智擎生技 4162.TWO
4Q 2024 法人座談會
2025/03/06

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副總經理暨發言人 張麒星

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. 2024 營運重點
2. 2024 營運概況
3. 產品進度
   a. PEP07
   b. PEP08
4. 2025年營運展望
5. Q&A

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2024年營運重點-營運持續成長與價值創造

市場端

安能得®(ONIVYDE®)新適應症進度

1. 2024年陸續獲得美國FDA、澳洲TGA、台灣FDA及歐盟EMA新適應症上市許可
2. 2024年第2季提出一線胰臟癌台灣健保補助申請
3. 2024年度歐亞銷售地區之淨銷售額達到第二期銷售里程碑，收取美金5千萬元之銷售里程碑授權金

*ONIVYDE®尚不屬於中國醫保目錄內藥品報銷範圍

LIPORAXEL®

1. 2024年11月與上海諾邁西醫藥科技簽署經銷合約

研發端

新產品研發進程逐步加快

1. 持續進行PEP07第一期血液及實體腫瘤試驗
2. 推進自研專案PEP08至IND ready階段 (1H25)
3. 持續推進數項早期研發項目

營運端

公司營運穩定成長

1. 至2024年底，現金及約當現金暨按攤銷後成本衡量之金融資產(三個月以上定存)達新台幣38.6億元
2. 2024年現金股利: 每股新台幣6元
3. 已完成第一階段範疇三溫室氣體盤查作業，數據將揭露於2024年永續報告書

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2024年營運概況

安能得® (ONIVYDE®) 營收趨勢

NT$(000)

項目 / 年份	2018	2019	2020	2021	2022	2023	2024 YOY (%)
台灣銷售收入	87,384	180,389	214,828	235,469	277,594	278,547	279,990 (+1%)
歐亞銷售權利金收入	109,825	133,651	271,584	419,366	376,789	426,652	543,286 (+27%)
里程碑金/授權金收入	96,221	0	569,600	0	0	62,470	1,700,028 (+2,621%)
合計	293,430	314,040	1,056,012	654,835	654,383	767,669	2,523,304 (+229%)

2024年營運概況

NT$(000)	2024	2023	Amount Change	% Change
營業收入	2,523,304	767,669	1,755,635	229%
營業成本	47,740	48,697	(957)	(2%)
營業毛利	2,475,564	718,972	1,756,592	244%
推銷費用	37,605	38,538	(933)	(2%)
管理費用	117,768	92,970	24,798	27%
研究發展費用	267,025	310,281	(43,256)	(14%)
營業費用	422,398	441,789	(19,391)	(4%)
營業利益	2,053,166	277,183	1,775,983	641%
營業外收入(支出)	109,829	60,791	49,038	81%
稅前淨利	2,162,995	337,974	1,825,021	540%
所得稅費用	411,965	63,324	348,641	551%
本期淨利	1,751,030	274,650	1,476,380	538%
基本每股盈餘(元)	12.19	1.91	10.28	538%

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產品進度

產品組合聚焦在癌症精準醫療

Program		Indications	Lead	Preclinical	Phase I	Phase II	Phase III	Approval	Commercial Rights	Partner
ONIVYDE® (liposomal irinotecan)		1L/2L PDAC	Approval						Milestone Royalty (EU/Asia) Taiwan Sales	IPSEN Innovation for patient care
DDR & Synthetic Lethality	PEP07 (CHK1i)	AML/MCL							Global	Sentinel ONCOLOGY
		Solid tumors								
	PEP08 (PRMT5i)	MTAP-del cancers							Global	PEI Owned
	PEP09	Undisclosed							Global	Undisclosed
	PEP10	Undisclosed							Global	PEI Owned

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PEP07

PEP07為最具潛力的口服CHK1抑制劑

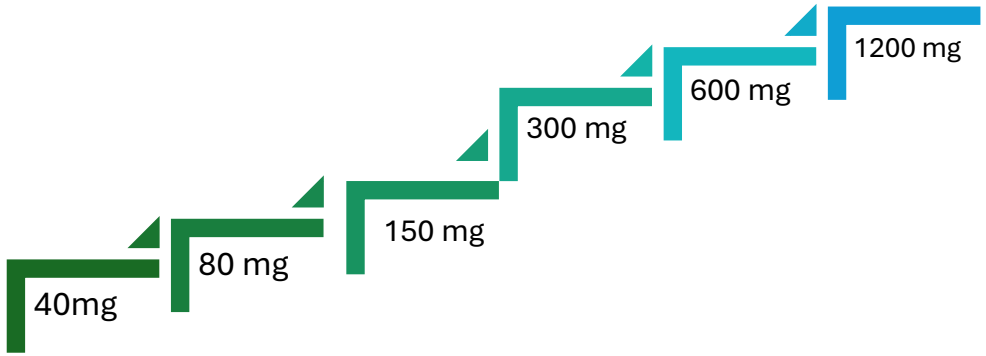
Criterion	PEP07	ACR-368 (Prexasertib)	SRA-737	BBI-355
Development Phase	Phase I	Phase II	Phase I/II	Phase I/II
Potency*				
CHK1 vs CHK2 Selectivity				
Oral Bioavailability				
BBB-Penetrating			Unknown	
Indications	AML/MCL Solid tumors	Endometrial cancer Ovarian cancer Bladder cancer	Solid tumors	Solid tumors

