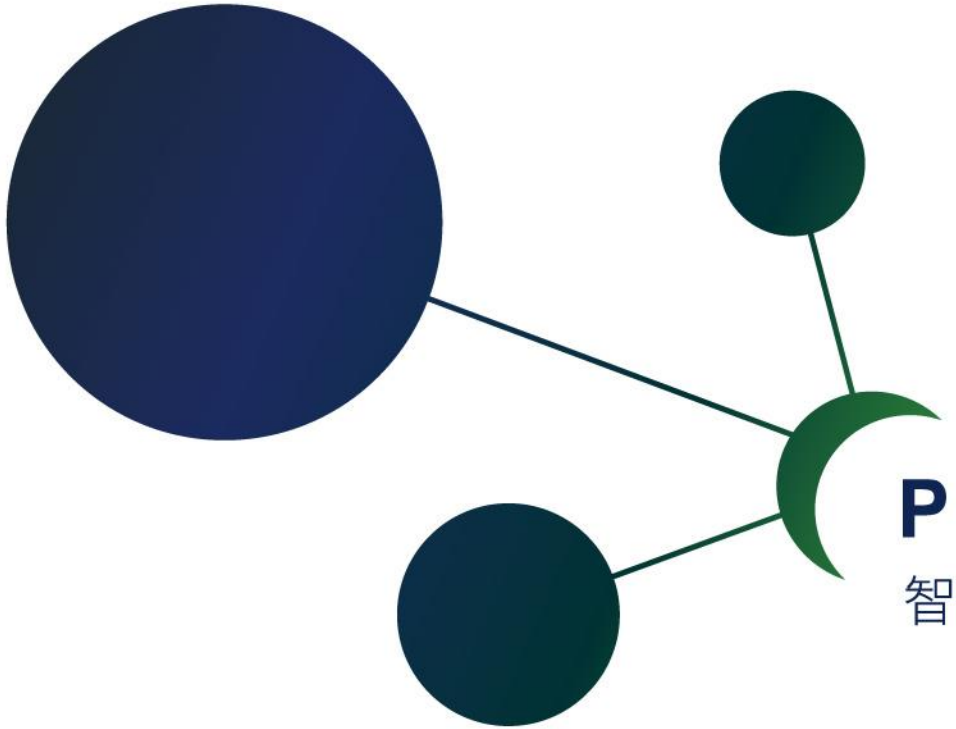


PharmaEngine

智 擎 生 技 製 藥

2022 QIC
生技產業論壇

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。

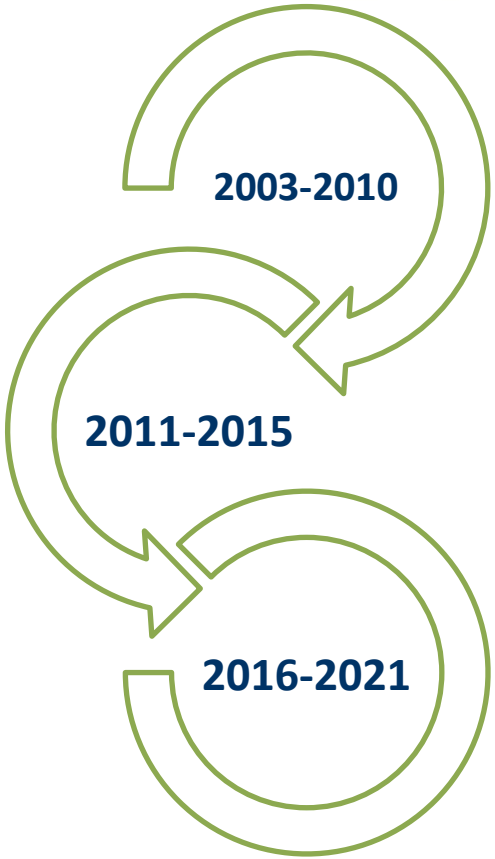
使命

提供癌症患者更多更好的治療選擇

願景

成為亞洲指標性癌症新藥開發公司

智擎新藥致力於癌症新藥研發近20年



2003- 2010

- 公司成立
- 2003年獨家引進 PEP02 亞洲區域 2003
- 2005年擴增引進PEP02至歐洲區域
- 2010年完成PEP02 二期二線胰臟癌美國/台灣臨床試驗

2011-2015

- 2011年授權安能得®
- 2012年台灣櫃買中心掛牌上櫃
- 2014年起轉虧為盈
- 2015年安能得® 為台灣第一支獲美國FDA癌症新藥藥證
- 2015年安能得®收錄進ESMO二線胰臟癌臨床標準用藥指引

2016-2021

- 2016年安能得®收錄進NCCN二線胰臟癌臨床標準用藥指引
- 2016年建置台灣地區市場銷售團隊
- 2020年達成第一期銷售里程碑金
- 2020年與英國Sentinel Oncology簽訂 PEP07 (SOL-578)獨家合作開發協議

