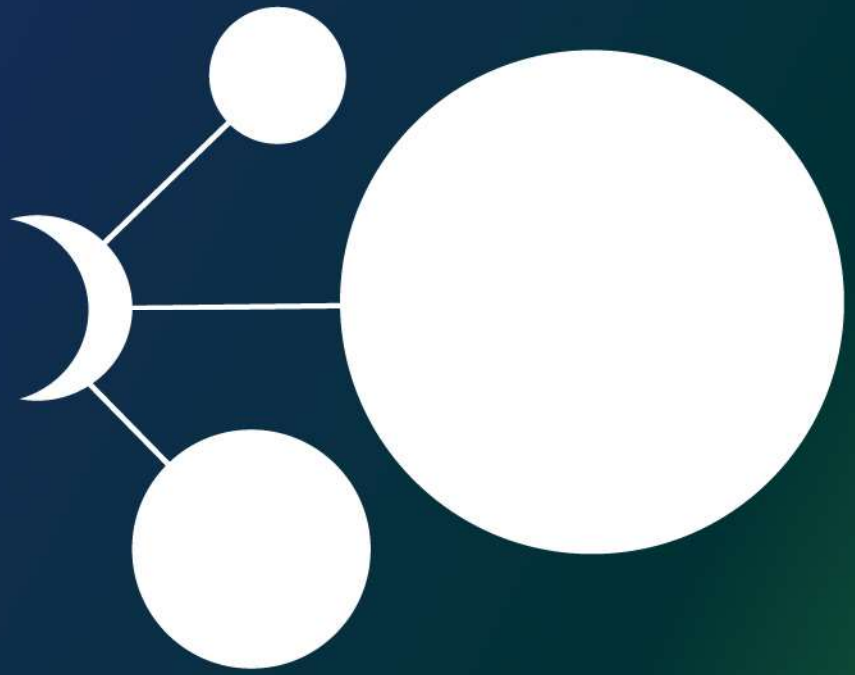
王宏仁 博士

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. 2021年營運亮點
2. 2021年營運概況
3. 研發專案進度
   - 安能得®(ONIVYDE) ®市場展望
   - PEP07 (SOL-578)
4. 2022年營運展望
5. Q&A



富含國際經驗的管理團隊

總經理

王宏仁 博士

投身製藥領域超過15年，專精藉由藥物評估、藥物動力學及醫療器材模型建構、特殊製劑設計來研發新型藥物傳輸/醫療器材的組合。於美國生技公司任職期間從事藥物開發，從臨床前到NDA/MAA申請的新藥開研發。曾參與等 Incivek、Kalydeco 和Orkambi等三個FDA / EMA批准上市產品的新藥開發。

- 麻省理工學院材料科學與工程博士學位、國立清華大學材料科學與工程碩士學位、國立台灣大學化學工程學士學位。
- 曾任職於Transform Pharmaceuticals公司、Vertex Pharmaceuticals公司, Microchips Biotech公司、Proteostasis Therapeutics公司歷任初階,中階,高階研發及公司主管。

國際級新藥研發顧問團隊

PharmaEngine 智擎生技製藥

Hagop Youssoufian, MSC, MD
Former Chief Medical Officer at BIND Therapeutics

Alex Vo, Ph.D.
Executive Director, DMPK, Preclinical Science, Atea Pharmaceuticals

Chia-Chi Lin, MD
Professor, Graduate Institute of Clinical Medicine, NTUCM ; Attending Physician, NTUH

Chiao-Wen Chen, Ph.D
Executive Director, Institute for Drug Evaluation Platform, Development Center of Biology

Steven Witowski, Ph.D.
Principal of Witowski CMC Consulting, LLC

Dan Belmont, Ph.D.
Former Vice President, Head of Pharmaceutical Development at Vertex Pharmaceuticals, President of Full Sails Consulting LLC.

Cynthia Gao, MBA
Associate Director, US Commercial Distribution Quality, Biogen and Founder of Pharma Quality 360

Wen-Cherng Lee, Ph.D.
Former Biogen Director, former EVP, Chemistry of Kangpu Biopharmceuticals

2021年公司持續穩健成長與價值創造

銷售端

1. 安能得二線胰臟癌治療納入韓國健保
2. 安能得於歐亞地區銷售權利金維持高度成長動能
   - 日本地區銷售動能強勁
3. 安能得一線胰臟癌/二線小細胞肺癌全球三期臨床收案完成

研發端

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

1. 超過20% 營收持續投入研發
2. 2021在現金及約當現金暨按攤銷後成本衡量之金融資產
   - 流動達新台幣38億元
3. 穩定的股利配發策略
   - 2021年現金股利新台幣2.7元/股 (+8% YoY)