**Cell line model*

PEP07: Phase I/Ib 臨床開發策略

Mono Dose Escalation in AML and MCL

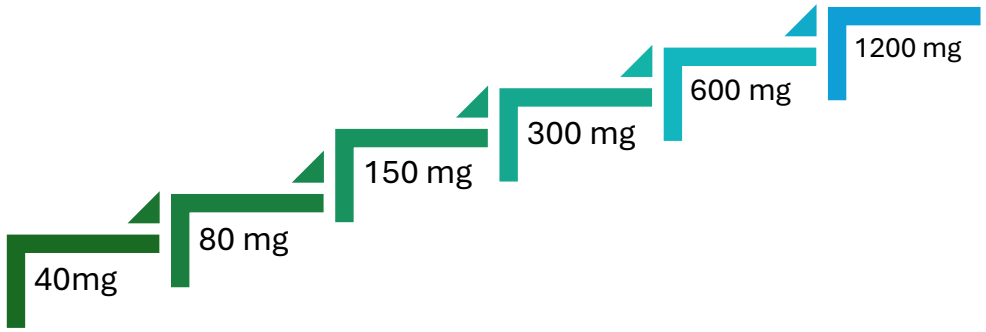
- Study design
  - ✓ Accelerated titration plus traditional 3+3 design
  - ✓ Once a DLT, or ≥ Grade 2 AE related to PEP07 at any dose level ➔ 3+3



Ph1b Combo, dose escalation/expansion in selected hematologic cancer; AML or MCL

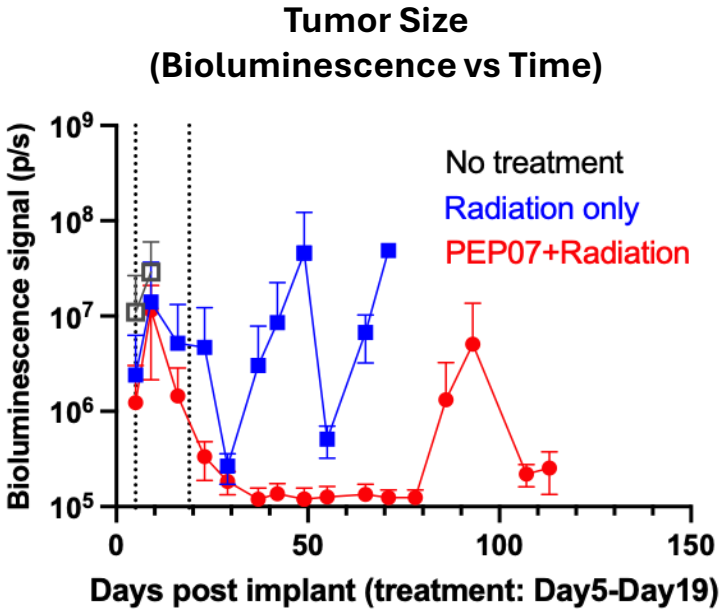
Mono Dose Escalation in Solid Tumors

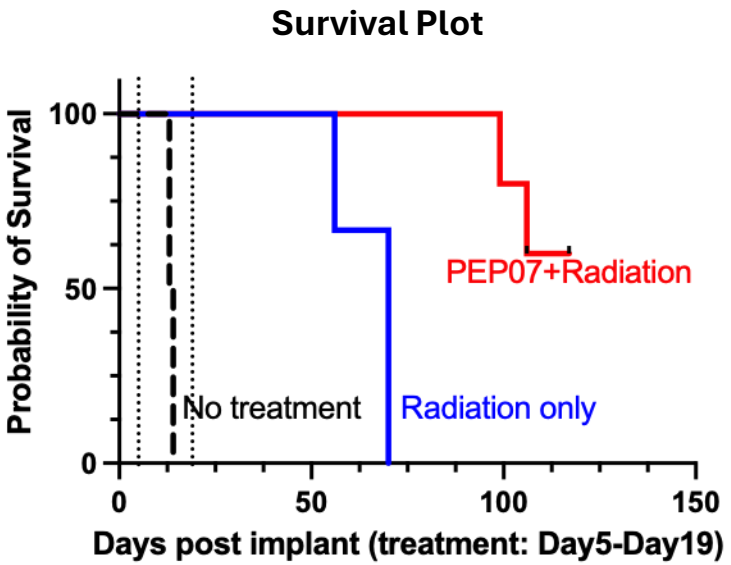
- Study design
  - ✓ Accelerated titration plus traditional 3+3 design
  - ✓ Once a DLT, or ≥ Grade 2 AE related to PEP07 at any dose level ➔ 3+3



Ph1b Combo, dose escalation/expansion in selected solid tumors

PEP07合併放射線治療在腦癌動物模型中具顯著療效





Other combination candidates including Standard of Care therapies or anti-body conjugate drugs in selective indications.