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

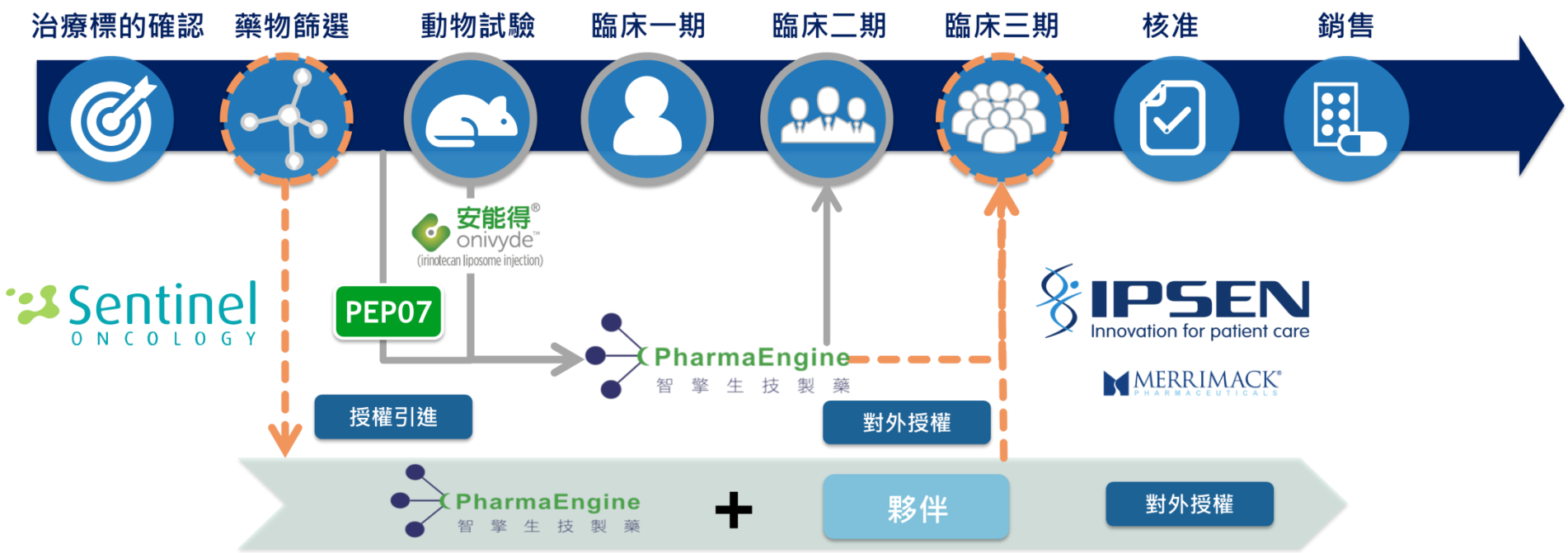
Steven Witowski, Ph.D.
Principal of Witowski CMC Consulting, LLC

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

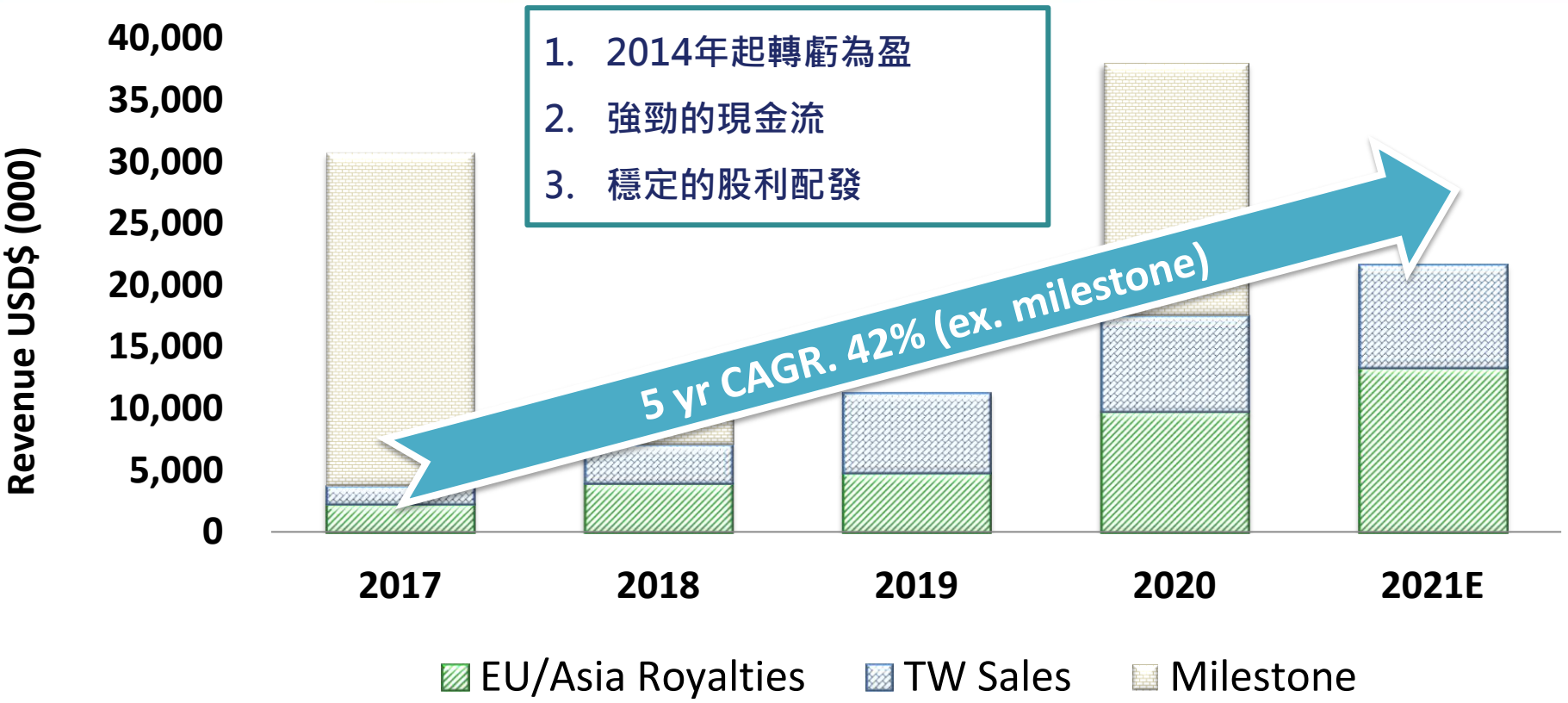
Wen-Cherng Lee, Ph.D.
Former Biogen Director, former EVP, Chemistry of Kangpu Biopharmceuticals