2021年營運概況

安能得®歐亞銷售權利金大幅增長

安能得營收成長趨勢

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	20/21 YoY (%)
台灣銷貨收入	40,651	87,384	180,389	214,828	235,469	9.6%
歐亞銷貨權利收入	63,526	109,825	133,651	271,584	419,366	54.4%
里程碑金/授權金收入	749,500	96,221	0	569,600	0	-
合計	853,677	293,430	314,040	1,056,012	654,835	(38%)

5 yr CAGR. 42% (ex. milestone)

2021年全年營運概況

單位:新台幣仟元	2021	2020	Amount Change	% Change
營業收入	654,835	1,056,012	(431,273)	(38)
營業成本	37,073	37,234	(161)	(0.4)
營業毛利	617,762	1,018,778	(401,016)	(39)
推銷費用	36,731	37,115	(384)	(1)
管理費用[1]	81,885	76,230	5,440	7
研究發展費用	136,887	95,728	41,159	43
營業費用	255,073	209,073	46,000	22
營業利益	362,689	809705	(447,016)	(55)
營業外收入(支出)[2]	182,706	(57,230)	239,936	N.A.
稅前淨利	545,395	752,4745	(207,079)	(28)
所得稅費用	119,364	148,194	(28,830)	(19)
本期淨利	426,031	604,281	(178,250)	(29)
股本	1,465,968	1,465,968	-	-
基本每股盈餘(元)	2.95	4.15	(1.2)	(29)

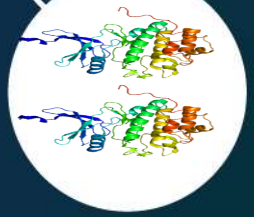
註1. :包含預期信用減損利益215仟元 ; 註2. :營業外收入增加主要係收取PEP503的補償金，美金6.5M(NTD182百萬)