PEP07:潛在適應症與市場價值

Potential Indication	Cancer type	2022 Incidence*	Global Market Size^ 2023 ($ Bn)	Market Size CAGR 2024-2032^
High Potential	Acute Myeloid Leukemia	165,500	2.1	10.7%
	Gastric Cancer	968,350	4.7	13.5%
	Soft Tissue Sarcoma	42,500	1.4	8.5%
	GBM	321,476	2.9	8.6%
	SCLC	372,100	5.12	12.3%
	Ovarian Cancer	324,398	3.5	6.3%
Potential	NSCLC	2,108,000	19.56	9.28%
	Pancreas	510,566	3.0	13.2%

#Global DNA repair drugs market is forecasted to grow from US$6.79 billion in 2023 to US$29.69 billion in 2034, a CAGR of 14%.

* Globocan 2022
^Source: Global market insight
#Source: https://www.researchandmarkets.com/reports/5923234

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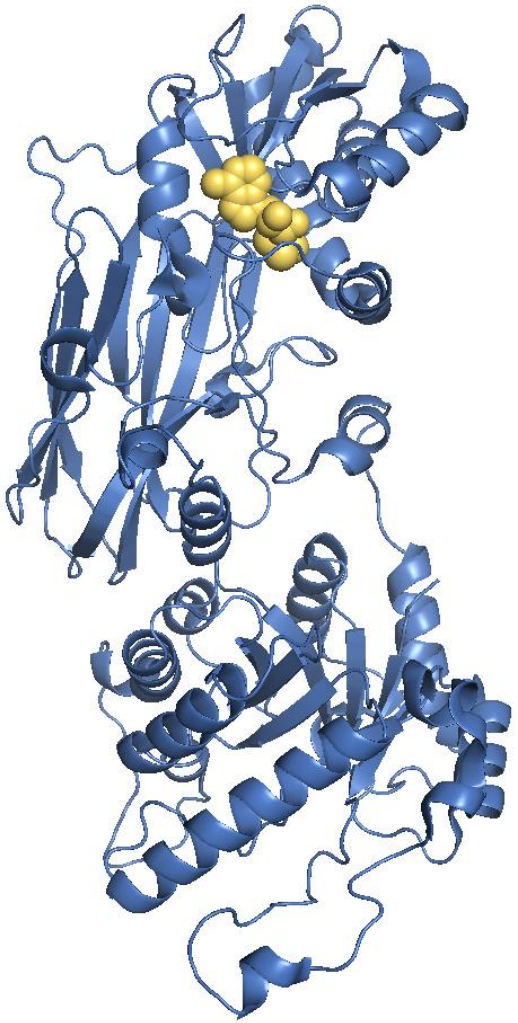
PEP08

PRMT5: 癌症治療新靶點

- PRMT5 plays critical roles in gene expression, RNA processing, DNA damage repair, and immune response.
- First generation PRMT5 inhibitors target PRMT5 in both cancer and normal cells. Since PRMT5 is an essential protein in human biology, lacking selectivity leads to narrow therapeutic window.
- MTAP homozygous deletion causes MTA accumulation in cells and is reported synthetical lethality with PRMT5 inhibition.
- MTAP homozygous deletion is observed in 10-15% of human cancers.
- An MTA co-operative PRMT5 inhibitor forms a ternary complex with PRMT5 and MTA which provides a unique mechanism to enhance both efficacy and safety in cancer treatments.