Virtual Pharmaceutical Company 營運模式



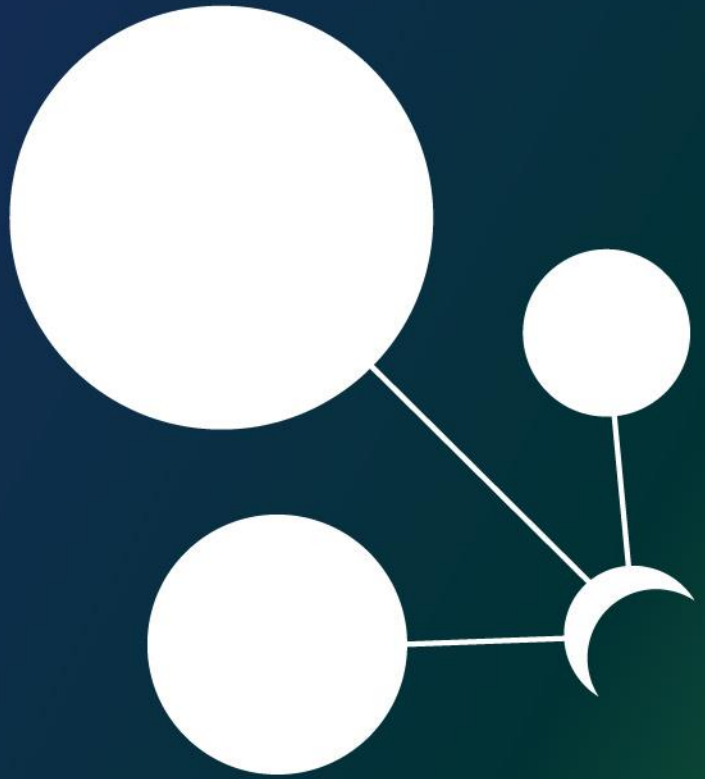
具獲利能力的研發型新藥公司

1. 2014年起轉虧為盈
2. 強勁的現金流
3. 穩定的股利配發



Taiwan Sales belongs to PharmaEngine, Inc.
Tiered royalties (high single – low double digit) in Europe/Asia (excl. TW) from Servier/IPSEN

2025年的願景



公司持續穩健成長與價值創造

銷售端

安能得®透過市場擴張與適應症延伸達到產品生命週期的延展

研發端

1項具授權潛力研發項目進入中後期程

2 項早期在研項目進入臨床一/二期

3 項先導藥物於前臨床期程

營運端

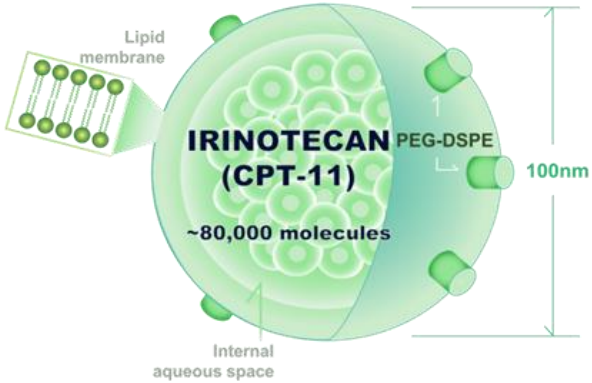
- +20% 營收持續投入研發
- 穩定的股利配發策略
- 引進、授權與策略購併

