

Energenesis
Biomedical



股票
代號 6657

證交所主題式業績發表會

2024.4.11

Energy Balance



2012 於台灣創立

28 名員工



5 博士 **15** 碩士

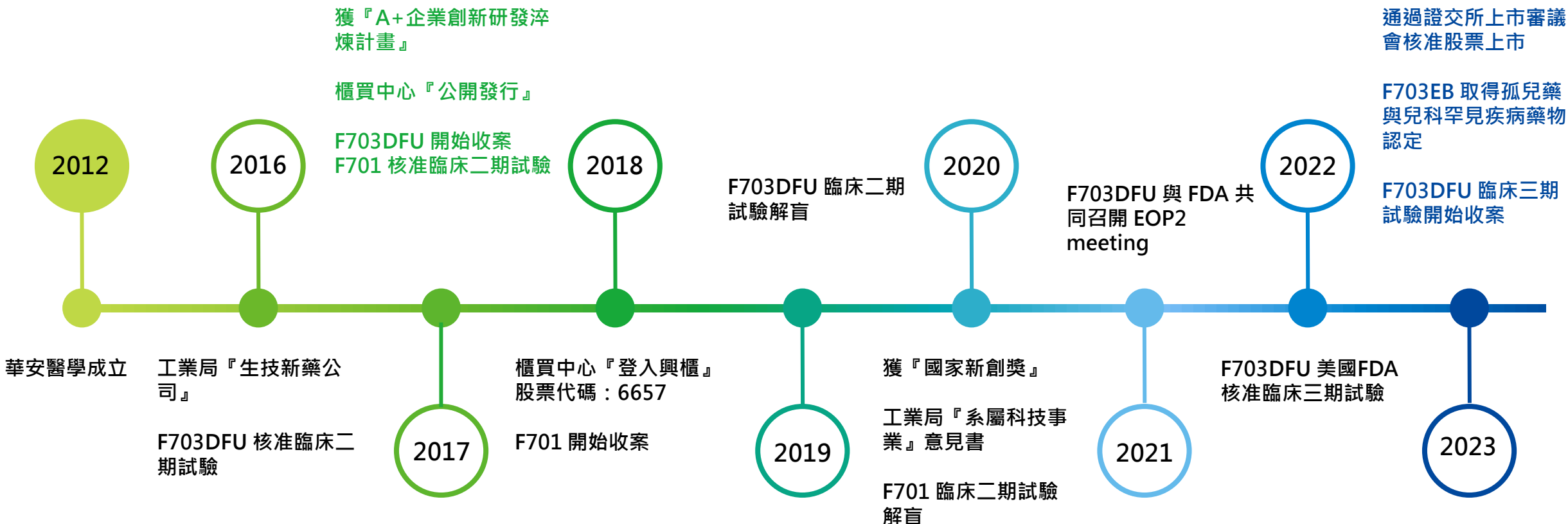


2023 於臺灣證券交易所上市交易，股票代號 6657

專注於運用獨特的 **ENERGI** 藥物平台發展新藥



華安醫學公司沿革



公司沿革

- ✓ 2012/08/28 成立
- ✓ 2017/08/18 公開發行
- ✓ 2018/08/08 登錄興櫃 (TW 6657)
- ✓ 2023/06/12 上市交易

資本額

- ✓ 額定：新台幣 10 億
- ✓ 實收：新台幣 7.6 億

主要股東名稱	持有股數 (股)	持股比例
陳翰民	5,967,295	8.28%
元大商業銀行受託保管專戶	4,747,037	6.23%
邱王乙	4,180,786	5.54%
三福環球股份有限公司	1,771,000	2.32%
洪坤南	1,684,192	2.15%
旭富製藥科技股份有限公司	1,602,895	2.10%
崇裕投資股份有限公司	1,167,500	1.53%
松鶴國際資本股份有限公司	1,000,000	1.31%
黃錦花	827,000	1.14%
林宗頤	700,000	0.92%
小 計	23,647,705	31.53%
其 他	52,576,295	68.47%
合 計	76,224,000	100.00%

(基準日：2024.3.31)

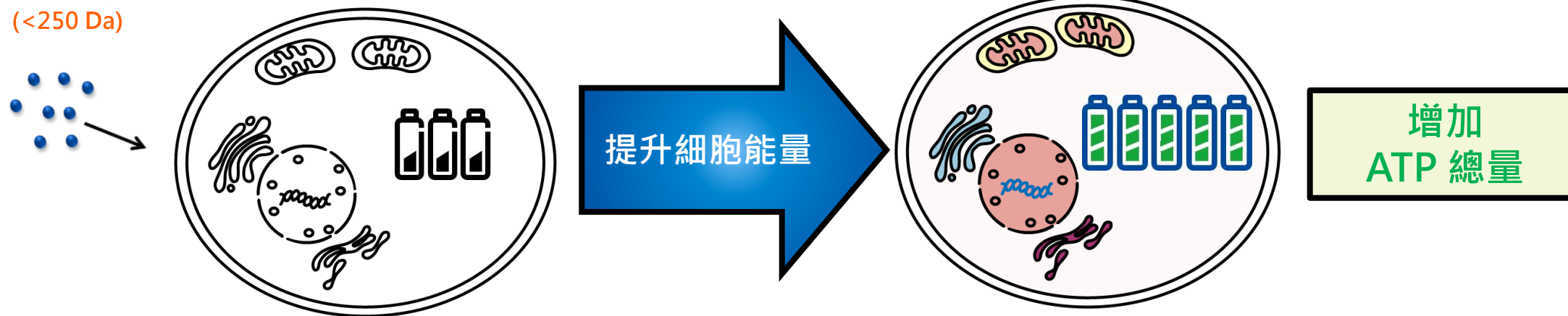
ENERGI-藥物研發平臺

提升細胞能量，治療疾病的小分子新藥

Energy Balance

- ENERGI 小分子藥物 (MW < 250 Da)
- 新穎藥物機轉 (MOA) : 提升細胞內腺嘌呤三磷酸腺苷 (ATP)

ENERGI 分子
(< 250 Da)



- ATP 是生物體內的能量分子，無安全疑慮與副作用。
- 華安佈局臺、美、歐、中國、日韓等主要市場達 30 項以上「應用專利」，專利數持續增加中。

ENERGI 核心應用

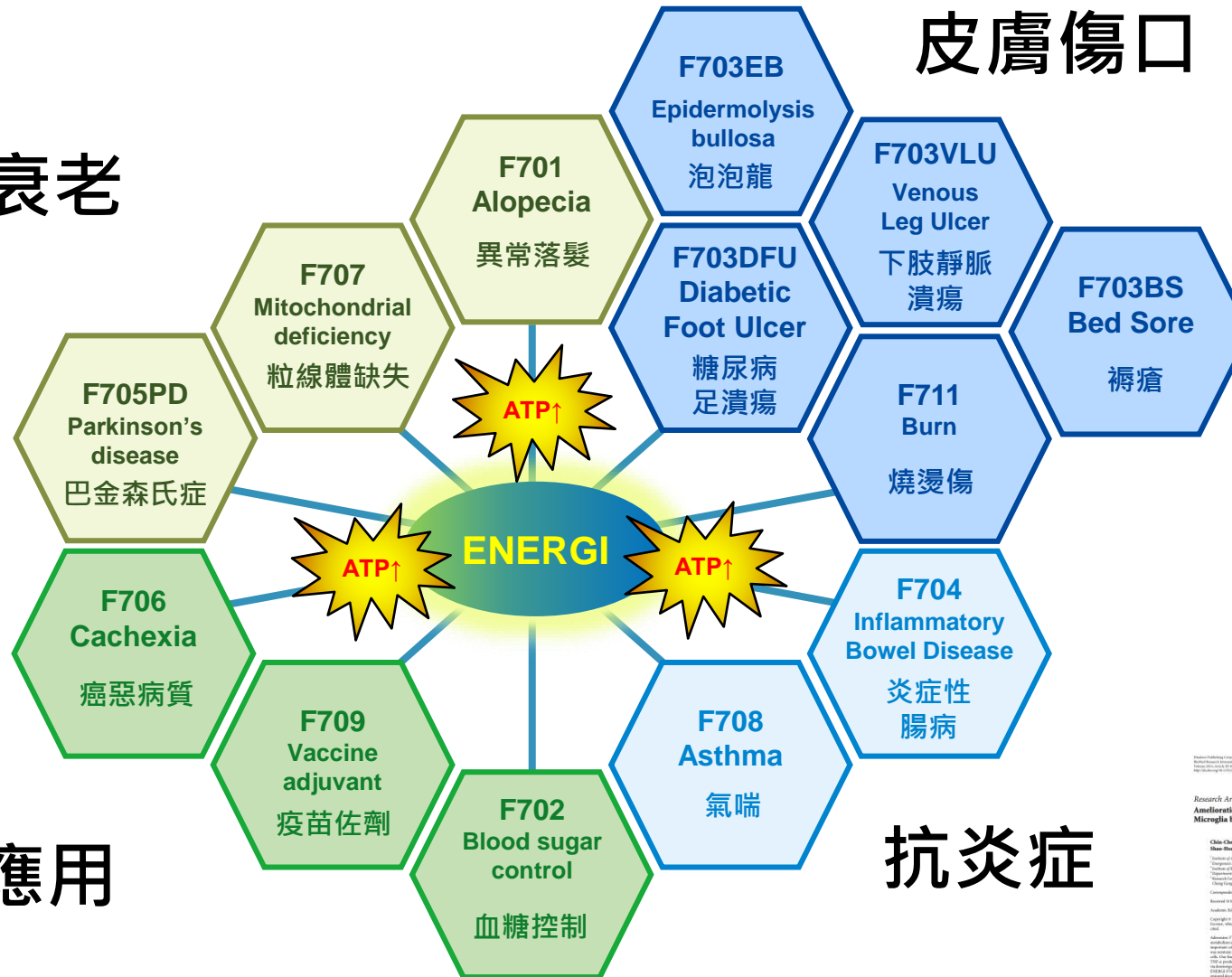
研究發表超過20篇



EXPERT OPINION
AMP-activated protein kinase activators in diabetic ulcers: from animal studies to Phase II drugs under investigation

AMP-activated protein kinase (AMPK) is a heterotrimeric enzyme composed of α , β , and γ subunits. It is a key regulator of cellular energy homeostasis, and its activation is stimulated by low energy states, such as fasting, exercise, and hypoxia. AMPK activation leads to the phosphorylation of various substrates, including acetyl-CoA carboxylase (ACC) and HMG-CoA reductase (HMGCR), which inhibits fatty acid synthesis and promotes fatty acid oxidation. AMPK also plays a role in glucose metabolism, insulin sensitivity, and mitochondrial biogenesis. In the context of diabetic ulcers, AMPK activation is thought to be beneficial for wound healing by promoting angiogenesis, reducing inflammation, and improving cellular energy levels. This review discusses the role of AMPK in diabetic ulcers and the potential of AMPK activators as a novel class of drugs for the treatment of these wounds.