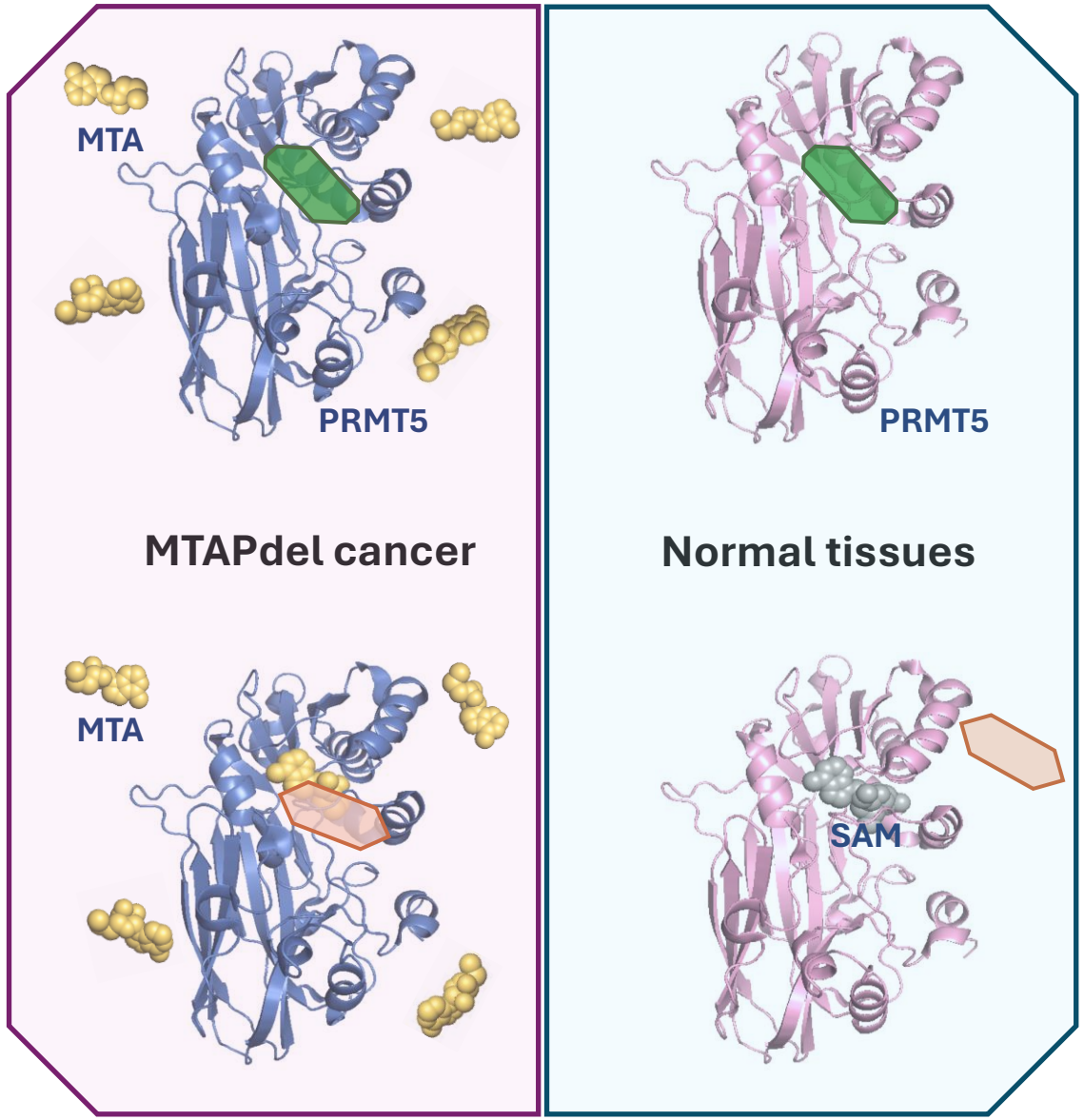


PRMT5:MTA
PDB: 7S1S

比較第一代和第二代PRMT5抑制劑之差異

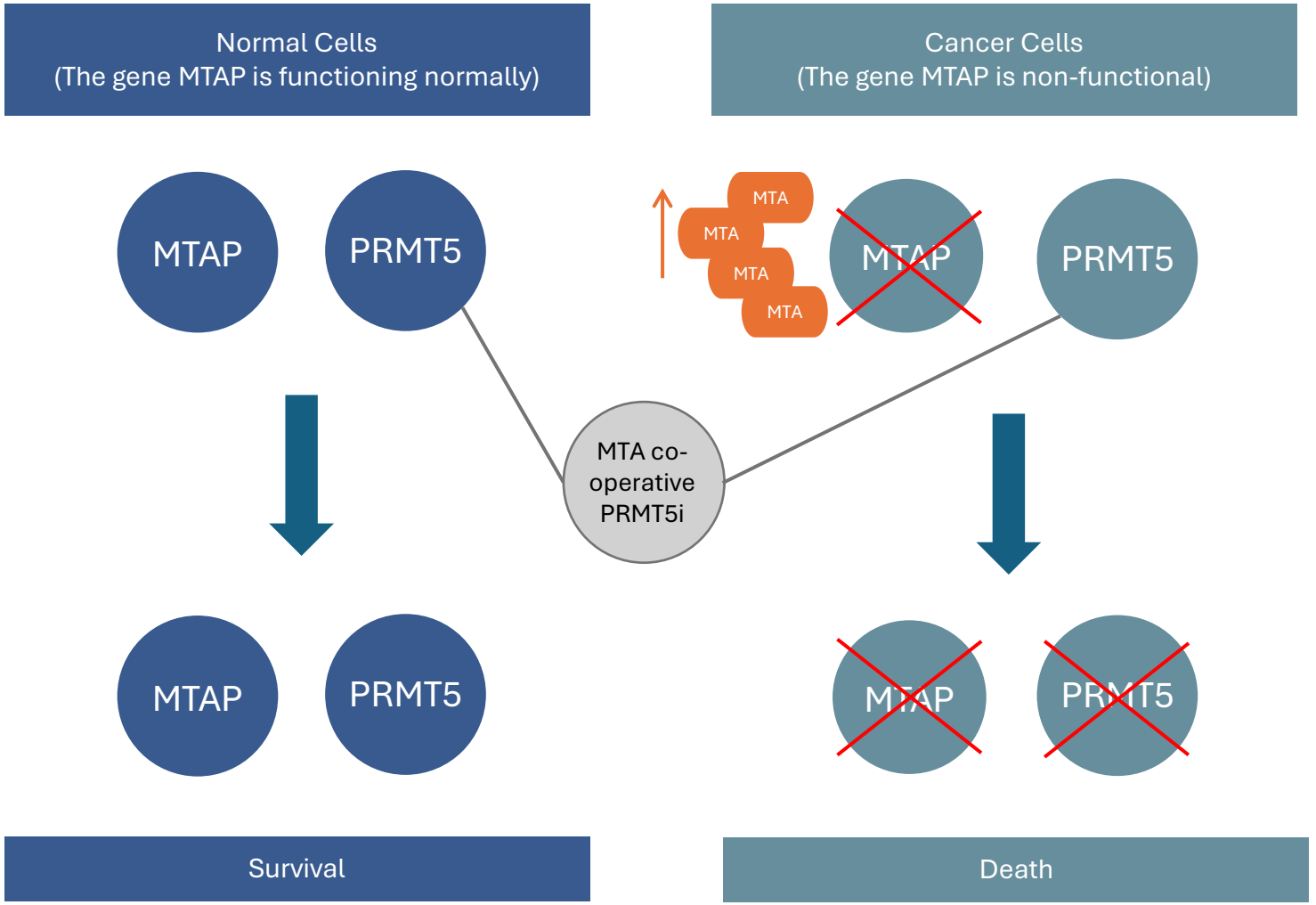
1st generation PRMT5i

2nd generation
MTA co-operative PRMT5i



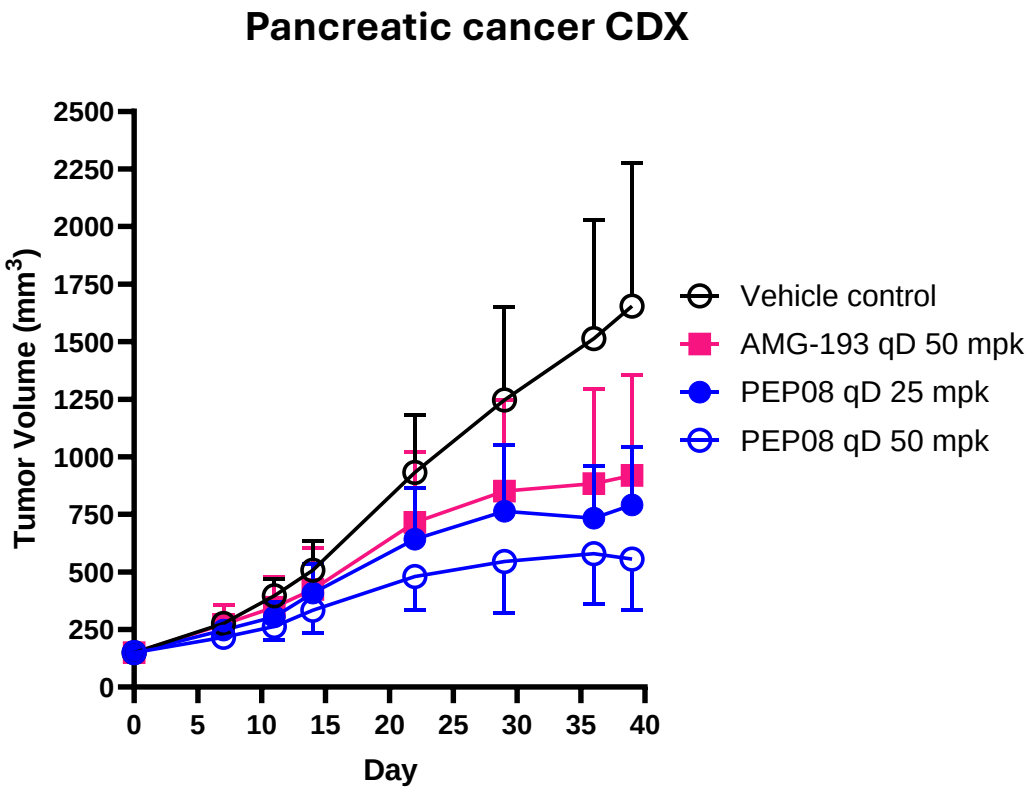
- Unlike 1st generation PRMT5 inhibitors bind PRMT5 unselectively in both cancer cells and normal tissues, 2nd generation, MTA co-operative PRMT5 inhibitors only target to MTAP deletion cancer cells due to the higher concentration of MTA in cancer cells.
- This unique mechanism provides excellent efficacy and improved therapeutic window.