銷售端

安能得®產品生命週期的延展

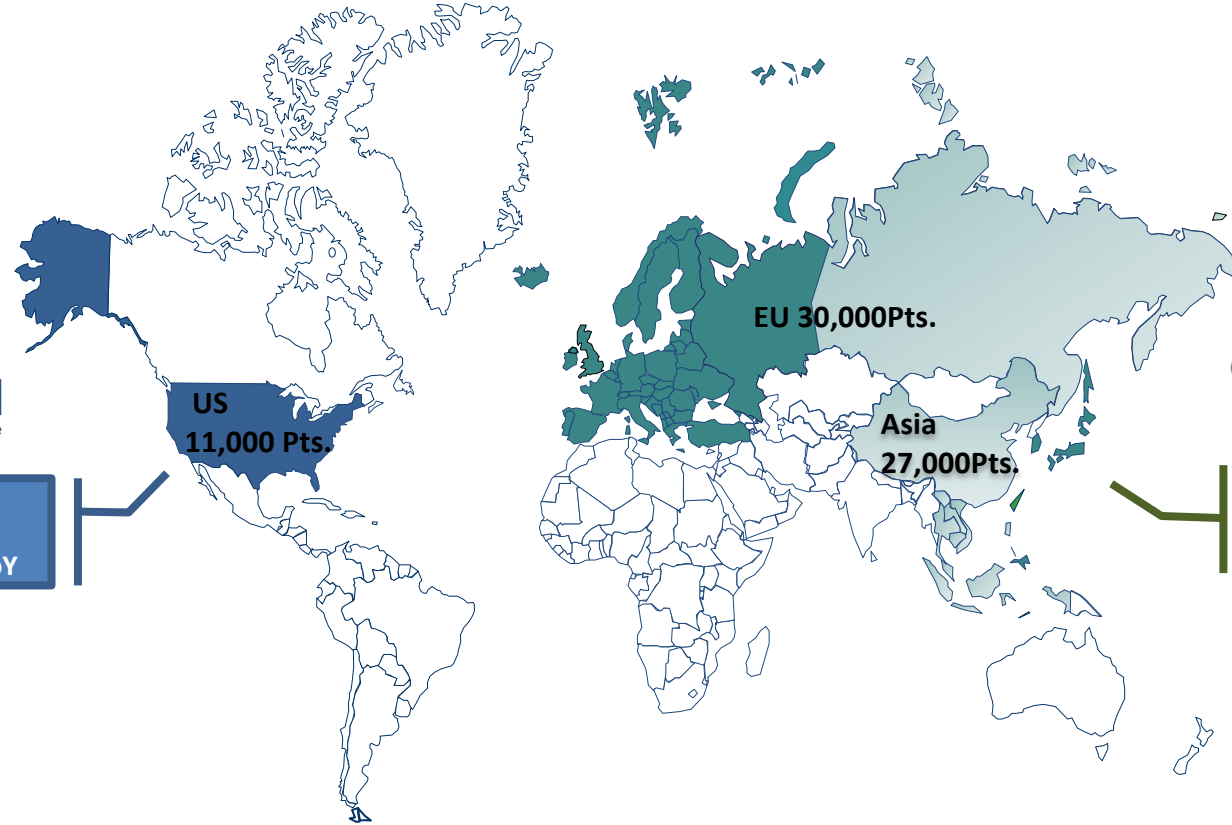
安能得®為全球二線胰腺癌標準治療(post-Gemcitabine)

- First FDA-approved drug in post-gemcitabine pancreatic cancer
- Category 1 evidence in NCCN and ESMO clinical practice guideline



- ONIVYDE® is a liposome formulation of irinotecan
- Sustained release profile
- Preferential tumor accumulation
- Site-specific activation