抗衰老



其他應用

Adenosine supplement delays senescence in cultured human follicle dermal papilla cells

Adenosine (Ado) is a nucleoside that plays a role in various biological processes, including cell growth, differentiation, and signaling. In the context of hair follicle biology, Ado is thought to be important for maintaining the health of dermal papilla cells (DPCs), which are essential for the regeneration of hair follicles. This study investigated the effects of Ado on DPCs in culture. The results showed that Ado treatment significantly reduced the number of senescent cells and delayed the onset of senescence. Ado also increased the expression of growth-promoting factors and improved the overall health of the DPCs. These findings suggest that Ado may be a potential therapeutic agent for hair loss and skin aging.

Adenine Combined with Cisplatin Promotes Anticancer Activity against Hepatocellular Cancer Cells through AMPK-Mediated p53/21 and p38 MAPK Cascades

Adenine is a purine base that has been shown to have anticancer properties. In this study, adenine was combined with cisplatin to investigate its synergistic effects on hepatocellular carcinoma (HCC) cells. The results showed that the combination treatment significantly increased the cytotoxicity of cisplatin against HCC cells. This effect was mediated through the activation of AMPK, which in turn regulated the p53/21 and p38 MAPK signaling pathways. The activation of these pathways led to increased cell cycle arrest and apoptosis. These findings suggest that adenine may be a promising adjuvant for cisplatin-based cancer therapy.

Adenine analogue ENERGI-F706 induces apoptosis of 786-O renal carcinoma cells via S-adenosylmethionine-activated protein kinase activation

ENERGI-F706 is an adenine analogue that has been shown to induce apoptosis in 786-O renal carcinoma cells. This study investigated the mechanism of action of ENERGI-F706. The results showed that ENERGI-F706 treatment led to the activation of S-adenosylmethionine-activated protein kinase (SAM-activated protein kinase), which in turn induced apoptosis. This effect was associated with the downregulation of anti-apoptotic factors and the upregulation of pro-apoptotic factors. These findings suggest that ENERGI-F706 may be a potential therapeutic agent for renal carcinoma.

ENERGI-F703 gel, as a new topical treatment for diabetic foot and leg ulcers: A multicenter, randomized, double-blind, phase II trial

Diabetic foot and leg ulcers are a major cause of disability among patients with diabetes mellitus. ENERGI-F703 gel is a new topical treatment for these ulcers. This study was a multicenter, randomized, double-blind, phase II trial comparing ENERGI-F703 gel to a standard treatment. The results showed that ENERGI-F703 gel significantly improved wound healing and reduced the time to complete healing. These findings suggest that ENERGI-F703 gel may be a promising new treatment for diabetic ulcers.

Modulation of adenosine phosphoribosyltransferase-mediated salvage pathway to accelerate diaphoretic wound healing

Adenosine phosphoribosyltransferase (APRT) is an enzyme involved in the salvage pathway of adenosine. This study investigated the role of APRT in wound healing. The results showed that APRT inhibition significantly delayed wound healing. This effect was associated with increased inflammation and reduced angiogenesis. These findings suggest that modulation of the APRT-mediated salvage pathway may be a potential strategy to accelerate wound healing.

Diabetic foot ulcers: A challenging disease that can be treated with a novel, non-pharmacological approach

Diabetic foot ulcers (DFUs) are a major complication of diabetes mellitus. This review discusses the challenges of DFU treatment and introduces a novel, non-pharmacological approach. The approach involves the use of ENERGI-F703 gel, which has been shown to improve wound healing and reduce inflammation. This approach may offer a new, effective treatment option for DFUs.

The anti-inflammatory function of adenine occurs through AMPK activation and its downstream transcriptional regulation in THP-1 cells

Adenine has been shown to have anti-inflammatory effects. This study investigated the mechanism of adenine's anti-inflammatory function. The results showed that adenine treatment led to the activation of AMPK, which in turn regulated the transcription of inflammatory factors. This effect was associated with reduced inflammation and improved cell function. These findings suggest that adenine may be a potential anti-inflammatory agent.

Amelioration of LPS-induced Inflammation Resolves by AMPK Activation

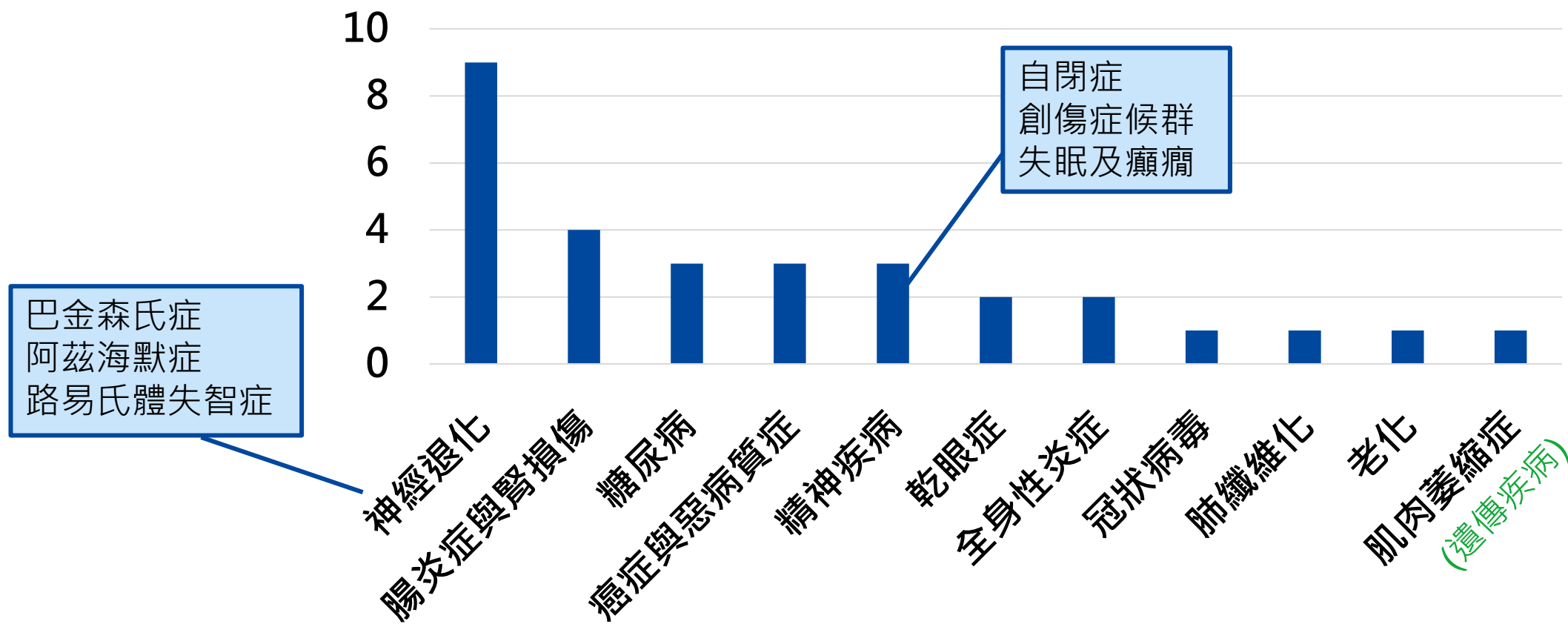
Lipopolysaccharide (LPS) is a potent inducer of inflammation. This study investigated the role of AMPK in resolving LPS-induced inflammation. The results showed that AMPK activation significantly reduced the inflammatory response. This effect was associated with the downregulation of pro-inflammatory factors and the upregulation of anti-inflammatory factors. These findings suggest that AMPK activation may be a potential strategy to resolve inflammation.

Introduction

The purpose of this review is to discuss the role of AMPK in various biological processes and its potential as a therapeutic target. AMPK is a key regulator of cellular energy homeostasis and plays a role in metabolism, signaling, and disease. This review highlights the importance of AMPK in health and disease and discusses the potential of AMPK activators as a novel class of drugs.

擴大學術合作加速新藥開發

- 3 年執行 **30 件** 學術合作案，加速評估 ENERGI 治療潛力。



擴大學術合作加速新藥開發










主題	件數	合作單位
神經退化疾病 (巴金森氏症、阿茲海默症、路易氏體失智症)	9	中山醫學大學、宜蘭大學、長庚大學、國防醫學院、陽明大學、臺北醫學大學、輔仁大學
精神相關疾病 (自閉症、創傷症候群、失眠及癲癇)	3	陽明大學、臺灣大學
糖尿病	3	中山醫學大學、國家衛生研究、臺北醫學大學
癌症與惡病質症	3	中國醫藥大學、輔仁大學
乾眼症	2	中山醫學大學、臺北醫學大學
細胞激素釋放症	2	輔仁大學、國家動物中心
發炎性腸道疾病	2	中山醫學大學、國家動物中心
腎損傷	2	臺大醫院
肌肉萎縮症 (罕病)	1	耕莘醫院
冠狀病毒	1	中興大學
肺纖維化	1	中興大學
老化	1	陽明大學