產品專案進度

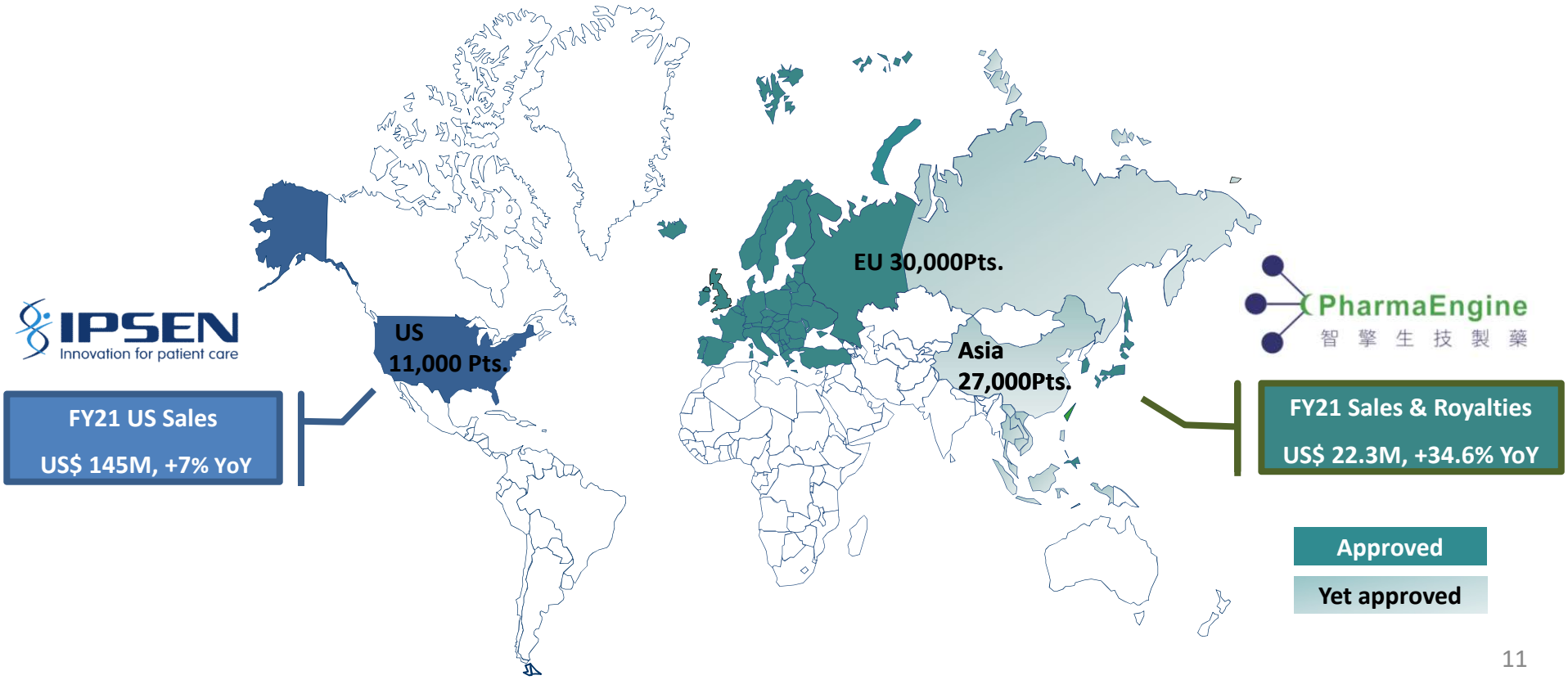
安能得®維持良好的產品週期管理

PEP07 (SOL-578) 如預期完成臨床前試驗

數項新專案進入授權評估

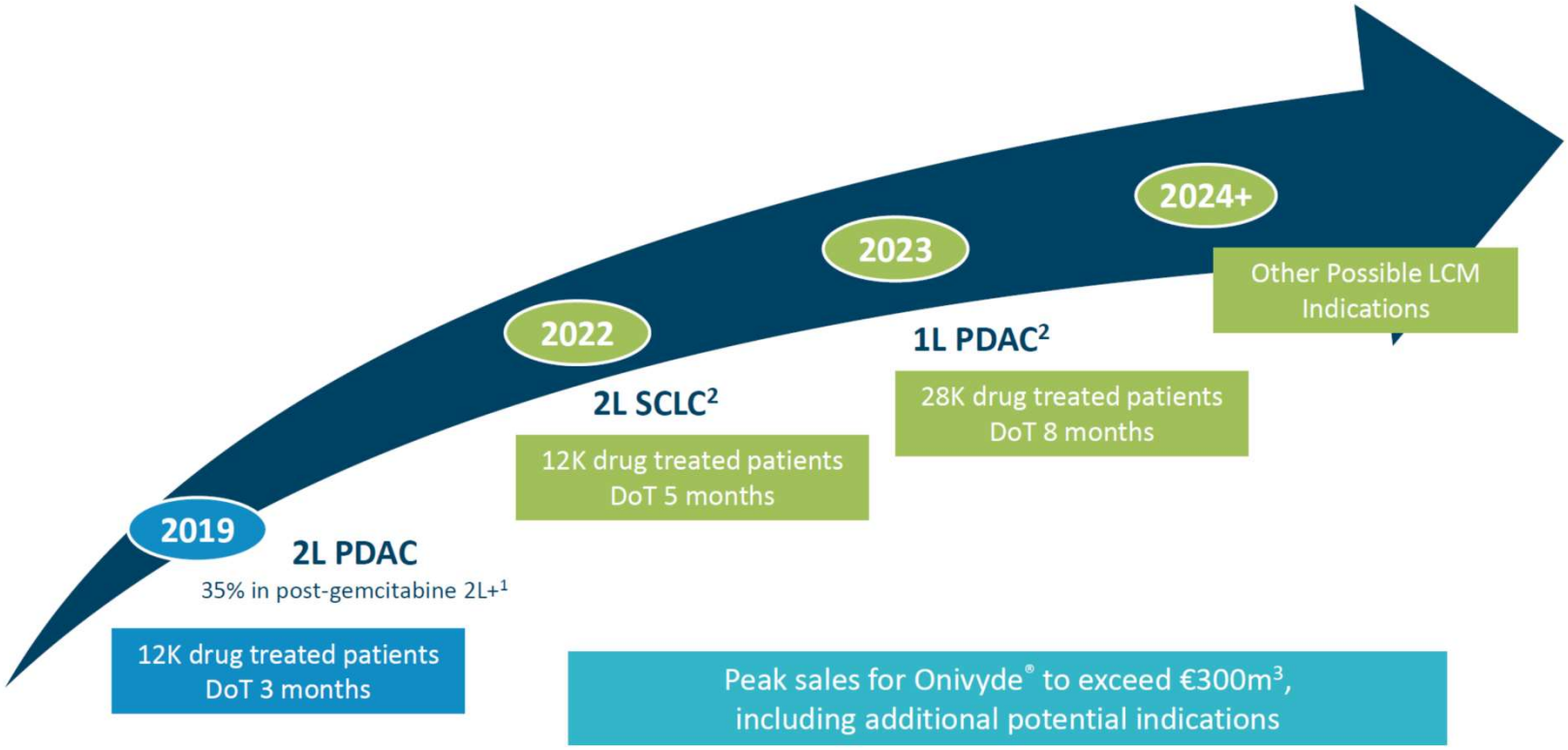


安能得®在全球銷售持續較強的成長動能



Patients are prescribed 3-4 vials of Onivyde every two weeks, with an average four-month regimen. Source: WHO ; Ipsen FY2021 earnigns