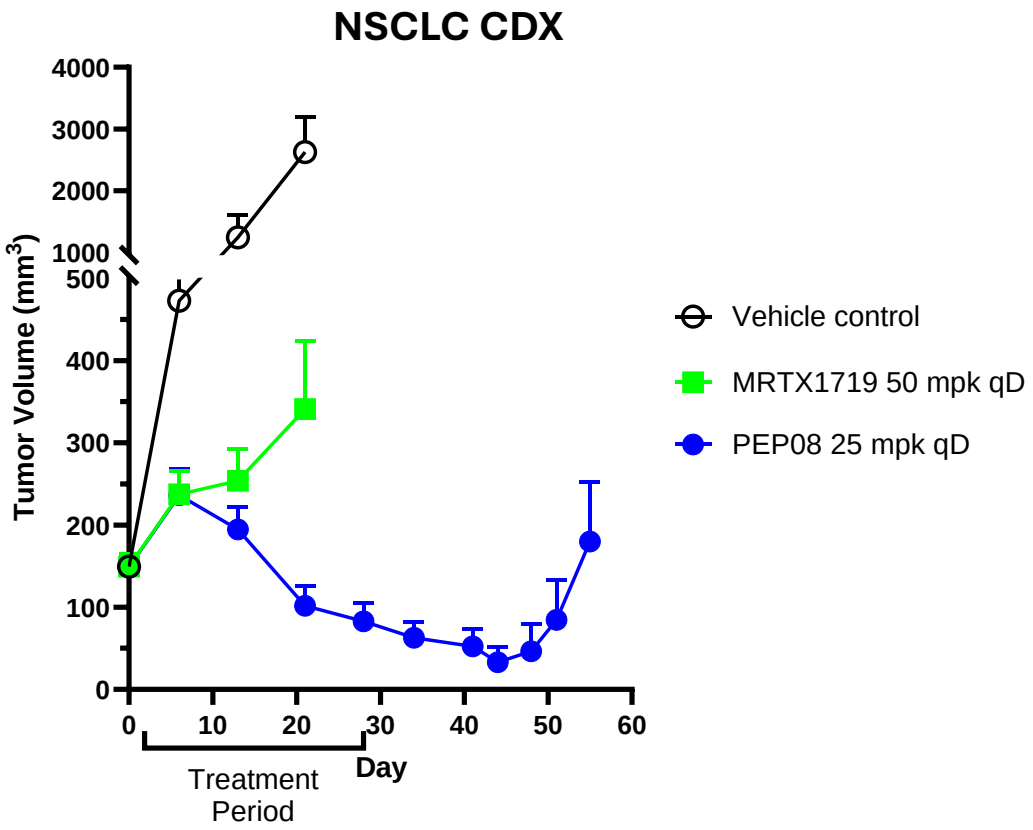
MTAP基因缺失及合成致死



MTA co-operative PRMT5 inhibitors only target to MTAP deletion cancer cells. Cancer cells with MTAP deletions are highly dependent on PRMT5 for survival, making them susceptible to synthetic lethality when PRMT5 is inhibited.

PEP08在MTAP基因缺失腫瘤動物模型中具顯著療效





PEP08為最具潛力的第二代MTA Cooperative PRMT5抑制劑

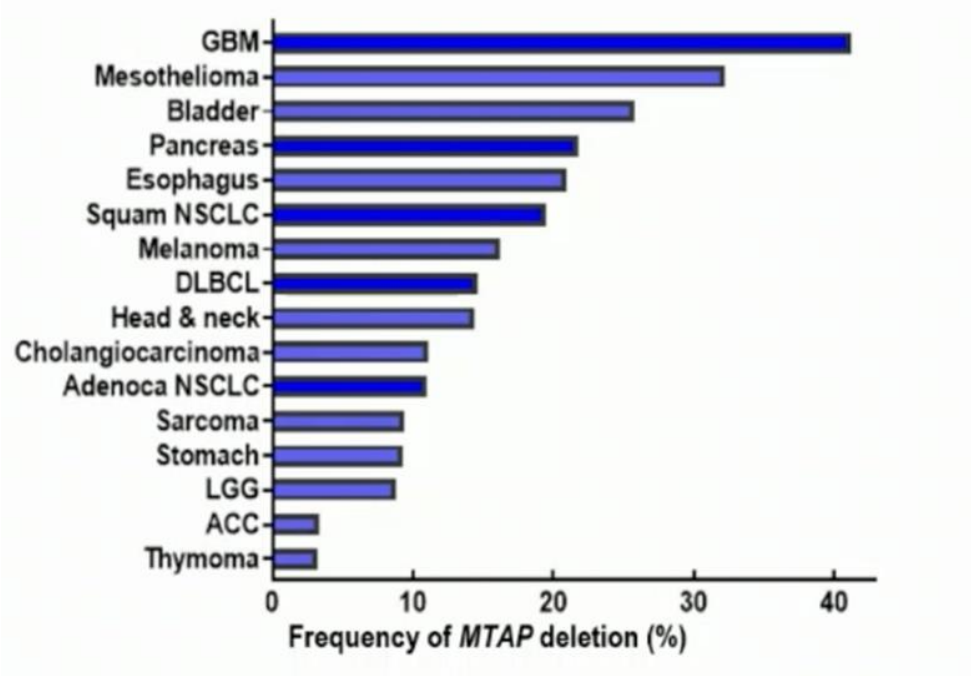
Criterion	PEP08	AMG-193	BMS-986504 (MRTX1719)	TNG462	AZ3470
Development Phase	IND-enabling	Phase 1/2	Phase 1/2	Phase 1/2	Phase 1/2
Potency*					
MTAP selectivity					
BBB-penetrating					
Indication	MTAP-deleted cancers				
	Solid tumors	NSCLC	NSCLC, PDAC Mesothelioma	NSCLC PDAC	Solid tumors r/r cHL