3 年 30 件 學術合作案

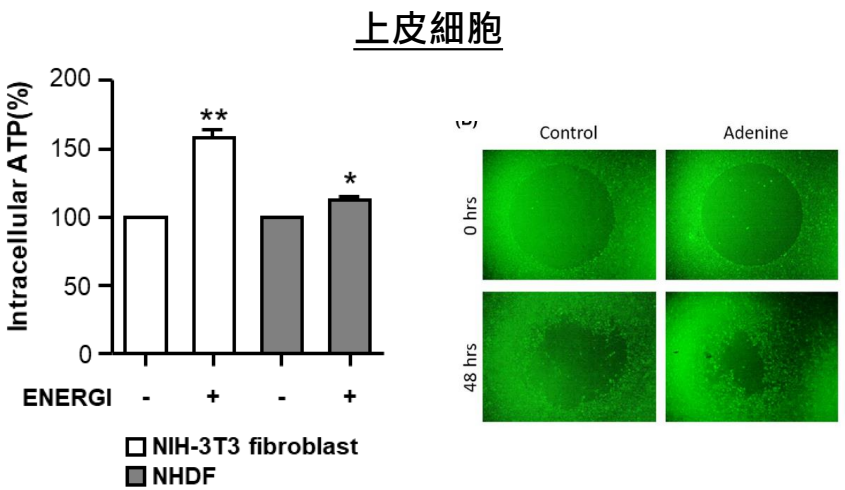
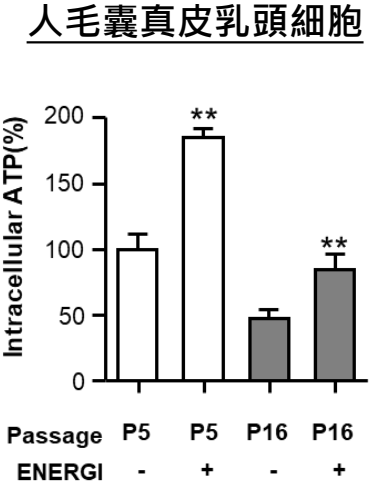
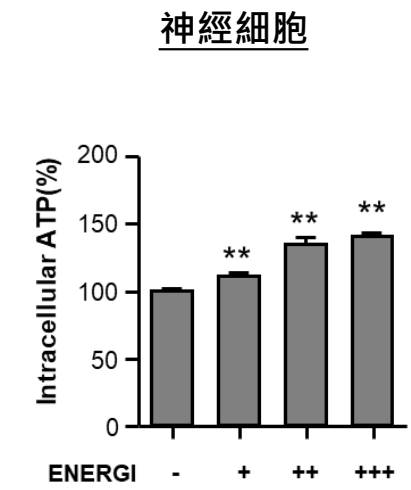
加速評估 ENERGI 治療潛力

No.	Journal Abbreviation	Year & Volume Issue	Title	Link
1	EClinicalMedicine	2022 Jul 10;51:101497.	ENERGI-F703 gel, as a new topical treatment for diabetic foot and leg ulcers: A multicenter, randomized, double-blind, phase II trial.	https://pubmed.ncbi.nlm.nih.gov/35844773/
2	Pharmaceuticals (Basel)	2022 Jun 26;15(7):795.	Adenine Combined with Cisplatin Promotes Anticancer Activity against Hepatocellular Cancer Cells through AMPK-Mediated p53/p21 and p38 MAPK Cascades.	https://pubmed.ncbi.nlm.nih.gov/35890094/
3	FASEB J	2021 Mar;35(3):e21296.	Modulation of adenine phosphoribosyltransferase-mediated salvage pathway to accelerate diabetic wound healing.	https://pubmed.ncbi.nlm.nih.gov/33675115/
4	Life (Basel)	2021 Dec 16;11(12):1408.	The Cell Protective Effect of Adenine on Hypoxia-Reoxygenation Injury through PPAR Delta Activation.	https://pubmed.ncbi.nlm.nih.gov/34947939/
5	Pharmaceuticals (Basel)	2021 Aug 27;14(9):860.	Adenine Inhibits the Invasive Potential of DLD-1 Human Colorectal Cancer Cell via the AMPK/FAK Axis.	https://pubmed.ncbi.nlm.nih.gov/34577560/
6	Int J Med Sci	2020 Feb 24;17(5):678-684.	Adenine inhibits growth of hepatocellular carcinoma cells via AMPK-mediated S phase arrest and apoptotic cascade.	https://pubmed.ncbi.nlm.nih.gov/32210718/
7	Biosci Biotechnol Biochem	2019 Dec;83(12):2220-2229.	The anti-inflammatory function of adenine occurs through AMPK activation and its downstream transcriptional regulation in THP-1 cells.	https://pubmed.ncbi.nlm.nih.gov/31392929/
8	Eur J Pharmacol	2018 Jan 5;818:569-577.	Adenine accelerated the diabetic wound healing by PPAR delta and angiogenic regulation.	https://pubmed.ncbi.nlm.nih.gov/29162431/
9	Oncol Lett	2017 Nov;14(5):5575-5580.	Adenine causes cell cycle arrest and autophagy of chronic myelogenous leukemia K562 cells via AMP-activated protein kinase signaling.	https://pubmed.ncbi.nlm.nih.gov/29113185/
10	Exp Dermatol	2016 Feb;25(2):162-4.	Adenine supplement delays senescence in cultured human follicle dermal papilla cells	https://pubmed.ncbi.nlm.nih.gov/26477890/
11	J Proteomics	2015 Apr 29;120:204-14.	Identification of adenine modulating AMPK activation in NIH/3T3 cells by proteomic approach.	https://pubmed.ncbi.nlm.nih.gov/25797921/
12	PLoS One	2015 Nov 6;10(11):e0142283.	Activation of AMP-Activated Protein Kinase by Adenine Alleviates TNF-Alpha-Induced Inflammation in Human Umbilical Vein Endothelial Cells.	https://pubmed.ncbi.nlm.nih.gov/26544976/
13	Mol Med Rep	2015 Sep;12(3):4566-4571.	Purine analogue ENERGI-F706 induces apoptosis of 786-O renal carcinoma cells via 5'-adenosine monophosphate-activated protein kinase activation.	https://pubmed.ncbi.nlm.nih.gov/26062651/
14	DNA Cell Biol	2015 Feb;34(2):133-41.	AMPK activation inhibits expression of proinflammatory mediators through downregulation of PI3K/p38 MAPK and NF-κB signaling in murine macrophages.	https://pubmed.ncbi.nlm.nih.gov/25536376/
15	Biomed Res Int	2014;2014:692061.	Amelioration of LPS-induced inflammation response in microglia by AMPK activation.	https://pubmed.ncbi.nlm.nih.gov/25025067/
16	Expert Opin Investig Drugs	2014 Sep;23(9):1253-65.	AMP-activated protein kinase activators in diabetic ulcers: from animal studies to Phase II drugs under investigation.	https://pubmed.ncbi.nlm.nih.gov/24857754/

文獻眾多未能全數列出

CODE	INDICATIONS	Discovery	Lead opt.	Pre-clinical	Ph I	Ph II	Ph III	NDA	Market	
DERMATOLOGY & WOUND HEALING										
F703DFU	糖尿病足潰瘍						臨床三期 美國/台灣			
F701	異常性落髮						臨床三期 準備中			
F703VLU	下肢靜脈潰瘍						臨床二期 進行中			
F703EB	遺傳性表皮分解性水皰症 (泡泡龍)						取得美國FDA與歐盟EMA孤兒藥認定			
F711	燒燙傷									
NEURODEGENERATION										
F705PD	巴金森氏症						臨床一期 準備中			
METABOLIC SYNDROMES										
F702	血糖控制									
INFLAMMATION RELATED										
F704	發炎性腸道疾病									
OTHERS										
F706	癌惡病質									

三大主要臨床試驗以提高 **ATP** 為手段

傷口癒合		異常性落髮	巴金森氏症																																				
ENERGI-F703DFU 糖尿病足潰瘍凝膠	ENERGI-F703EB 泡泡龍乳膏	ENERGI-F701 防落髮外用劑	ENERGI-F705PD 巴金森氏症口服藥																																				
<p>加速細胞爬行</p> <p>上皮細胞</p>  <table border="1"> <caption>Intracellular ATP (%) - Epithelial Cells</caption> <thead> <tr> <th>Cell Type</th> <th>ENERGI</th> <th>Intracellular ATP (%)</th> </tr> </thead> <tbody> <tr> <td rowspan="2">NIH-3T3 fibroblast</td> <td>-</td> <td>100</td> </tr> <tr> <td>+</td> <td>~160**</td> </tr> <tr> <td rowspan="2">NHDF</td> <td>-</td> <td>100</td> </tr> <tr> <td>+</td> <td>~115*</td> </tr> </tbody> </table>		Cell Type	ENERGI	Intracellular ATP (%)	NIH-3T3 fibroblast	-	100	+	~160**	NHDF	-	100	+	~115*	<p>抗細胞衰老</p> <p>人毛囊真皮乳頭細胞</p>  <table border="1"> <caption>Intracellular ATP (%) - Human Hair Follicle Dermal Papilla Cells</caption> <thead> <tr> <th>Passage</th> <th>ENERGI</th> <th>Intracellular ATP (%)</th> </tr> </thead> <tbody> <tr> <td rowspan="2">P5</td> <td>-</td> <td>100</td> </tr> <tr> <td>+</td> <td>~185**</td> </tr> <tr> <td rowspan="2">P16</td> <td>-</td> <td>~50</td> </tr> <tr> <td>+</td> <td>~85**</td> </tr> </tbody> </table>	Passage	ENERGI	Intracellular ATP (%)	P5	-	100	+	~185**	P16	-	~50	+	~85**	<p>抗蛋白質聚集</p> <p>神經細胞</p>  <table border="1"> <caption>Intracellular ATP (%) - Nerve Cells</caption> <thead> <tr> <th>ENERGI</th> <th>Intracellular ATP (%)</th> </tr> </thead> <tbody> <tr> <td>-</td> <td>100</td> </tr> <tr> <td>+</td> <td>~115**</td> </tr> <tr> <td>++</td> <td>~140**</td> </tr> <tr> <td>+++</td> <td>~145**</td> </tr> </tbody> </table>	ENERGI	Intracellular ATP (%)	-	100	+	~115**	++	~140**	+++	~145**
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ENERGI-F703DFU