安能得®產品週期的延續



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

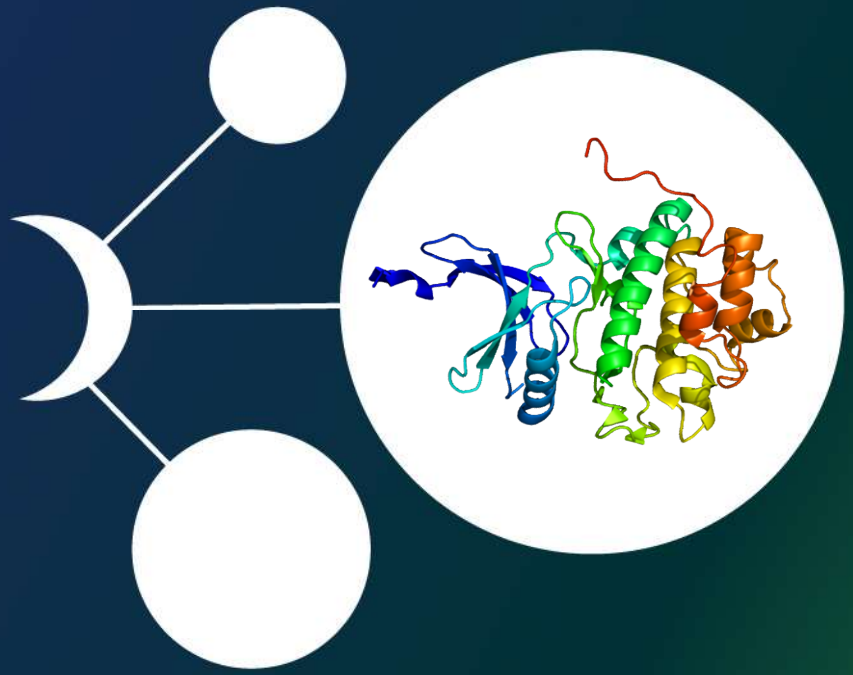
安能得®具有成為難治型癌症標準治療的潛力

1L PDAC	2L SCLC
5Y survival rate only 7%	5Y survival rate only 6%
Significant need for more effective therapies with reduced toxicity	Very few FDA approved therapies, highlighting need for new options
Ability to build on successful approvals for 2L PDAC & leverage our global partners to establish new SoC	Improved toxicity profile versus SoC chemotherapies with severe side effects
Existing commercial infrastructure & medical capabilities by our global partners	Strong leverage of current organization by our global partners

Source: IPSEN Capital Market Day 2020

PEP07 (SOL-578)

前臨床試驗進度符合預期



國際合作夥伴

PharmaEngine 智擎生技製藥

Sentinel ONCOLOGY

Founded	2005
Location	Cambridge, UK
Type	Privately Held
Focus	Oncology, Drug Discovery, Medicinal Chemistry & Collaboration
Partnerships	PHORMOST DRUGGING THE UNDRUGGABLE; SeattleGenetics; CASCADIAN THERAPEUTICS

Robert Boyle
CEO & Board of Directors

Stuart Travers
COO & Board of Directors

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

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

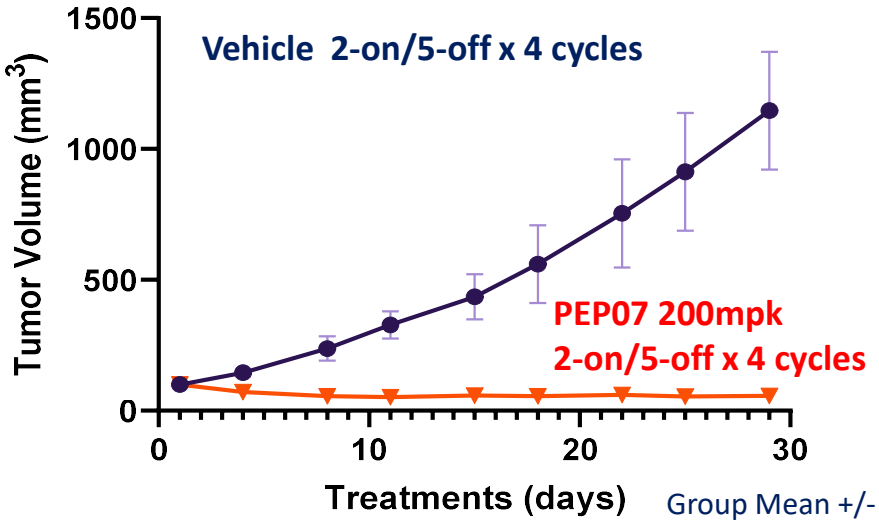
	Drug	Potency	Selectivity	Specificity	Oral Bioavailability
Eli Lilly	LY2606368	Excellent	Fair	Fair	Poor
Genetech	GDC-0575	Good	Fair	Good	Good
Sierra Oncology	SRA-737	Fair	Good	Unknown	Good
Esperas Pharma	LY2880070	Unknown	Unknown	Unknown	Unknown
PEI/Sentinel	PEP07/SOL-578	Excellent	Good	Good	Good

