懷特生技新藥股份有限公司

股票代號(4108)

2024年度法人說明會

公司設立: 1998年
股票上市: 2008年
資本額: NTD19.86億
負責人: 李伊俐

報告人
李伊伶總經理

懷特生技新藥(股)公司
PhytoHealth Corporation

免責聲明

1. 除了過去資料外，本次說明會所列事項若為前瞻性看法，此前瞻性看法可能受重大風險和不確定性因素影響而與實際結果有所差異。
2. 本簡報中對於未來之展望，係反應本公司截至目前為止對於未來的看法。對於這些看 法，倘若未來有因任何事件或環境變遷，本公司並不負有更新資料之責任。
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4. 本簡報內容包含所有歸屬於合併報表之個體。

公司簡介

懷特生技新藥致力透過西方科學驗證方式, 利用上千年以來華人廣為使用的植物藥材, 開發出符合西藥規格的植物藥,滿足目前不被滿足的臨床需求。

懷特生技新藥公司發展里程碑

1998 懷特生技新藥公司創立

2002 第一家新藥研發型公司通過經濟部推薦以科技股上櫃

2008 依照「生技新藥產業發展條例」以第一家新藥研發型公司上櫃轉上市

2009 ~ 2012
- 獲得衛生署TFDA成立後第一個處方新藥藥證：懷特血寶®注射劑
- 植物新藥精製廠落成啟用(通過衛福部PIC/S GMP認證)

2013 ~ 2016
- 懷特血寶®完成四期臨床試驗成果獲國際期刊發表
- 懷特痛寶®獲得新藥上市許可證
- 懷特血寶®獲得台灣健保給付
- 懷特痛寶®在台上市銷售

2017 ~ 2024

懷特新藥產品開發：２項已取得TFDA藥證

	產品功能/適應症 Product Function / Indication	臨床前試驗 Pre-Clinical	臨床一期 Phase I	臨床二期 Phase II	臨床三期 Phase III	新藥申請 NDA	獲得藥證 Approval
上市	懷特血寶® 治療癌因性疲憊症	全球唯一治療「癌因性疲憊症」(Cancer Related Fatigue)處方藥					
上市	懷特痛寶® 治療中到重度疼痛	新穎止痛 (Nalbuphine)口服劑型藥物					
研發中新藥	PHN031 (懷特骨寶®) 預防骨質疏鬆症	完成美國FDA核准Phase IIa臨床試驗					
研發中新藥	PHN033 (懷特糖寶®) 治療糖尿病腎病變	完成美國FDA核准Phase IIa 臨床試驗					
研發中新藥	懷特血寶®與抗癌藥物合併使用(Combo Therapy) 治療癌症	啟動PhaseII臨床試驗				RWE: 乳癌/大腸直腸癌	

全球植物藥市場在未來穩定成長

$49B
USD in 2024

$76B
USD by 2030

7.3%
CAGR

*Botanical and Plant-derived Drugs: Global Markets, BCC Research

植物新藥從開發到上市成功門檻高

懷特新藥成果豐碩

法規認可

懷特血寶®獲得國內TFDA 第一張新藥藥藥證
(April, 2010)

懷特工廠為首家PIC/S GMP植物精製廠
(September, 2016)

TFDA 核發10張新藥藥證中懷特取得2項
懷特血寶®PG2 : 癌因性疲憊症
懷特痛寶® :治療中到重度疼痛
(2020.3)

臨床療效驗證

24篇懷特血寶®研究文獻發表
前25% Top Leading Medical & Cancer Journals

懷特血寶®完成四期臨床試驗(N=323)
randomized, double-blind, multi-center clinical trial

20項臨床研究發表在醫學會
ASCO, MASCC, WCP, and TJCC

市場接受度

懷特血寶®獲健保給付之植物新藥
第一個獲健保給付之植物新藥
(2021.3)

懷特血寶被+70 家醫療院所採用
18 醫學中心 46 區域醫院

持續累積癌因性疲憊症臨床經驗
700+ 腫瘤專科醫師
19,000+ 病患使用經驗
12,500+ 醫護人員持續教育

建立植物藥價值鏈商化成功模式

R&D

- Unmet Need in oncology, anti-COVID-19..etc

Manufacturing

PhytoHealth's API Plant awarded with PIC/S GMP Certificate

RWE

- Data generation & Publication
- CME program

PhytoHealth

Sales & Marketing

- Market Access strategy: self –pay & reimbursement
- Focus on Hospital Channel
- Patient Group Advocacy on CRF