- 糖尿病足潰瘍外用凝膠

- 有效促進傷口癒合
- 針對未被滿足的慢性傷口醫療需求
- 美國與臺灣臨床三期試驗進行中

EOP2

Pre-IND

Ph III IND

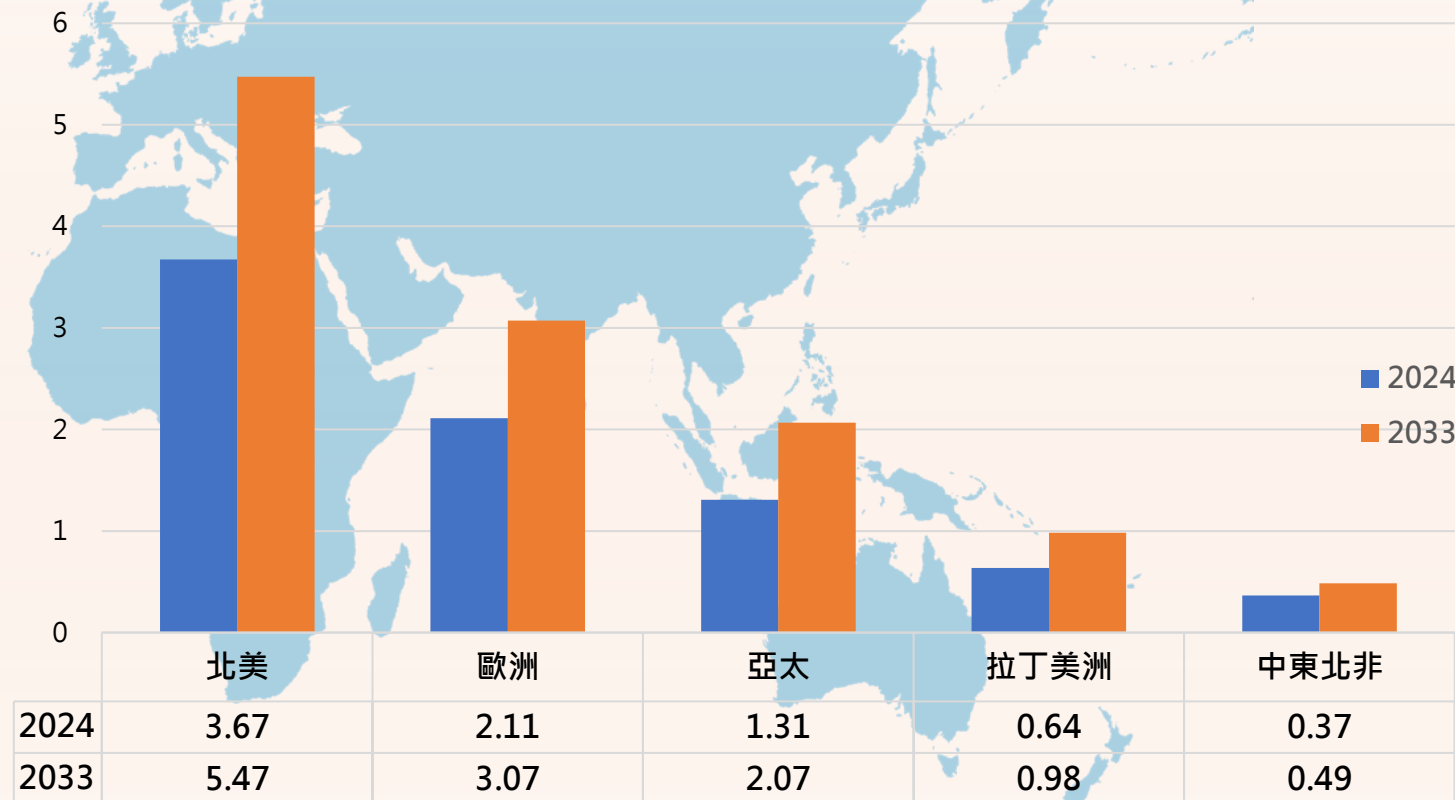
Ph III US/TW

困難傷口全球市場 (2024~2033)

- 2024 年為 81 億美元
- 2033 年為 121 億美元

困難傷口全球市場規模

市場規模 (十億美元)



- FDA 僅核可 Regranex® 作為糖尿病足潰瘍外用藥。
- Regranex® 是蛋白質藥物，價格高昂，大傷口效果有限。

全球市場

5.4 億

全球糖尿病患者 (2021)

IDF Diabetes Atlas, 10th ed.

34%

糖尿病患者可能發生足潰瘍

2.9%

糖尿病足潰瘍需要截肢

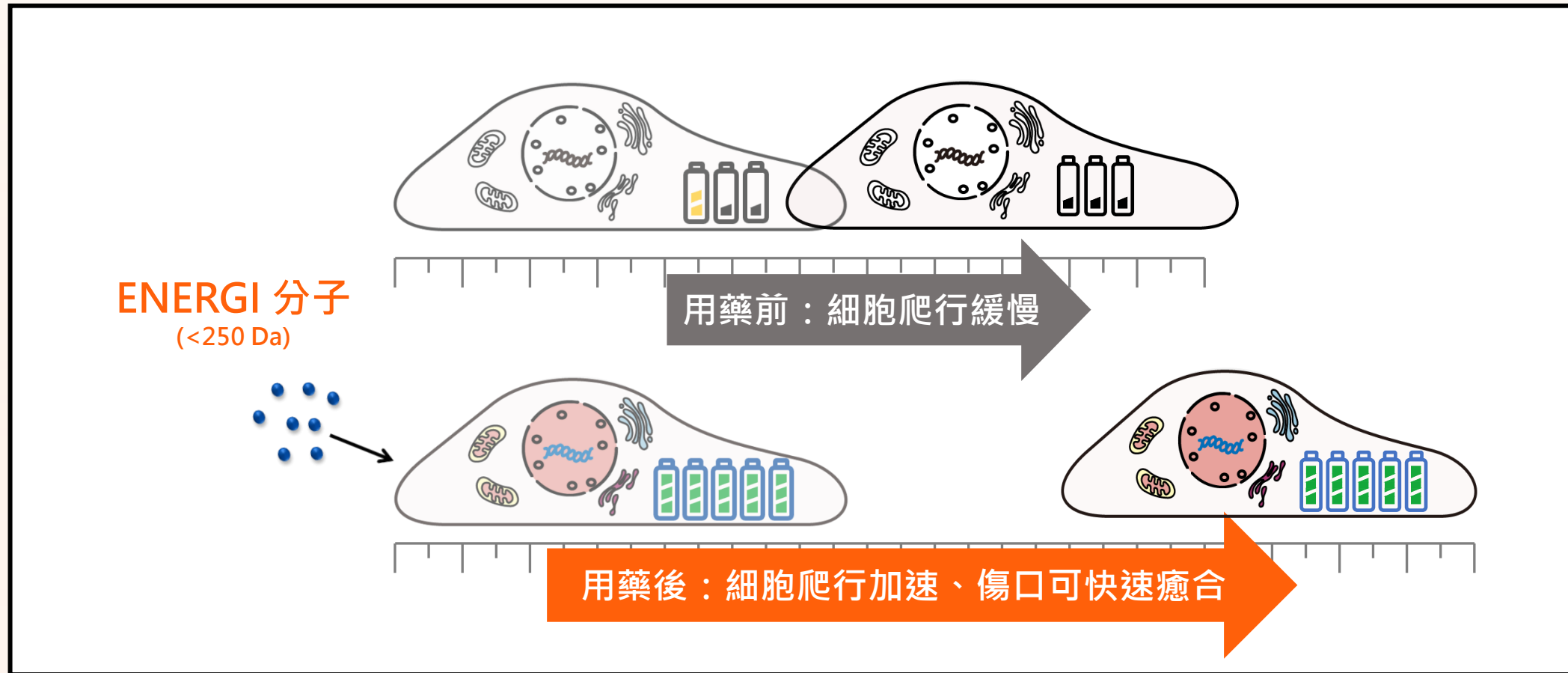
FDA 核准的藥物

Regranex®
(Smith & Nephews)



- 重組人類血小板衍生生長因子
- 只建議 5 cm² 以下傷口
- 價格昂貴 (US\$ 1,400 /15g · 3~4 條/療程)
- 市佔率 < 1%

- 創新藥物機制：藉由增加細胞能ATP 加速細胞爬行

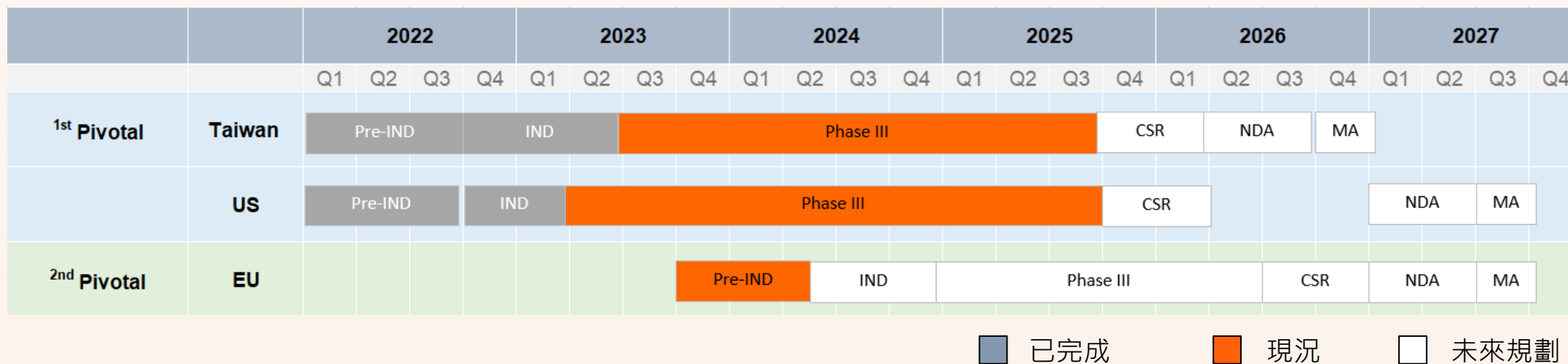


F703DFU 凝膠為糖尿病足潰瘍潛力新藥

	ENERGI-F703DFU 凝膠	Regranex® 凝膠	ON101 乳膏 (速必一®)
藥物分類	小分子藥物	生物製劑 (大分子藥物)	植物藥
活性成分	ENERGI	重組人類血小板衍生 生長因子	左手香與積雪草 萃取物
用藥途徑	皮膚外用	皮膚外用	皮膚外用
開發階段	美國與台灣臨床三期 執行中	FDA 核准上市	TFDA 核准上市
價格	預計 250~300 USD/25 g	1,400 USD/15g	9,800 NTD/15g

ENERGI-F703DFU 開發時程

- 現況：美國與臺灣臨床三期試驗收案中
- 試驗完成：預計為 2025



● 預期取證時程：

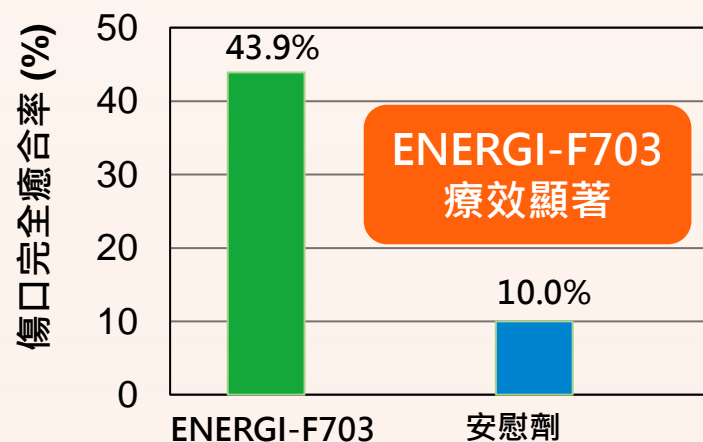
- ✓ 臺灣: 2026
- ✓ 歐洲: 2027
- ✓ 美國: 2026~2027