安能得®在全球銷售仍有較強的成長動能



IPSEN
Innovation for patient care

FY21 US Sales

US$ 145M, +7% YoY

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3Q21 Sales & Royalties

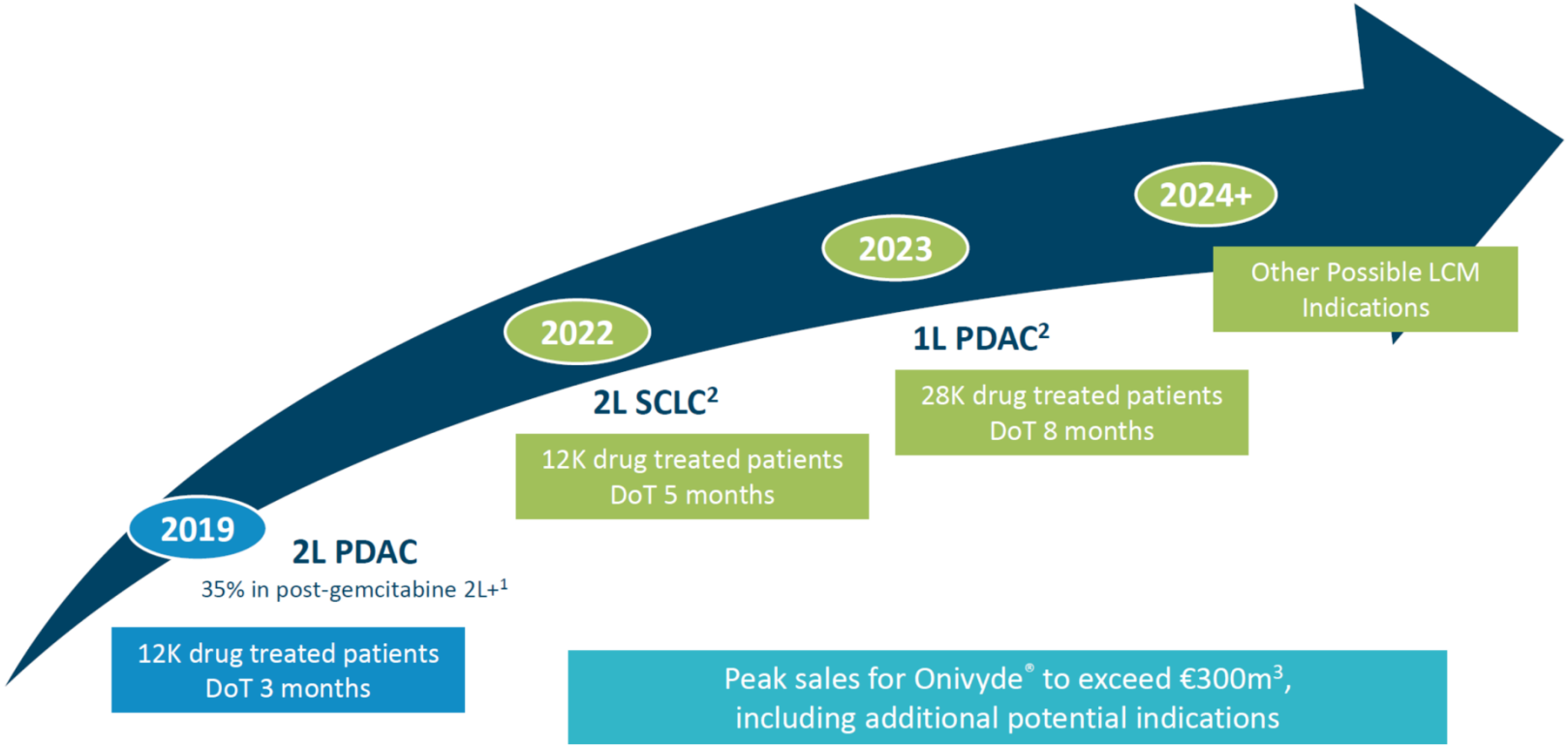
US$ 16.2M, +67% YoY

Approved

Yet approved

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®的適應症延伸



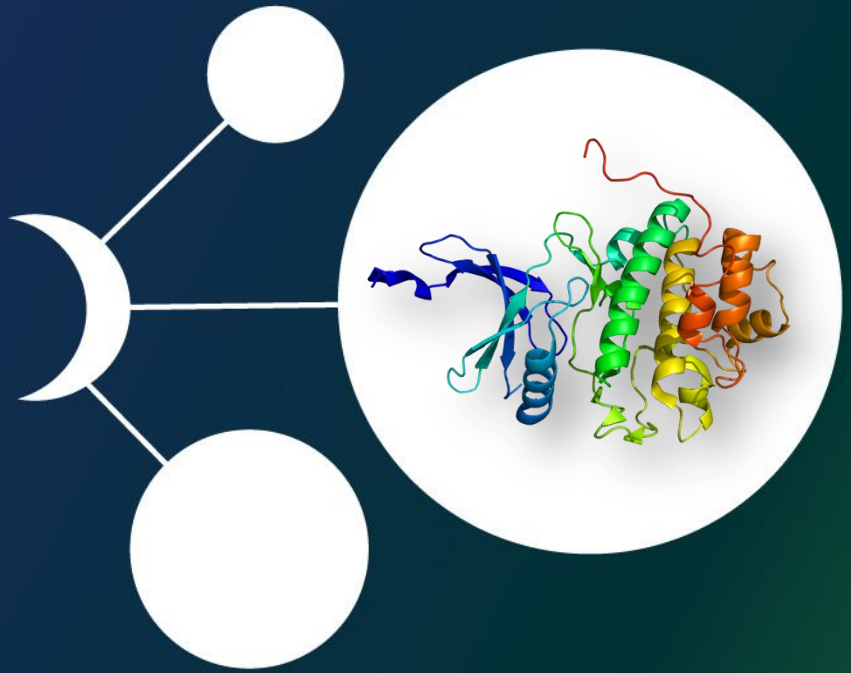
LCM: Life cycle management; PDAC: Pancreatic ductal adenocarcinoma; SCLC: Small cell lung cancer; DoT: Duration of treatment; 1L: First line; 2L: Second line; 1. IQVIA APLD claims, September 2020 ; 2. Expected submission dates ; 3. Risk adjusted; IPSEN Capital Market Day 2020