Excellent Good Fair Poor Unknown

PEP07 (SOL-578) : 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

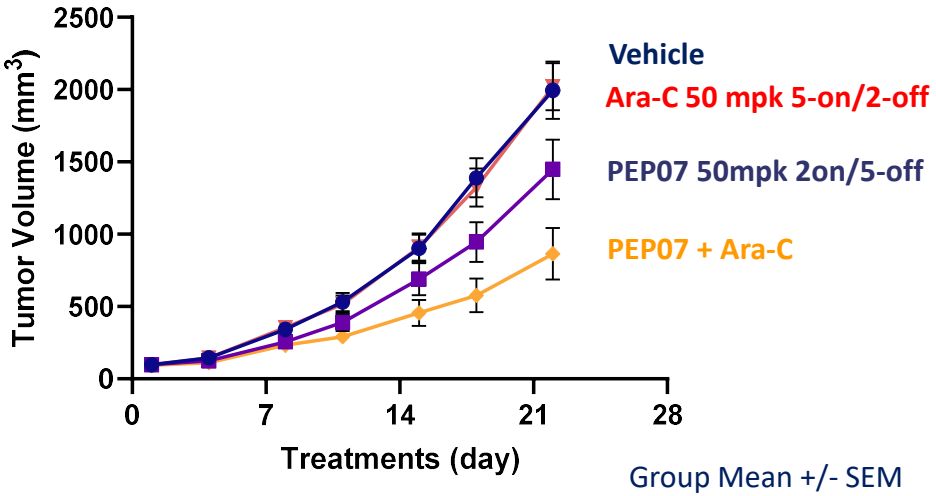
Acute Myeloid Leukemic (AML)