F703DFU 臨床二期結果具顯著療效

- 主要評估指標：用藥第12周傷口完全癒合的病人比率

PP 分析

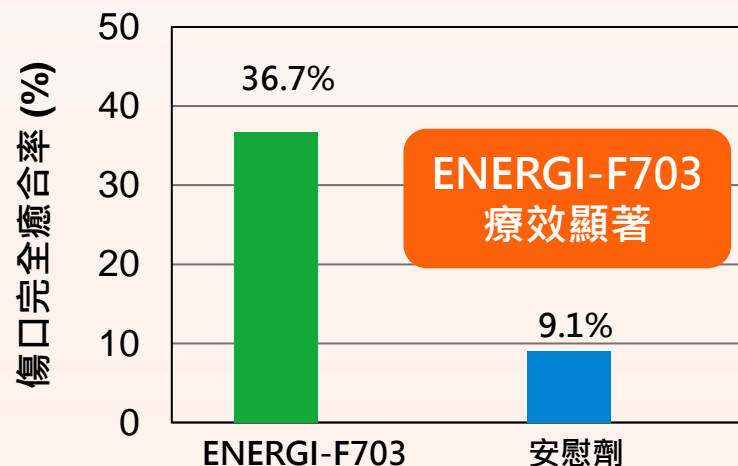
P < 0.05 (0.008)



	ENERGI-F703	安慰劑	合計
完全癒合	18	2	20
未癒合	23	18	41
人數	41	20	61
百分比	43.9%	10.0%	32.8%

ITT 分析

P < 0.05 (0.017)



	ENERGI-F703	安慰劑	合計
完全癒合	19	2	21
未癒合	33	20	53
人數	52	22	74
百分比	36.7%	9.1%	28.4%

- F703DFU 凝膠於收案傷口1.5 ~25 平方公分 (Wagner 傷口分級 1 和 2 級) 具有顯著療效

- 2022 年發表於國際知名科學期刊 *eClinicalMedicine*。
- F703DFU 顯著加速糖尿病足傷口癒合，且沒有副作用被觀察到。



The screenshot shows the top of a webpage for eClinicalMedicine. The header includes the logo 'eClinicalMedicine' and the text 'Part of THE LANCET Discovery Science'. On the right, there are links for 'Log in', a search icon, and a menu icon. Below the header, a blue banner contains the article title: 'ENERGI-F703 gel, as a new topical treatment for diabetic foot and leg ulcers: A multicenter, randomized, double-blind, phase II trial'. Below the title, the authors are listed: 'Jui-Yung Yang¹ • Cha-Chun Chen¹ • Shun-Cheng Chang¹ • Jiun-Ting Yeh¹ • Hui-Fu Huang¹ • Hwang-Chi Lin • et al.'. There are links for 'Show all authors' and 'Show footnotes'. Below that, it says 'Open Access • Published: July 09, 2022 • DOI: <https://doi.org/10.1016/j.eclinm.2022.101497>'. At the bottom of the banner, the article title is repeated: 'ENERGI-F703 gel, as a new topical treatment for diabetic foot and leg ulcers: A multicenter, randomized, double-blind, phase II trial'. In the background of the banner, there is a diagram of a clinical trial flowchart with boxes for 'Screening (N=173)', 'Randomization', and 'Safety population (N=173)'. The 'Screening' box lists criteria: 'Unmet eligibility', 'Ulcer size decrease', 'Ulcer size < 1 cm²', 'ABI < 0.8', 'infection', 'Poor nutrition status', 'Needs pre-treatment', and 'Willing to advance to final treatment'.

eClinicalMedicine. 2022 Jul 10;51:101497.

ENERGI-F703DFU 臨床二期實例

案例 1 Grade 2 (2.0 cm²) 3 週療程傷口完全癒合



- 同一患者的相鄰傷口

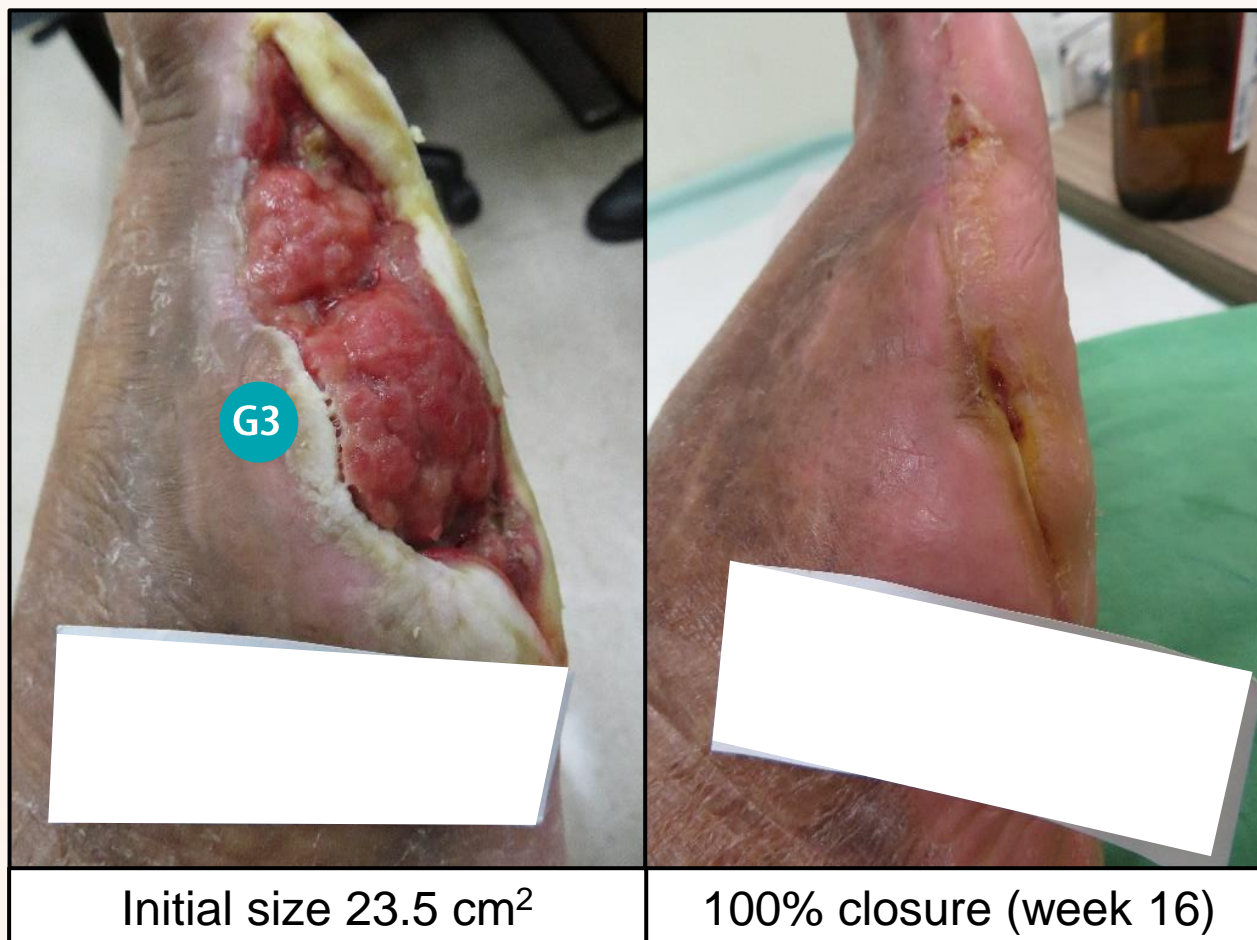
案例 2 Grade 3 (4.1 cm²) 9 週療程傷口完全癒合



- 截肢史患者的復發傷口

ENERGI-F703DFU 治療大傷口

案例 3 **Grade 3** (23.5 cm²) : 12 + 4 週療程傷口完全癒合



- 大型傷口
- 16 週完全癒合

ENERGI-F701

- 異常性落髮外用劑

- 創新應用機制 – 抗細胞老化
- 快速防止落髮
- 適用雄性禿與女性異常性落髮

Preclinical

Phase II completion

現行治療方式

- 落建 (minoxidil)



- 促進生髮
- X 防止落髮

- 使用初期會顯著落髮，且須終生使用

- 柔沛 (finasteride)