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

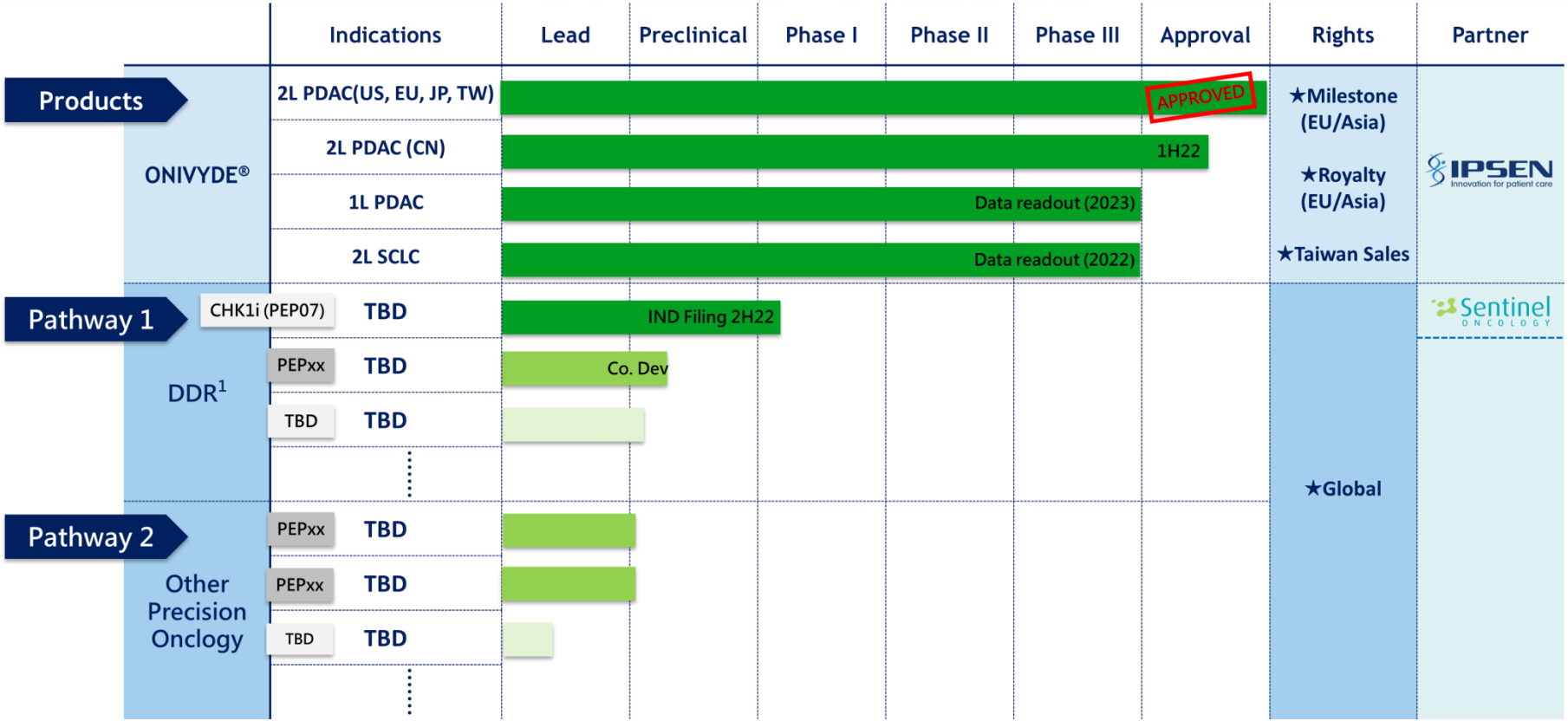
Source: IPSEN Capital Market Day 2020

在研項目



產品組合

PharmaEngine 智擎生技製藥



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

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	PHAREMOST 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.

