Genovate Biotechnology Co., Ltd.
健亞生物科技股份有限公司

17 November 2023

公司基本資料

- 成立日期：**1993**年**3**月
- 實收資本額：**10.94**億
- 員工人數：**186**人
- 主要股東：行政院國家發展基金管理會 **(26.71%)**

- 合作夥伴：

Daiichi-Sankyo
Passion for Innovation. Compassion for Patients.™

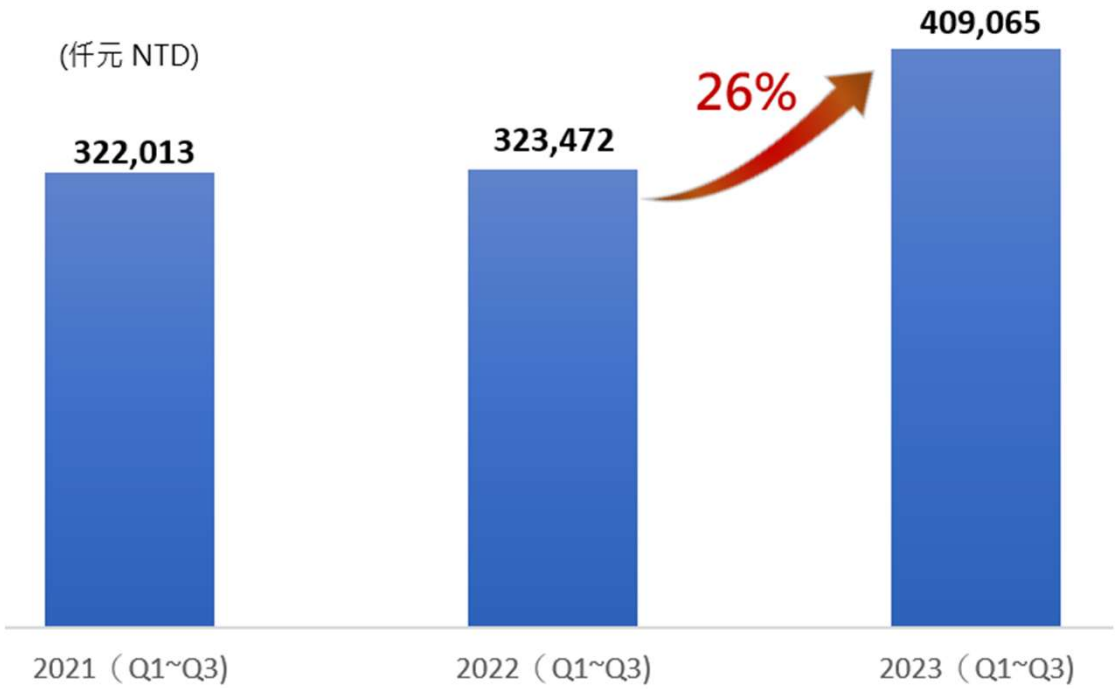
東生華製藥 tsh biopharm

天義企業集團 UIC GROUP

Tcmbio 泰宗生物科技股份有限公司

giddi 吉帝藥品股份有限公司 Giddi Pharma Company Limited

營業收入走勢-2021年~2023年前三季



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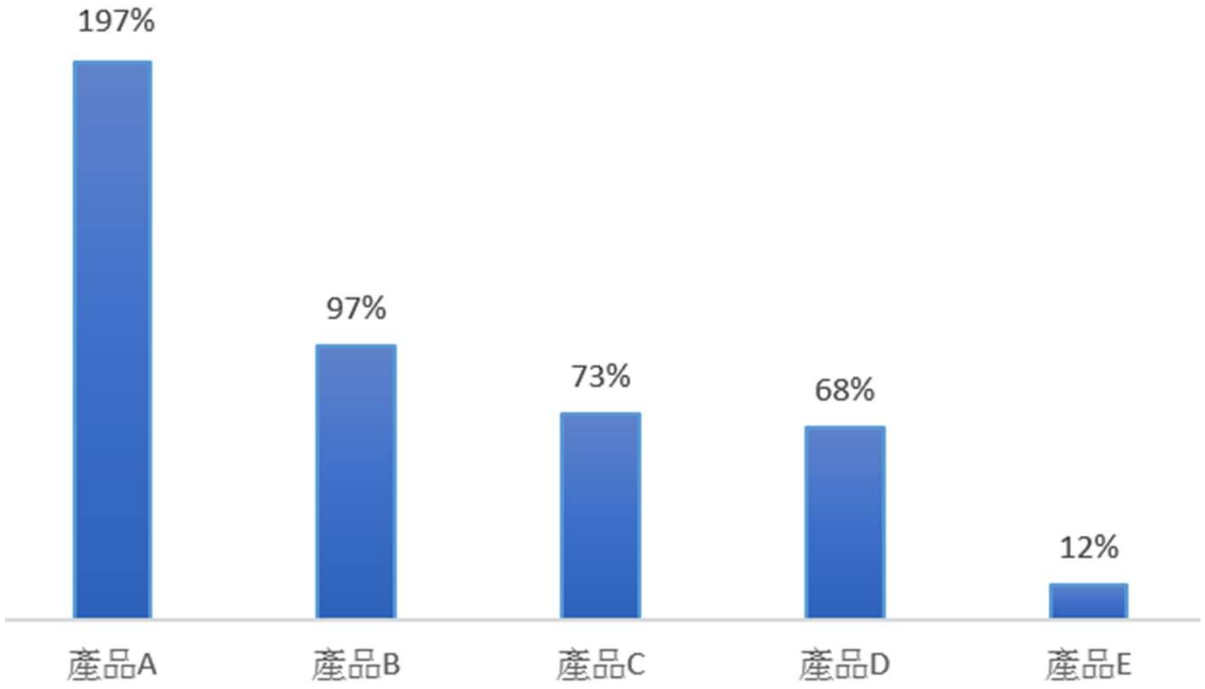
主要成長率之產品（GBL）-2023年Q3



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新藥/新醫材產品進度

計畫/開發階段	IND	Ⅰ	Ⅱ	Ⅲ	NDA	合作夥伴
Mycocep™ （狼瘡腎炎）					台灣上市	五年專賣權 （9/25/2018-9/25/2023）
PMR （間歇性跛足） （預防二次中風）				美國 Pre-NDA會議完成		美國先上市
GBL121 （糖尿病）			石藥於2023年4月在中國完成新藥申請（NDA）送件			1. 永信、中化、南光、信東、東洋、健亞 2. 中國石藥集團