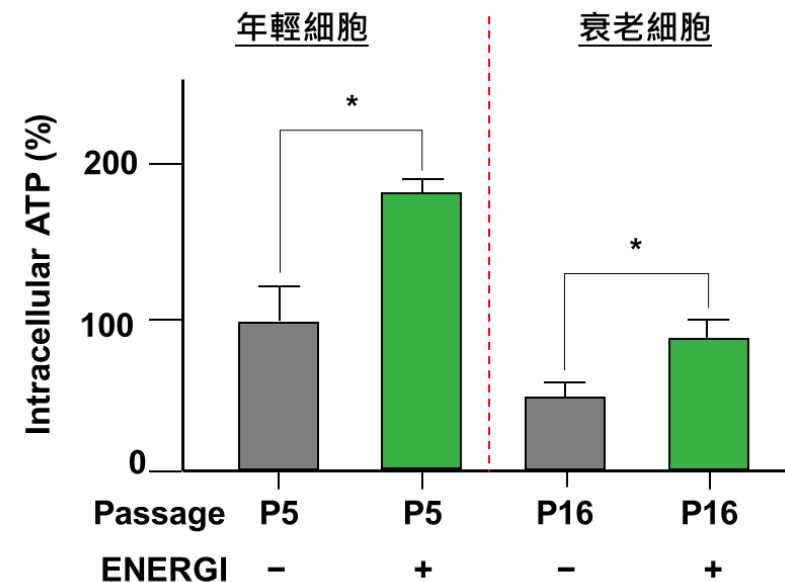
- X 促進生髮
- 防止落髮

- 影響性功能
- 僅用於雄性禿

專利期已過，現為學名藥

新藥：ENERGI-F701

- 毛囊細胞衰老是造成落髮的原因之一
- ENERGI 提高細胞 ATP，恢復生髮週期

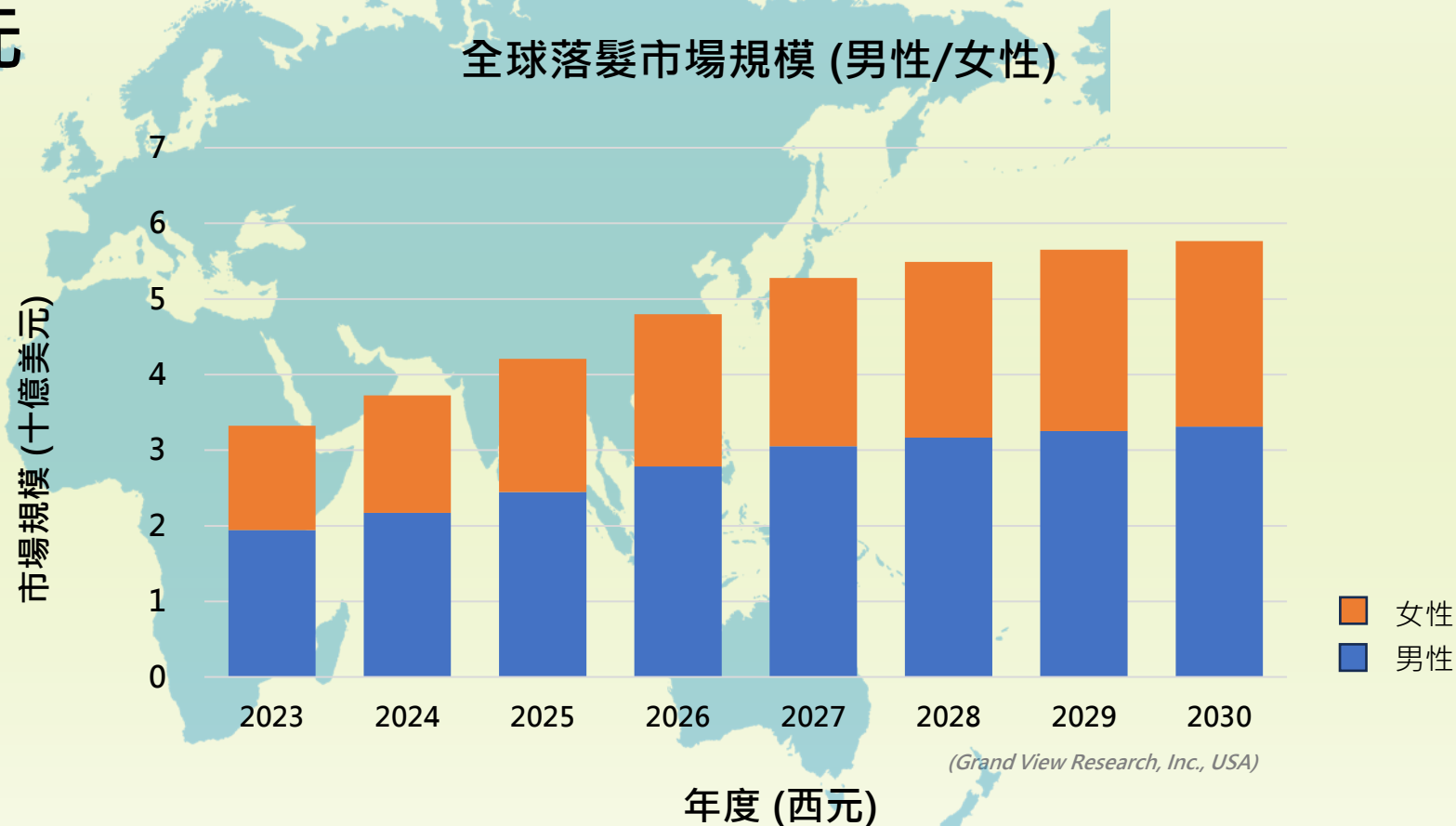


男女皆可使用 ENERGI-F701

落髮用藥全球市場 (2023~2030)

- 2023 年為 33 億美元
- 2030 年為 58 億美元

- 市場缺乏新藥！



- ENERGI-F701: 用藥 2 個月改善率達 75 %
- 安慰劑: 試驗後 80% 為相同或較差

✓ 結果顯示 F701 改善 AGA 落髮

ENERGI-F701 男性試驗案例

	ENERGI-F701		安慰劑		合計
顯著改善	6	37.5%	0	-	6
改善	6	37.5%	3	20.0%	9
相同	4	25.0%	11	73.3%	15
較差	0	-	1	6.7%	1
人數	15	-	16	-	31

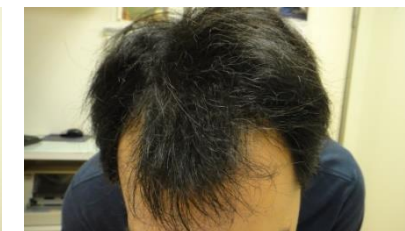
- 受試者：31 名 20~60 歲男性 AGA 患者
- 以上為醫師評估之結果

ENERGI-F701 男性試驗案例

用藥前

用藥2個月

AGA III



AGA III

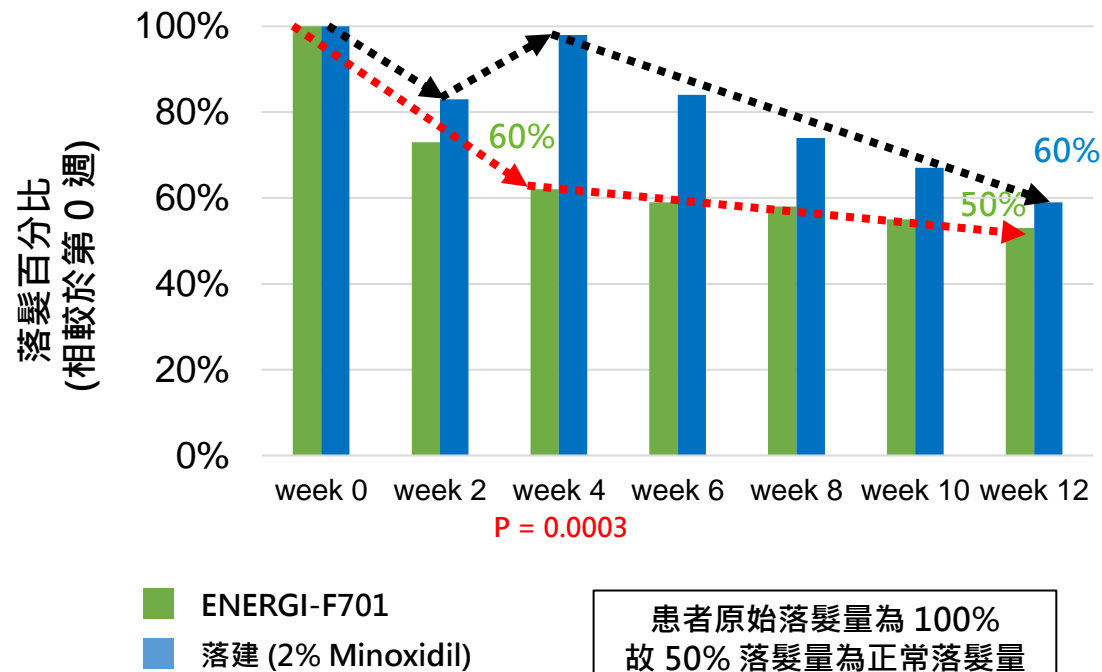


女性二期試驗：防止落髮 (NCT03351322)

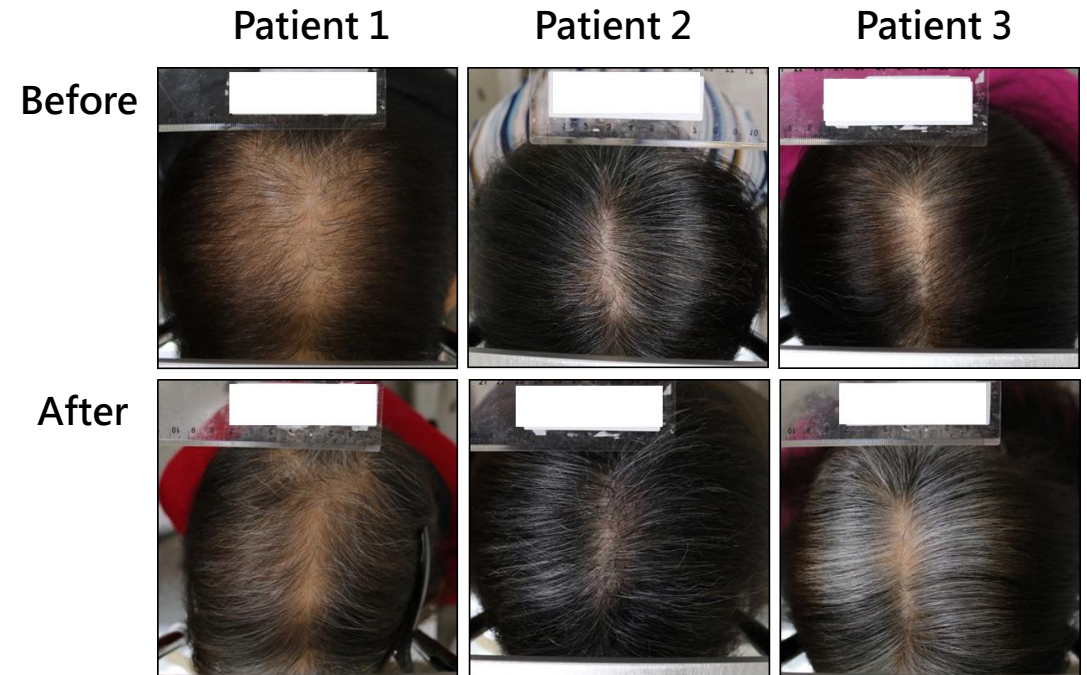
- ENERGI-F701: 用藥 4 周 落髮量降至 60%
- 落建: 用藥 12 周降至 60%

✓ 結果顯示F701 快速防止落髮

治療後落髮百分比



ENERGI-F701 試驗案例



ENERGI-F703EB

- 遺傳性表皮分解性水皰症(泡泡龍) 乳膏

- 加速泡泡龍患者傷口癒合
- 已取得美國 FDA 孤兒藥 (ODD) 及罕見兒科疾病 (RPD) 認定
- 歐盟 EMA 孤兒藥認定
- 臨床二期試驗準備中

Discovery

Phase II Preparing

遺傳性表皮分解性水皰症 (泡泡龍)

- 泡泡龍是罕見且嚴重的遺傳疾病，患者因皮膚結構蛋白的基因突變，導致皮膚和黏膜極度脆弱，輕微的摩擦或壓力就能造成破皮或水泡。

Outer Skin Breakdown Blister

Epidermolysis Bullosa

RARE	GENETIC	ANYONE	NOT CONTAGIOUS	NO CURE
				
One in seventeen thousand live births affected.	Hereditary, but parents may not know they are carriers.	Equally affects Both Genders and Every Ethnic Group.	Being genetic, there is no risk of 'catching' EB.	yet ! But Research is hopeful. Current treatment is based on Wound Care and Pain Management.