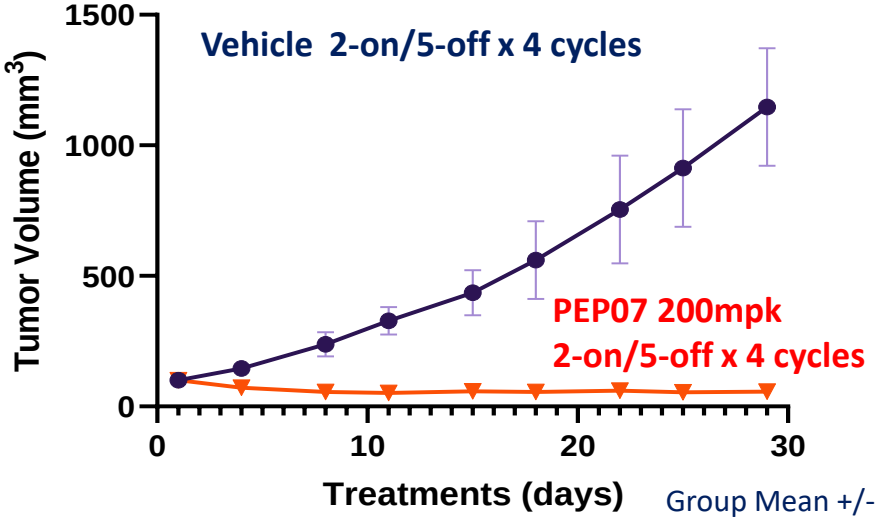
	Drug	Potency	Selectivity	Specificity	Oral Bioavailability
Eli Lilly	LY2606368				
Genetech	GDC-0575				
Sierra Oncology	SRA-737				
Esperas Pharma	LY2880070				
PEI/Sentinel	PEP07/SOL-578				

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

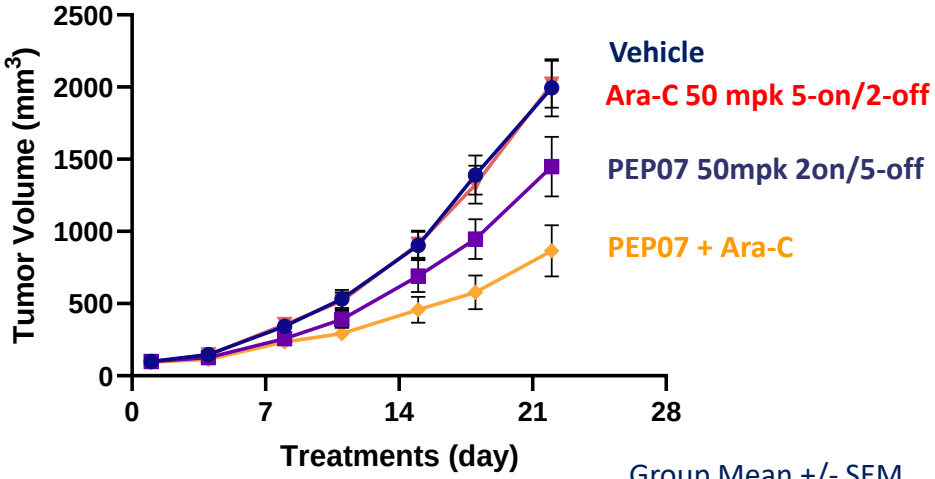
Acute Myeloid Leukemic (AML)