Ara-C Sensitive



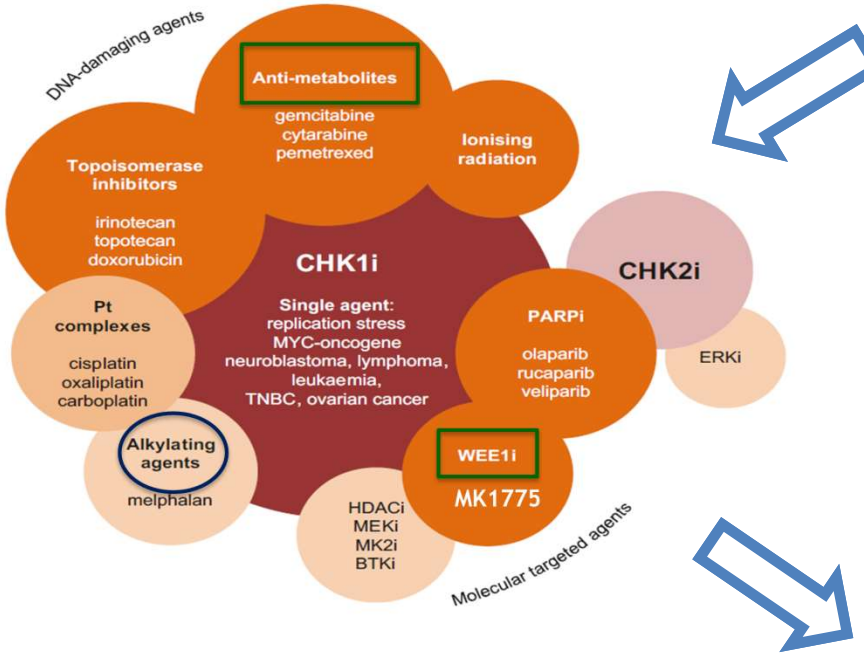
Group Mean +/- SEM
n=8/group

Ara-C Resistant



Group Mean +/- SEM
n=8/group

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

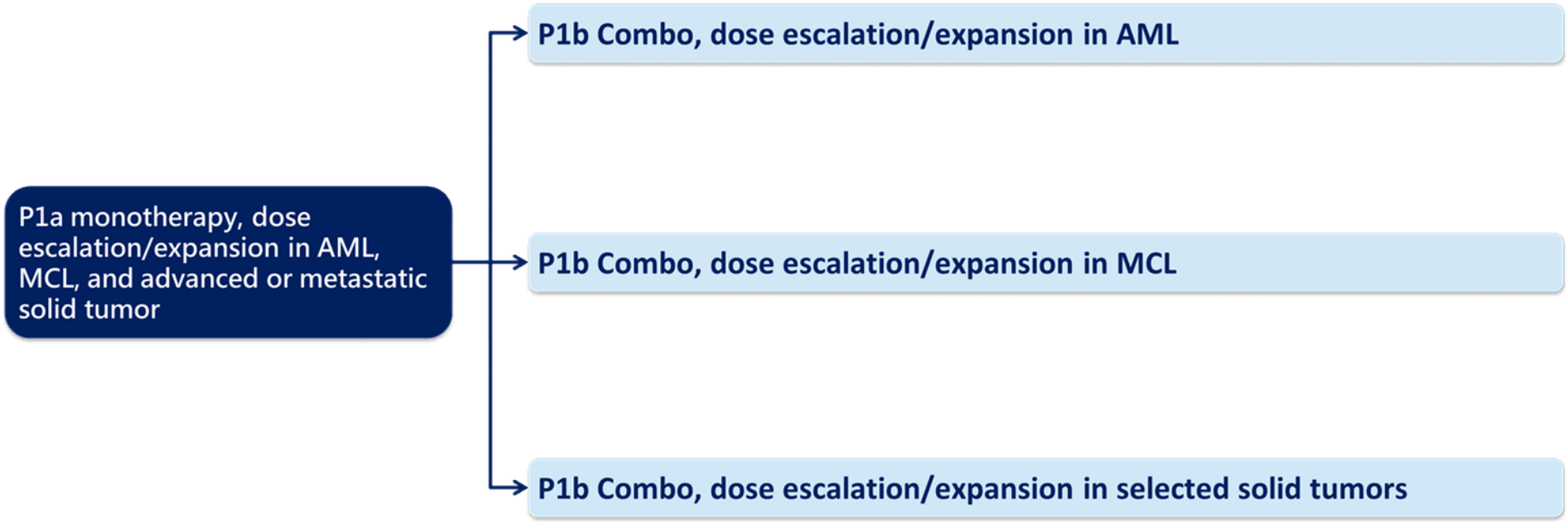
Green: Synergism ; Blue: Additivity

Clinical Trial Designs and Indications Guidance

：Synergistic effect verified in PEP07
：Additive effect observed in PEP07

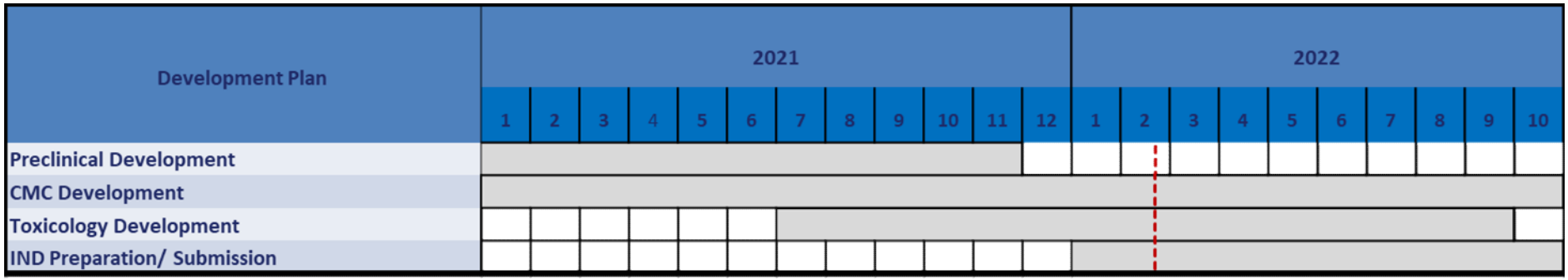
Targeting the DNA Damage Response for Anti-Cancer Therapy 241-276, 2018