**Viability in vitro in MTAP del cell line model*

MTAP基因缺失在癌症發生頻率及市場潛力

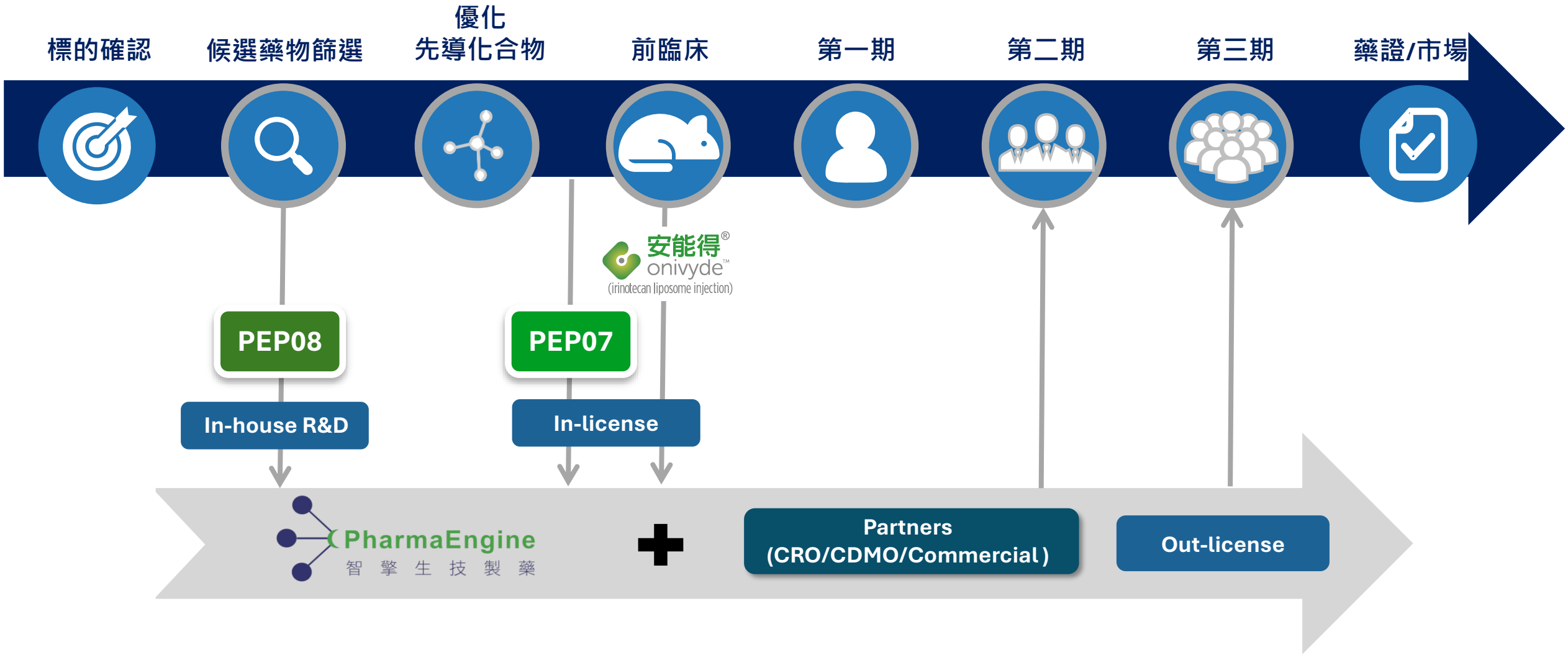
Cancer type	Incidence*	% of MTAP Deletion	Eligible Patients No.
GBM	321,476	42%	135,020
Bladder	613,791	25%	153,448
Pancreas	510,566	22%	112,325
NSCLC	2,108,000	13%	274,040
ESCC	510,716	10%	51,072
HNSCC	795,453	10%	79,545
Stomach	968,350	8%	77,468
DLBCL	193,553	15%	29,032
Total			911,950