Ara-C Sensitive



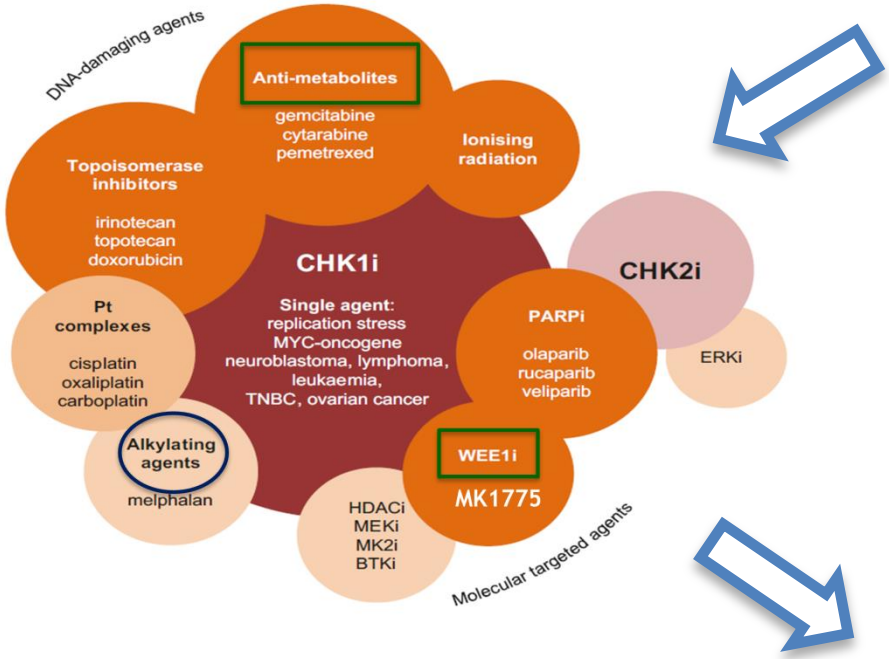
Group Mean +/- SEM
n=8/group

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

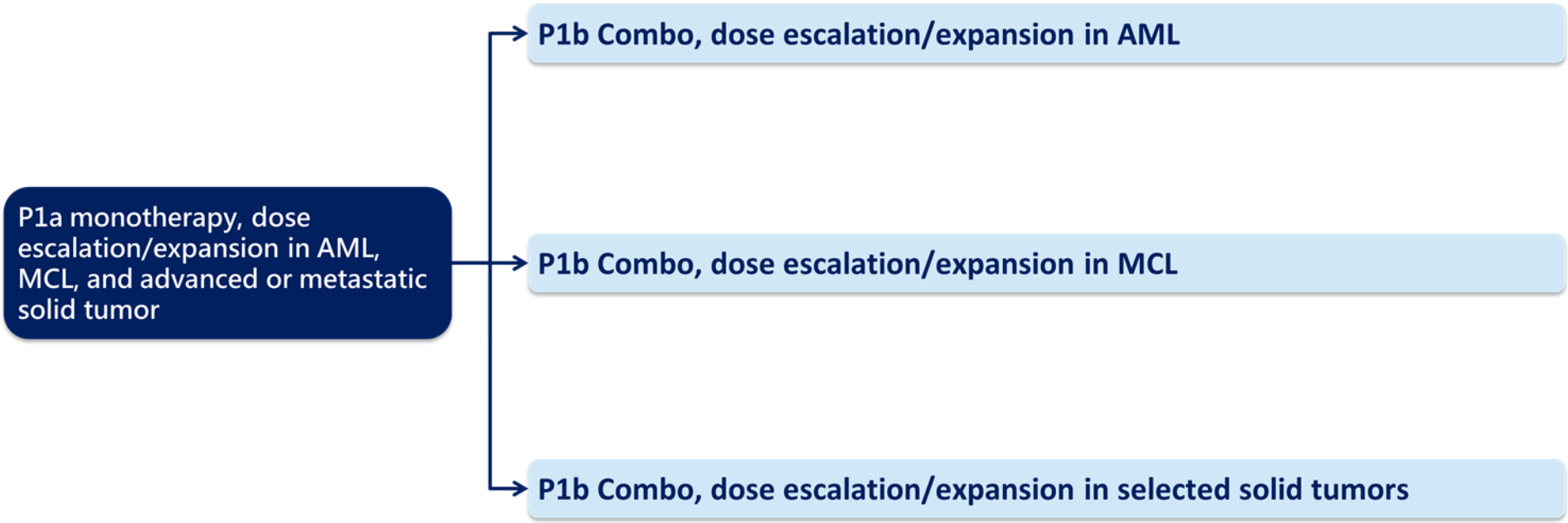
Green: Synergism ; Blue: Additivity

Clinical Trial Designs and Indications Guidance

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

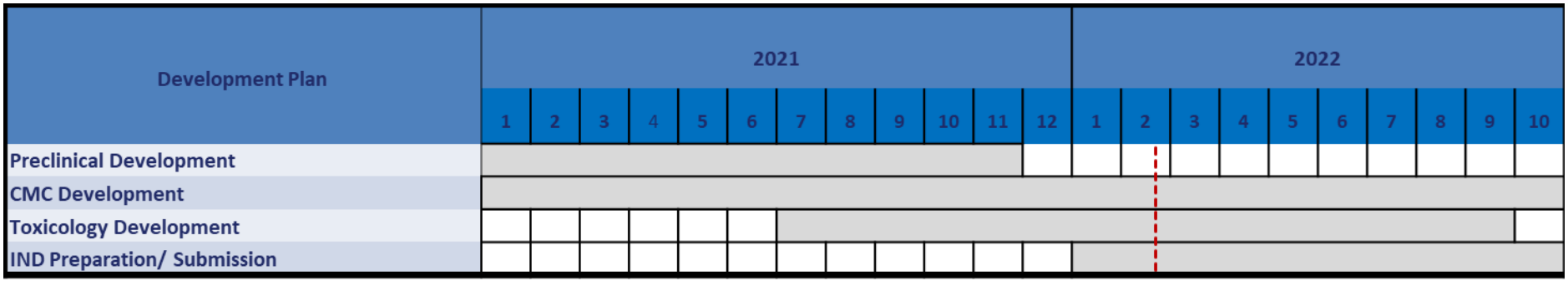
Targeting the DNA Damage Response for Anti-Cancer Therapy 241-276, 2018

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: 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. 二線胰腺癌治療取得中國藥證
2. 二線胰腺癌於歐洲多國將陸續核保
3. 二線小細胞肺癌(SCLC)三期臨床數據公告
4. 一線胰腺癌三期臨床數據公告(2022+)

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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