2023-2024 重要進展

1. 懷特血寶®(PG2)合併術前化放療於局部晚期食道癌病患延長整體存活期(Overall Survival)研究結果發表於2024 ESMO (歐洲臨床腫瘤醫學會)

懷特生技新藥(股)公司
PhytoHealth Corporation

2024 9月 ESMO 年會發表

BARCELONA 2024 ESMO congress

BARCELONA SPAIN
13-17 SEPTEMBER 2024

食道癌臨床試驗：

- **執行期間：02.19.2019-02.06.2025**
- **執行機構：馬偕, 三總, 亞東, 雙和**
- **進度: 2023.2所有病患完成試驗, 持續追蹤**
- **收案：48人　可評估：38人**

Immunomodulatory Effects and Improved Survival of PG2 plus Preoperative Chemoradiotherapy in Patients with Locally Advanced Esophageal Cancer

1435P

L.-M. Mok[1], W.-C. Huang[1], H.-C. Lin[2], Y.-J. Chen[3], M.-L. Chan[1], Y.-L. Lai[3], T.-W. Huang[4], P.-Y. Chang[5], Y.-F. Su[6], C.-Y. Liu[7], C.-H. Hsieh[8], C.-J. Teng[9], C.-Y. Wu[9], C.-S. Chung[10], L.-S. Wang[11], J.-T. Tsai[12], C.-T. Yeh[13], T.-H. Tsai[14]

[1]Division of Thoracic Surgery, Department of Surgery, Mackay Memorial Hospital, Taipei City, Taiwan, [2]Division of Hematology and Oncology, Department of Internal Medicine, Mackay Memorial Hospital, Taipei City, Taiwan, [3]Department of Radiation Oncology, Mackay Memorial Hospital, Taipei City, Taiwan, [4]Division of Thoracic Surgery, Department of Surgery, Tri-Service General Hospital, National Defense Medical Center, Taipei City, Taiwan, [5]Division of Hematology and Oncology, Department of Medicine, Tri-Service General Hospital, National Defense Medical Center, Taipei City, Taiwan, [6]Department of Radiation Oncology, Tri-Service General Hospital, National Defense Medical Center, Taipei City, Taiwan, [7]Division of Thoracic Surgery, Department of Surgery, Far Eastern Memorial Hospital, New Taipei City, Taiwan, [8]Division of Radiation Oncology, Department of Radiology, Far Eastern Memorial Hospital, New Taipei City, Taiwan, [9]Division of Hematology and Oncology, Department of Internal Medicine, Far Eastern Memorial Hospital, New Taipei City, Taiwan, [10]Division of Gastroenterology and Hepatology, Department of Internal Medicine, Far Eastern Memorial Hospital, New Taipei City, Taiwan, [11]Division of Thoracic Surgery, Department of Surgery, Taipei Medical University-Shuang Ho Hospital, New Taipei City, Taiwan, [12]Department of Radiation Oncology, Taipei Medical University-Shuang Ho Hospital, New Taipei City, Taiwan, [13]Department of Medical Research and Education, Taipei Medical University-Shuang Ho Hospital, New Taipei City, Taiwan, [14]Institute of Traditional Medicine, School of Medicine, National Yang Ming Chiao Tung University, Taipei City, Taiwan

Background

Esophageal squamous cell carcinoma (ESCC) treatment remains challenging due to its high recurrence rates and discouraging survival outcomes.

Astragalus Polysaccharides (PG2, PhytoHealth Corporation, Taiwan), as a drug therapy for cancer-related fatigue relief, has the ability to modulate macrophage polariz… and synergistically anti-cancer effect. PG2 combined with neoadjuvant chemor…

This stu… major p… effects …

Study …

Design …

Patien…

Efficac…

Immunomodulatory markers

Conclusion:

「癌因性疲憊症」藥物合併化放療

- 可透由調控癌症免疫微環境
- 達到有效提高整體存活率

Fig 1. Study Schema

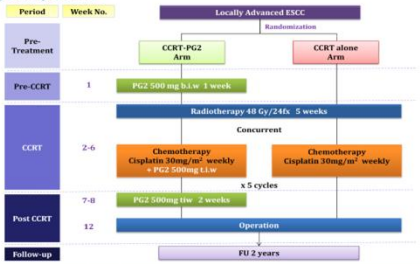


Fig 2. Subject Disposition

Unspecified	5(23.81%)	5(29.41%)	
Unknown	1(4.76%)	0(0%)	
Tumor location, n (%)			
Lower third/GE	6(28.57%)	4(23.53%)	1
Middle third	10(47.62%)	9(52.94%)	
Upper third	5(23.81%)	4(23.53%)	
Pre-CCRT clinical stage, n (%)			
IIB	5(23.81%)	2(11.76%)	0.198
IIIA	5(23.81%)	9(52.94%)	
IIIB	11(52.38%)	6(35.29%)	
ECOG, n (%)			
0	8(38.1%)	4(23.53%)	0.487
1	13(61.9%)	13(76.47%)	
BMI			
Mean(SD)	23.01(3.31)	21.82(3.75)	0.315
Median(IQR)	22.1(3.8)	21.47(6.6)	
(Min,Max)	(18.08, 31.99)	(16.17, 27.22)	
PG-SGA rating/Nutrition status , n (%)			
A, well nourished	13(61.9%)	11(64.71%)	1
B, moderately malnourished	8(38.1%)	6(35.29%)	
Radiotherapy technique, n (%)			
VMAT	14(66.67%)	7(41.18%)	0.235
IMRT	5(23.81%)	8(47.06%)	
TomoTherapy	2(9.52%)	1(5.88%)	

SD, Standard deviation; IQR, Interquartile range; GEJ, Gastroesophageal junction.

- There was no statistically significant difference in demographic and cancer characteristics between the different treatment arms.

Results

Fig 3. Overall Survival in the ITT Population

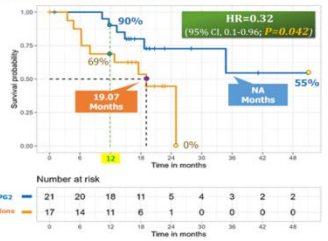
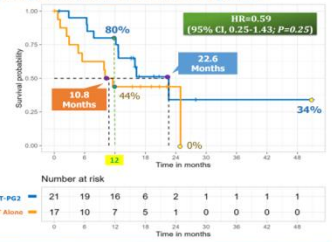


Fig 4. Progression-free Survival in the ITT Population



- CCRT combined with PG2 resulted in significantly superior overall survival (OS) compared to CCRT alone (P=0.042).

Table 2. Tumor Response in the ITT Population

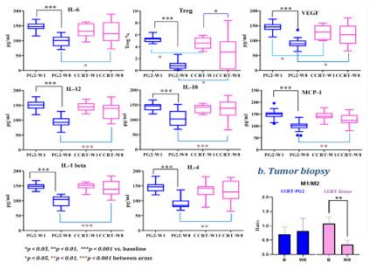
Response	CCRT-PG2	CCRT Alone	P value
Clinical response	N=20	N=16	
Overall response, n (%)			0.388
CR	4 (20.00%)	3 (18.75%)	
PR	13 (65.00%)	7 (43.75%)	
SD	2 (10.00%)	2 (12.50%)	
PD	1 (5.00%)	4 (25.00%)	
ORR, n (%)	17 (85.00%)	10 (62.50%)	0.146
DCR, n (%)	19(95.00%)	12(75.00%)	0.149
Pathological response	N=20	N=10	
MPR, n (%)	20(100.00%)	8(80.00%)	0.103

CR, complete response; PR, partial response; SD, stable disease; PD, progressive disease; ORR, objective response rate; DCR, disease control rate; MPR, major pathologic response

- The ORR of CCRT-PG2 arm was greater than that of CCRT alone arm by 20%
- Progressive disease made surgery unfeasible for 5% of cases in CCRT-PG2 arm, while 25% in CCRT alone arm.
- Primary tumor MPR rate was achieved by 100% in CCRT-PG2 arm and 80% in CCRT alone arm, respectively.

Fig 5. Immune Biomarker Results in the ITT Population

a. Blood/serum sample



b. Tumor biopsy

- CCRT-PG2 arm exhibited a significant decline in blood Regulatory T (Treg) cell proportions.
- The suppressions of the serum levels of proinflammatory cytokines, immune-suppressive cytokines, and angiogenic growth factors were observed in CCRT-PG2 arm, with a significant difference compared to the CCRT alone arm.
- PG2 reduced CCRT-induced polarization of tumor-associated macrophages (TAM) from M1 to M2.

Funding

This work was supported by PhytoHealth Corporation, Taiwan.