* Globocan 2022



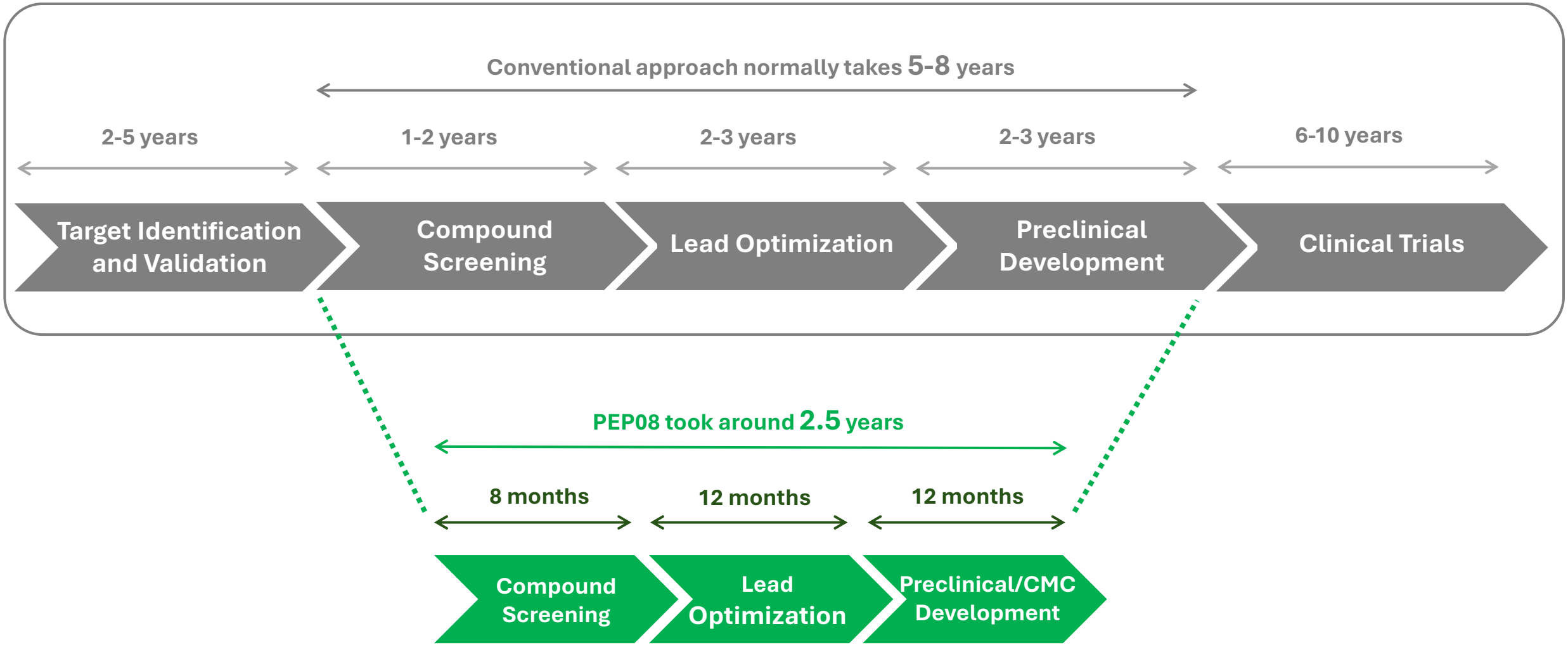
Source: 2024 ESMO poster

Virtual Pharmaceutical Company 商業模式



彈性、靈活、科學及數據導向

智擎核心價值加速藥物開發



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2025年營運展望

2025年營運展望

01 確認PEP07第一期血液及實體腫瘤臨床試驗之最大耐受劑量

02 提交PEP08 IND申請 (1H25)

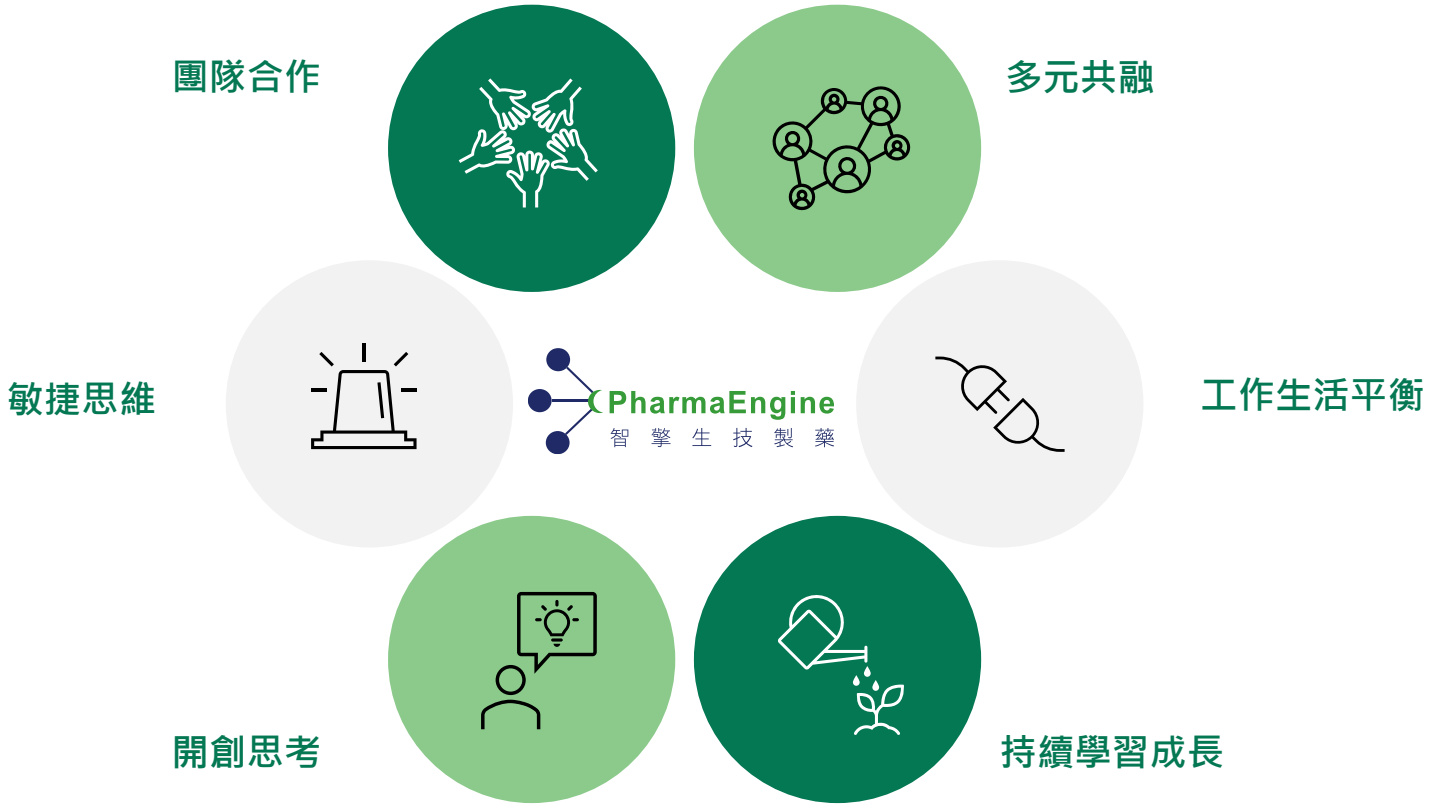
03 持續擴充及推進研發產品組合

04 取得安能得®一線胰腺癌健保藥價

05 申請LIPORAXEL® 台灣新藥許可

06 2025年開始轉換20%營運相關用電來源為綠色能源，未來每年遞增10%之綠電使用率，至2030年達到營運用電70% 來自綠電的目標

智擎核心價值



THANK YOU

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