PEP07 (SOL-578) 早期臨床研發佈局



Preclinical biomarker study is ongoing for further design of clinical trials

PEP07 (SOL-578) 發展計畫



Preclinical

Anti-tumor efficacy in two AML models and MCL model
Synergistic with Ara-C including Ara-C resistance model
Efficacy study for solid tumors ongoing
Biomarker evaluation ongoing

CMC

Identified novel salts
Kg-scale ready for GMP production

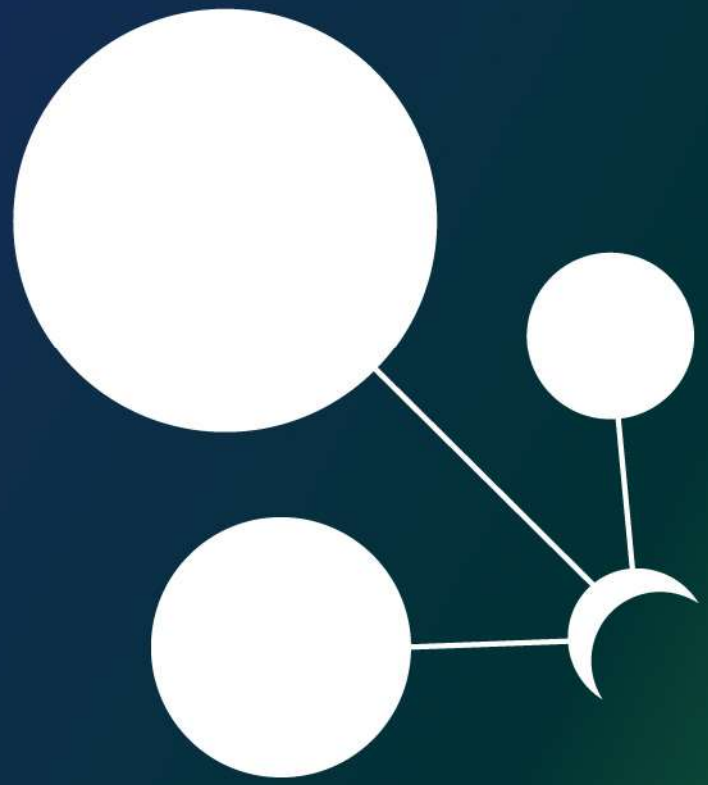
Toxicology

GLP study initiated

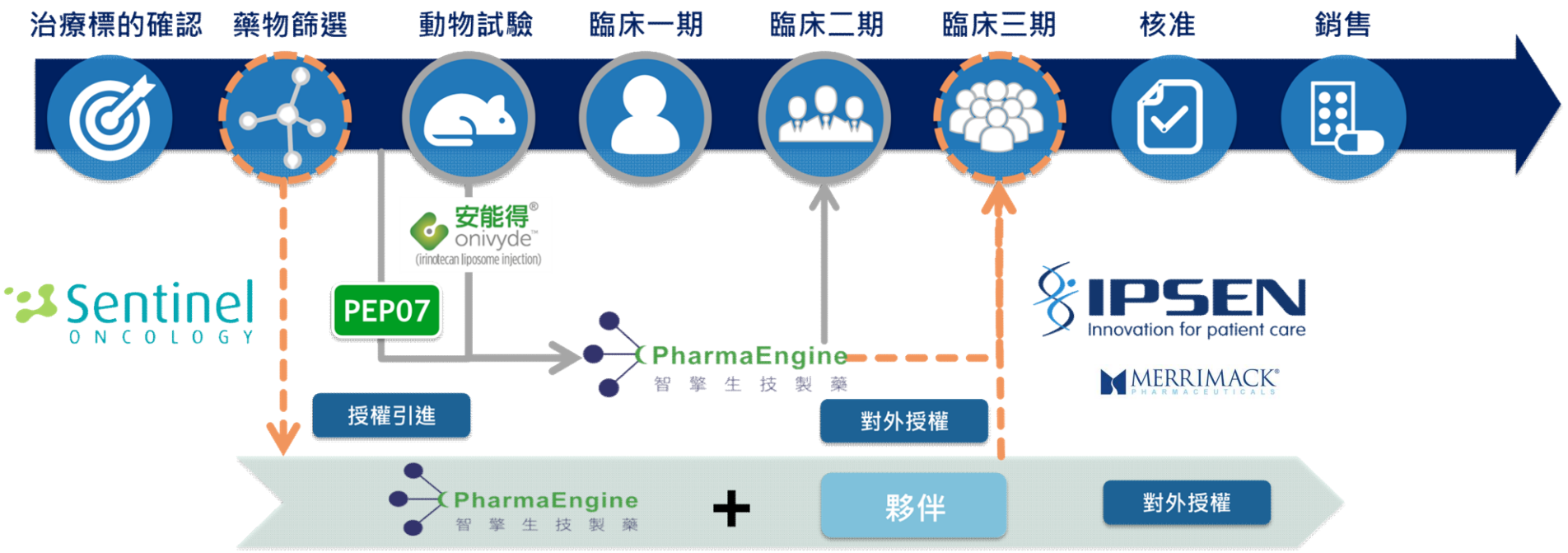
IND Prep. & Sub.