Conclusions

PG2 combined with preoperative CCRT in advanced esophageal cancer has shown promising improvements in OS and modulation of the immune microenvironment.

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Presented by: Lai-Man Mok MD ORCID: [0009-0005-3090-1306] (https://orcid.org/0009-0005-3090-1306)

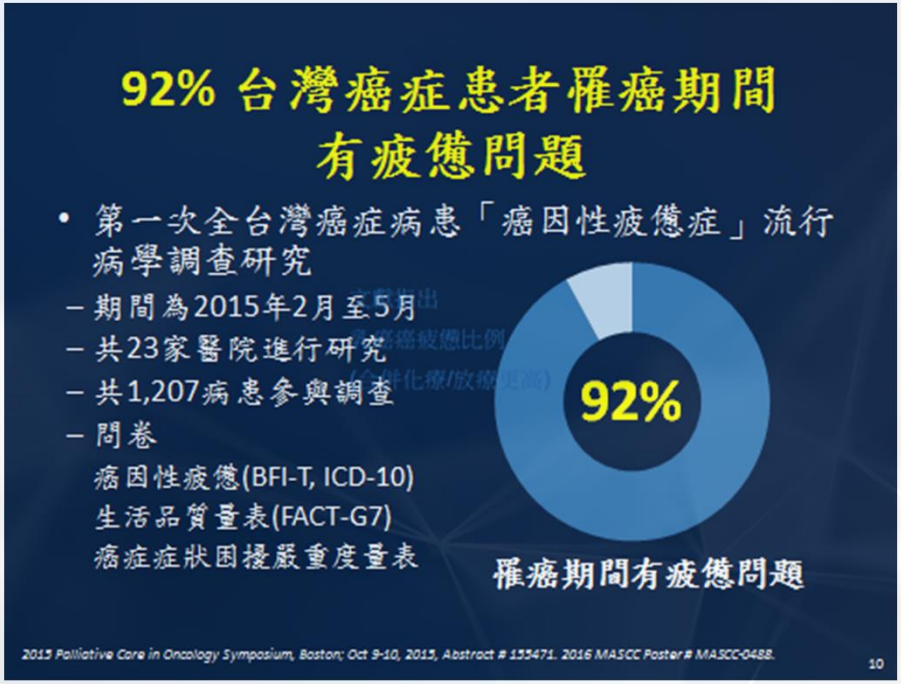
2024 懷特血寶 國內外學術發表

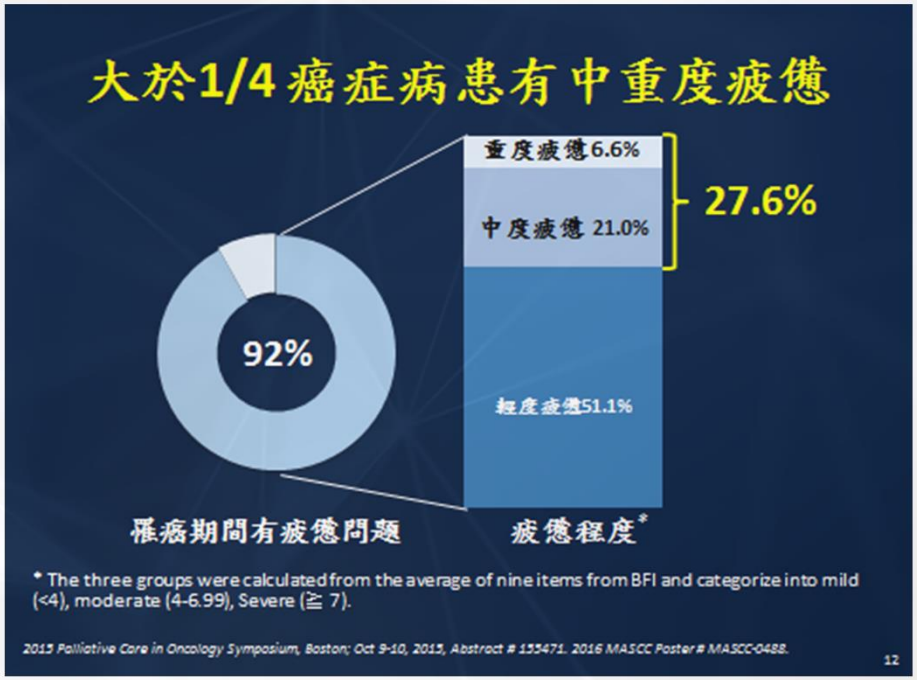
[PG2 合併化療於大腸直腸癌病患RWE]