Source: Debra Ireland

F703EB 乳膏可用於所有類型的 EB 患者



現行療法

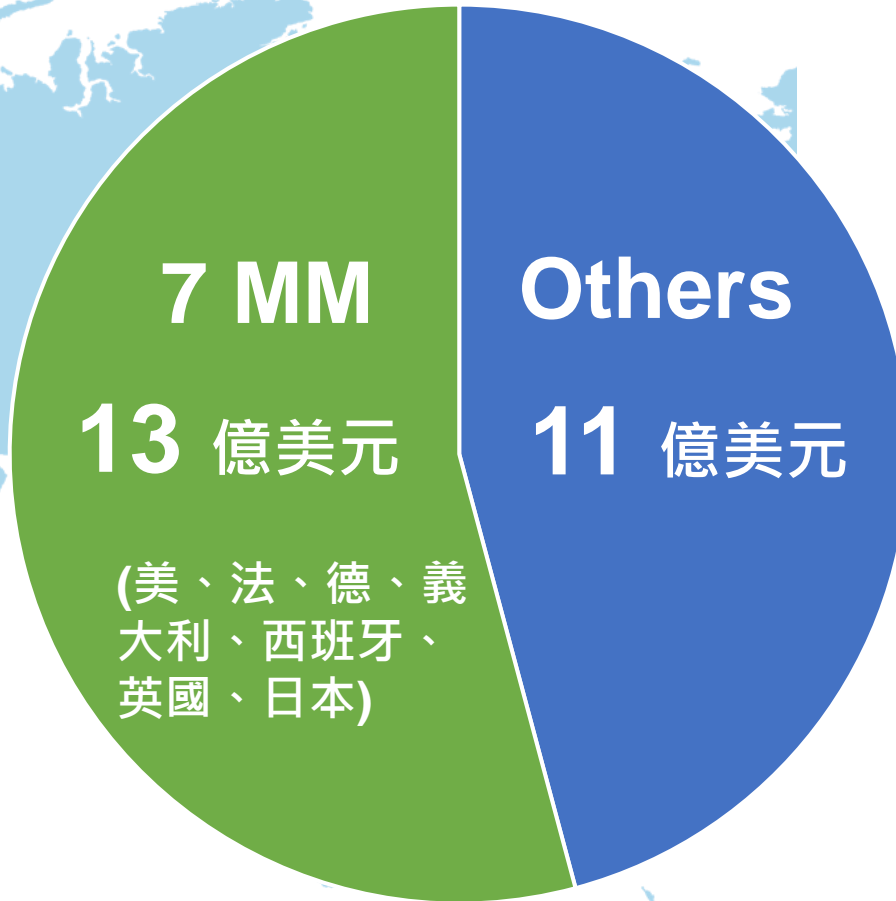
- 現行治療以症狀控制為主。
- 2023年 FDA 通過 Krystal's VYJUVEK™ 基因療法用於 DEB 患者，年費用達 63 萬美元，非常高昂。
- Chiesi 公司的樺樹皮萃取物新藥 Filsuvez® 凝膠則用於 DEB 和 JEB。

ENERGI-F703EB 乳膏

- 所有 EB 患者皆可使用
- 作為加速傷口癒合的第一線藥物

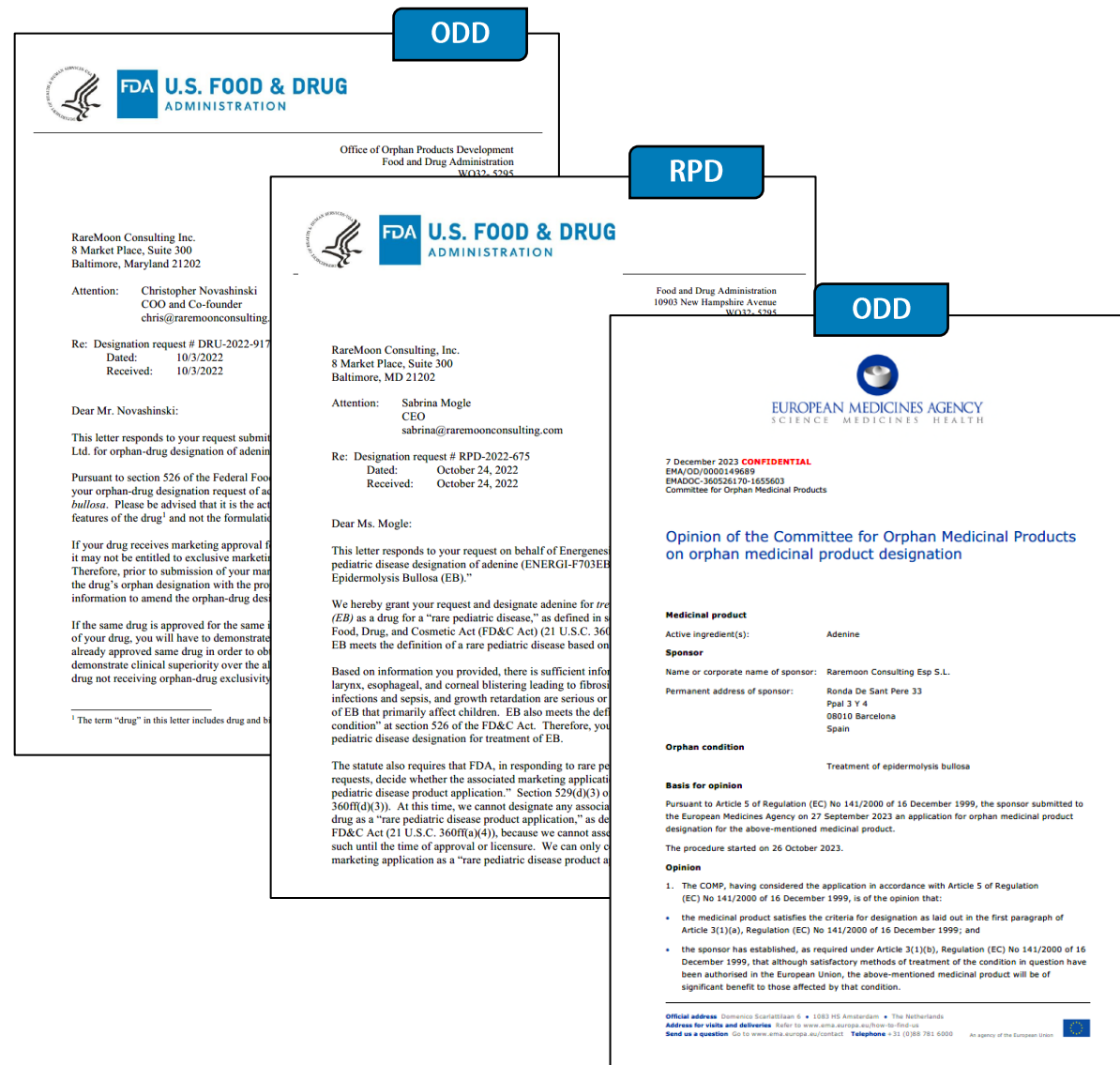
EB 全球市場為 24 億美元 (2023)

- 全球 EB 患者 > 500,000 人
市場規模 > 24 億美元
- 7大主要市場患者 > 46,500 人
市場規模 > 13 億美元



F703EB 取得孤兒藥資格

- FDA
 - 孤兒藥認證 (ODD) : 已取得
 - 兒科罕見疾病認證 (RPD) : 已取得
- EMA
 - 孤兒藥認證 (ODD) : 已取得



ENERGI-F705PD

- 巴金森氏症口服藥

- 創新手段：抗 α -synuclein 蛋白質聚集
- 動物實驗證實可反轉 PD 症狀
- 臨床一期試驗準備中

Discovery

Phase I Preparing

ENERGI-F705PD 治療 PD 的創新手段

常見的症狀為動作障礙



Nouvelle Iconographie de la Salpêtrière, vol. 5., p.226

現行療法

PD 患者
多巴胺減少

- 多巴胺 (dopamine) 療法為主
 1. 增加多巴胺吸收
 2. 避免多巴胺分解
 3. 模擬多巴胺之功能
 4. 減少 PD 症狀

ENERGI-F705

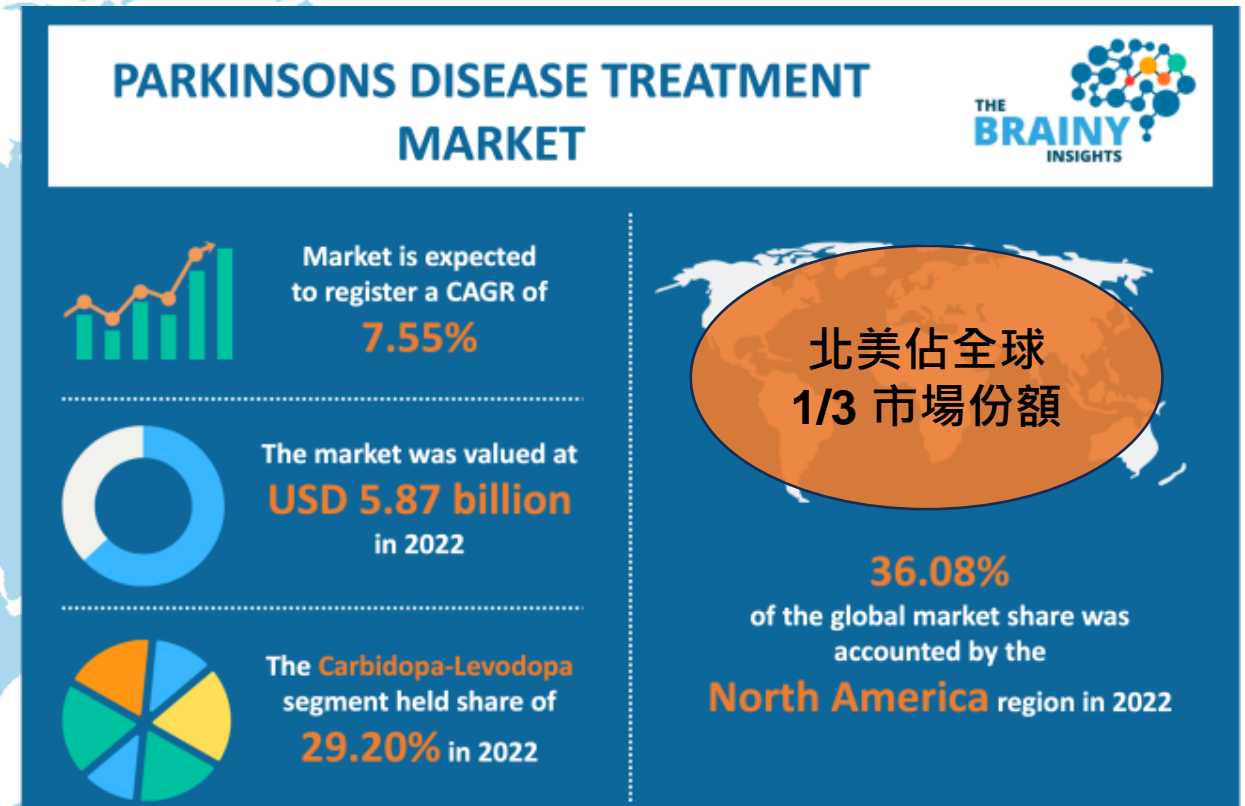
PD 患者
 α -synuclein
蛋白質聚集於
神經細胞

- 抗- α -synuclein 蛋白質聚集

ENERGI 提高細胞內 ATP, 細胞能量 ATP 另另作為生物助溶劑 (hydrotrope) 減少蛋白質堆積。

PD 全球市場為 58.7 億美元 (2022)