Target submission on 2022Q3

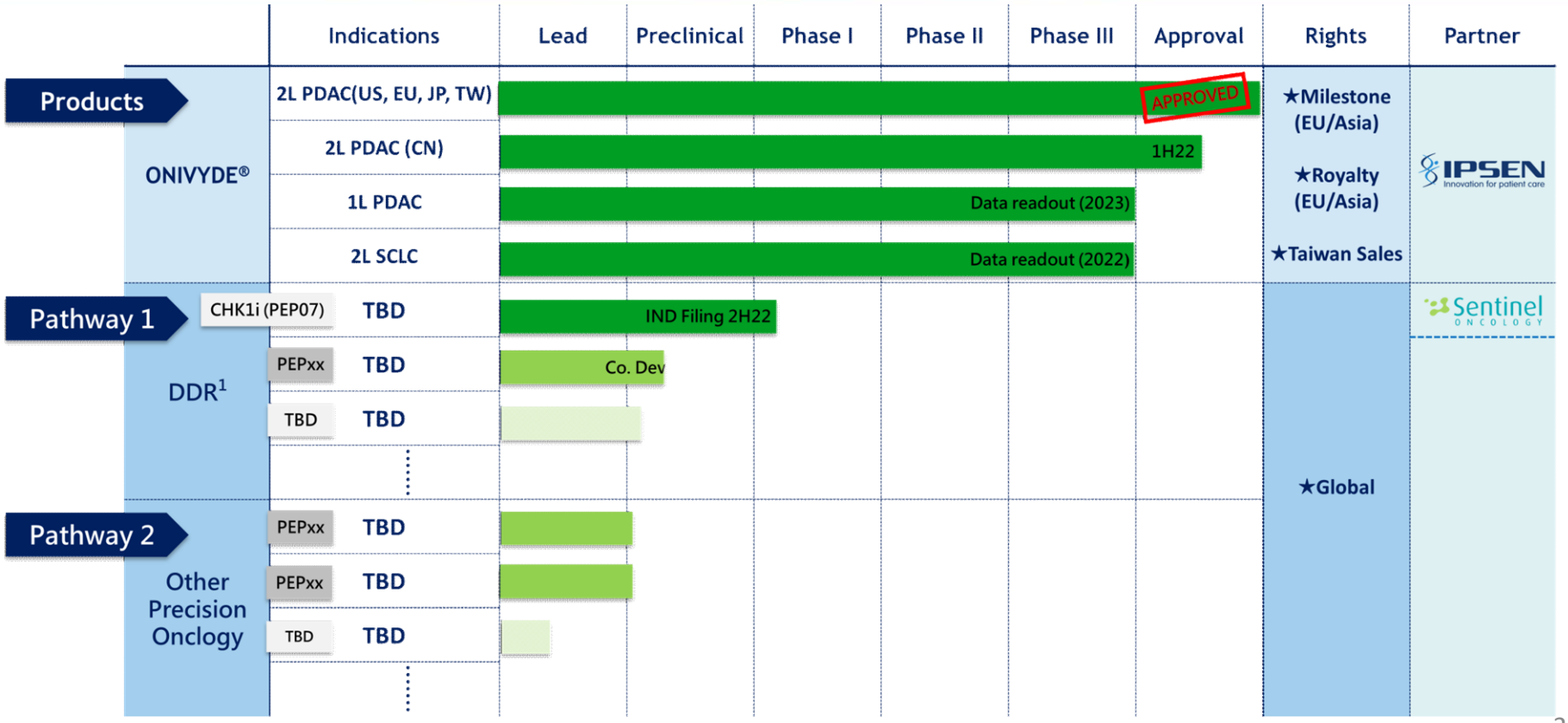
2022年
營運展望



Virtual Pharmaceutical Company 營運模式



產品組合



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

2022: Year of Revitalization and Marching Forward

PharmaEngine 智擎生技製藥

安能得®產品生命週期的延展

1. 二線胰腺癌陸續取得藥證與醫保
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. DDR標靶新藥PEPxx
3. 其他癌症精準靶位新藥開發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