[PG2 健保乳癌RWE臨床效益]

2. 與各界合作強化「癌因性疲憊症」醫病決策

國內調查顯示92%病患罹癌期間有癌因性疲憊症(Cancer Related Fatigue, CRF)問題





依據「癌因性疲憊診療與照護指引」*, 中到嚴重程度疲憊必須經過藥物治療

黃耆多糖注射劑有臨床實證顯示可改善中重度癌因性疲憊症

(藥物治療推薦第一順位, Level 1A, GradeA)

*註：*Management of Cancer Related Fatigue in Taiwan-An Evidence Based Consensus of screening, assessment and treatment: Japanese Journal of Clinical Oncology (JJCR 2022* Volume 53, Issue 1, January 2023*)*. 2023. 11台灣癌症安寧緩和醫學會 發表更新

與各界合作強化「癌因性疲憊症」醫病決策

3. 懷特痛寶®(Oraphine)上市銷售

懷特痛寶® Oraphine® - A Novel Oral Analgesic

For Moderate to Severe Pain Management

全球第一個 Nalbuphine 口服劑型

專利技術提升口服生體可用率

服用後 15~30 分鐘內有效，Onset 快

呼吸抑制副作用具有天花板效應

低不良反應(相較於針劑劑型)
低成癮性(相較於mu鴉片類止痛劑)

非管制藥品(美國、歐盟及台灣) 不須管制藥品處方籤

Source : Summarized by PHC team

懷特生技新藥(股)公司
PhytoHealth Corporation

懷特痛寶: 急性術後多模式止痛口服鴉片類藥物理想選擇

- 目標自費術後止痛市場：婦產科、骨科、神經外科、一般外科
- 擴大國內醫院進用：三軍總醫院、高榮榮民總醫院、振興醫院等+20 HPs 進藥採用中
- 積極投入上市後研究及國際展業

4. 以新藥研發精神跨足保健

黃耆多醣 3.0

超進化

rAPP 耆多醣®

高效品種 / 新藥技術食品化

黃耆萃取

未知品種 / 已破壁未純化

黃耆片

無效品種 / 熬煮沖泡破壁不全

Indena S.p.A : MOU簽署 前進國際保健市場

indena
SCIENCE IS OUR NATURE. SINCE 1921

100 YEARS

懷特新藥
PhytoHealth

- 雙方 MOU and MTA 2024.2簽署完成
- 雙方將就懷特新藥研發的植物精萃原料進行共同開發，Indena將協助後續歐盟查驗登記與全球

財務資訊

簡明「資產負債表」

財務結構健全
1.現金充足
2.負債比率低

單位:仟元

科　目	113.6.30	%	112.12.31	%
流動資產	1,449,068	62	1,499,456	64
非流動資產	895,190	38	851,055	36
資產總計	**2,344,258**	**100**	**2,350,511**	**100**
流動負債	48,863	2	57,378	2
非流動負債	20,044	1	22,471	1
負債合計	**68,907**	**3**	**79,849**	**3**
股本	1,986,189	85	1,986,189	84
資本公積/累計虧損等	(36,130)	(2)	(60,083)	(2)
母公司權益	1,950,059	83	1,927,106	82
非控制權益	325,292	14	343,556	15
權益合計	**2,275,351**	**97**	**2,270,662**	**97**
負債與權益總計	**2,344,258**	**100**	**2,3550,511**	**100**

簡明「綜合損益表」

1.營收成長6%
2.費用增加係投入研發專案

單位:仟元

科　目	113年 1-6月		112年 1-6月		增減率%
	(A)	%	(B)	%	(A-B)/B
營 收 淨 額	**76,713**	**100**	**72,370**	**100**	**6**
營 業 毛 利	30,161	39	29,590	41	2
營業費用	(106,438)	(139)	(81,534)	(113)	31
營 業 損 失	**(76,277)**	**(100)**	**(51,944)**	**(72)**	**47**
營業外收支淨額	12,106	16	13,563	19	(11)
稅 前 淨 損	(64,171)	(84)	(38,381)	(53)	67
本期淨損-合併	(64,171)	(84)	(38,381)	(53)	67
淨損歸屬於母公司	(43,824)	(57)	(22,490)	(31)	95
每 股 盈 餘 (元)	**(0.22)**		**(0.11)**		


Thank You !