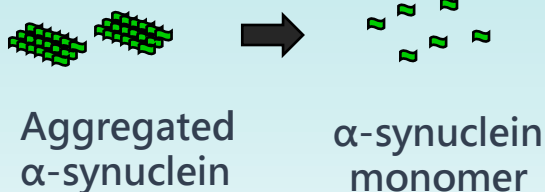
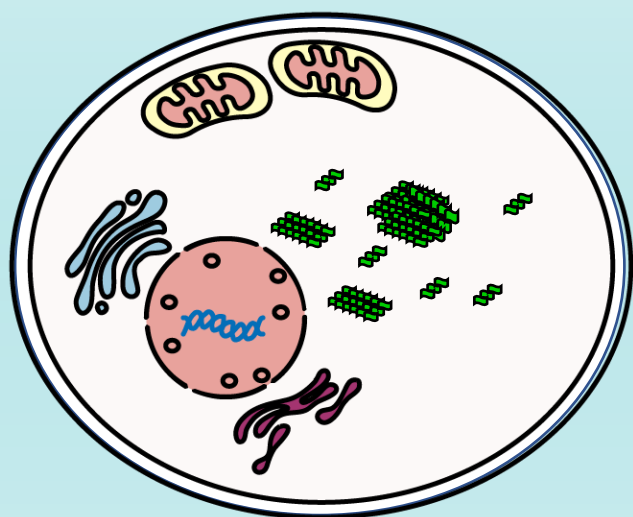
- 全球患者 > 1,000 萬人
 - 7MM 患者：250 萬人
 - 美國：110 萬人 (佔 7MM 45%)
- 2022 市場規模 58.7 億美元
 - Carbidopa-levodopa sales: 17 億美元
- 2030 市場規模 121.5 億美元



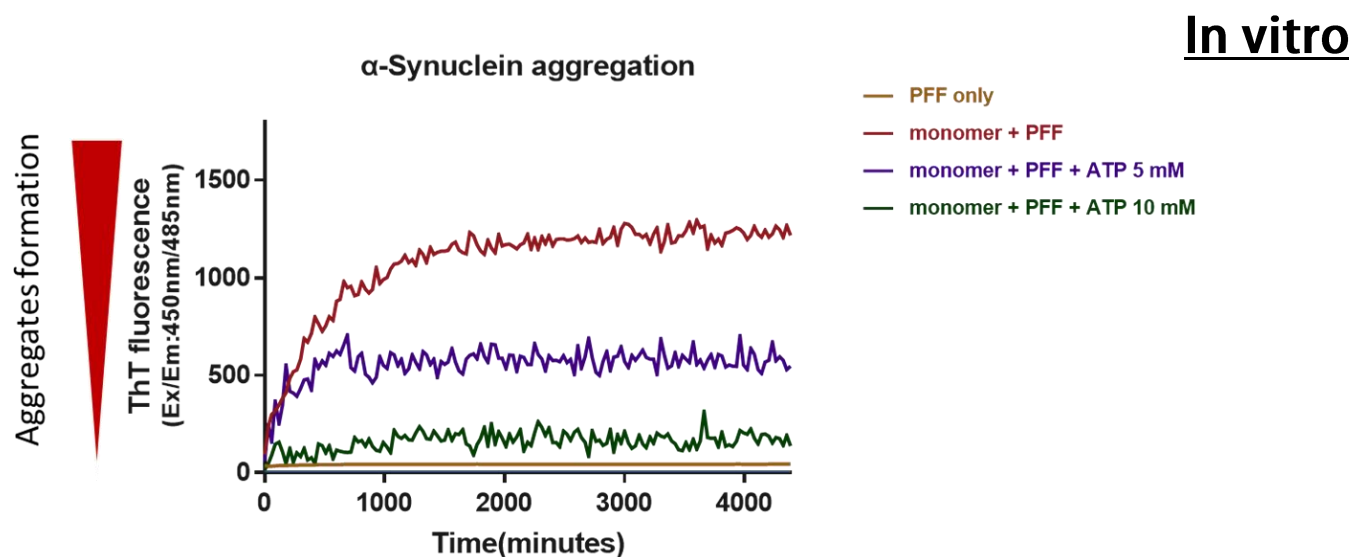
巴金森氏症治療手段

治療策略	名稱	機制	補償多巴胺細胞缺失	延緩疾病進程
First-in-class 創新藥物機制	ENERGI-F705	<ul style="list-style-type: none"> 增加 Tryrosin Hydroxylase 表現 避免蛋白質堆積 	✓	✓
增加多巴胺	Levodopa/Carbidopa	<ul style="list-style-type: none"> 結合多巴胺前驅物與代謝抑制劑 	✓	
避免多巴胺降解	Rasaline, Selegiline, Saffinamide	<ul style="list-style-type: none"> MAO 抑制劑 	✓	
	Entacapone, Tolcapone	<ul style="list-style-type: none"> COMT 抑制劑 	✓	
模擬多巴胺的效果	Pramipexole, Ropinirole, Rotigotine, Apomorphine	<ul style="list-style-type: none"> 多巴胺受體激動劑 (agonists) 	✓	
減緩運動症狀	Anticholinergic agents	<ul style="list-style-type: none"> 阻斷 acetylcholine 作用 	✓	
	Amantadine	<ul style="list-style-type: none"> 混和型 (dopamine release, anticholinergic, NMDA antagonist) 	✓	

- ENERGI 增加細胞內 ATP，ATP 有助於避免 α -synuclein 蛋白質聚集。



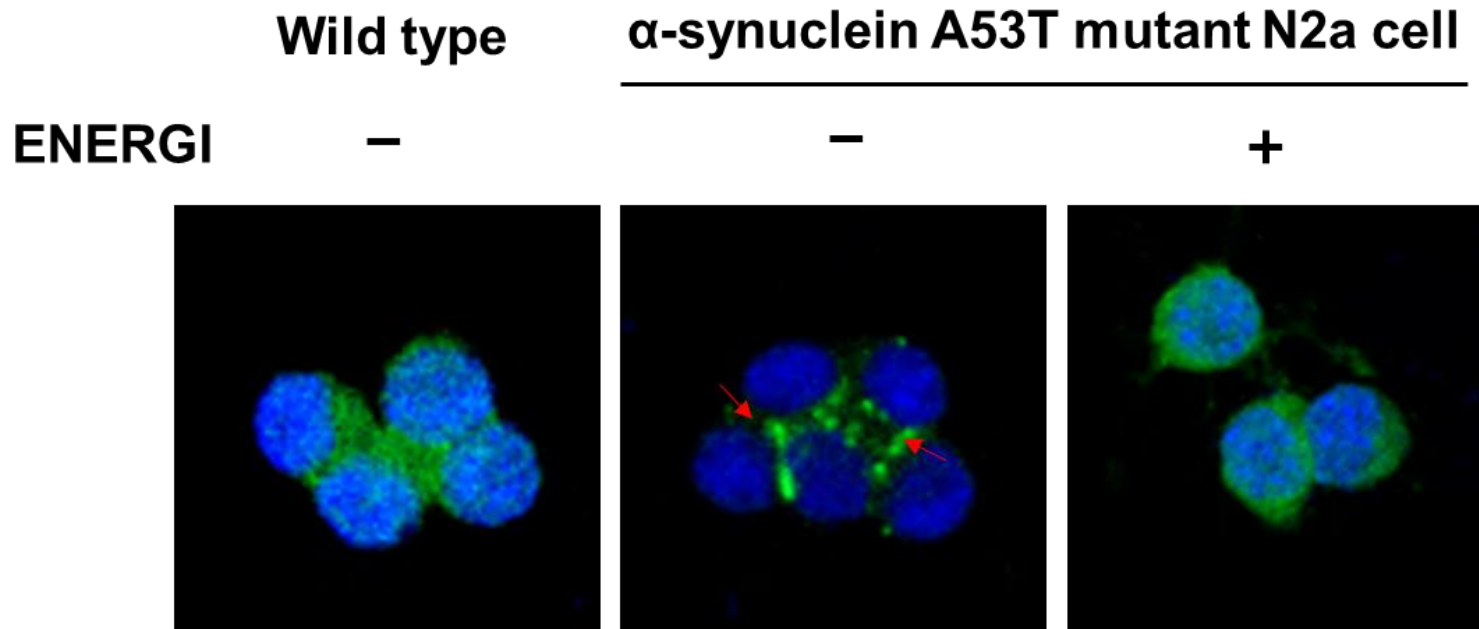
作用機制：
ATP 作為生物性助溶劑避免蛋白質不正常推積



Unpublished data from Energenesis Biomedical

- 利用 α -syn 突變細胞株，我們驗證 ENERGI 能減少 α -syn 蛋白質聚集。

細胞實驗



Unpublished data from Energenesis Biomedical

巴金森氏症小鼠平衡木實驗 證實 **ENERGI** 能夠改善小鼠運動能力

動物實驗

巴拉刈
(巴金森氏症小鼠)



巴拉刈 + F705 藥物



ENERGI-藥物研發平臺

- 啟動細胞自愈機制
- 為困難疾病治療找到新的方向