NF02 （難治型癲癇）	已正式納入受試者					浩宇生醫 （聚焦超音波）
GX17 （自體免疫疾病）	通過美國 IND 臨床I期準備中					

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腦中風簡介

- 腦中風主要可分為兩種形式，分別是出血性腦中風與缺血性腦中風。缺血性腦中風又可稱為腦梗塞(cerebral infarction)，主要原因是由於腦血管阻塞所造成，又可細分為腦栓塞或腦血栓，而缺血性腦中風則佔了腦中風病患的八成以上。
  - 腦血栓（Thrombosis）：血液的黏稠度較大，就會形成小血塊，配合腦部的動脈血管發生粥狀硬化，這些血塊會沉積在動脈中形成斑塊，使動脈的管腔變狹窄，就會發生栓塞的問題，造成血液流通受阻，因而造成腦部產生缺氧性壞死。
  - 腦栓塞（Embolism）：腦部以外的部位會形成較大的血塊、硬化斑塊、脂肪、氣泡等物質，經由血液運行到腦部之後，直接阻塞腦部血管，導致腦部發生缺氧性壞死。
- 國內腦中風就醫人數逐年成長，2022年突破47萬人，其中，50歲以下佔一成，60歲以下佔四分之一，出現年輕化趨勢。台灣腦中風學會曾研究發現，抽菸者的中風年齡中位數比非抽菸者小11.4歲，且中風後死亡率大約2倍，提醒民眾戒菸。
- 依健保統計顯示，2020年至2022年因急性缺血性腦中風住院人數每年約4萬人，中風後部分病人無法回復原有工作或需輪椅代步，嚴重者終生臥床需他人照護，造成病人與家屬極大的經濟負擔及照護壓力，倘若在腦中風初期及早介入治療，可大幅改善預後。

Landmark randomised controlled trials evaluating antiplatelet therapy in secondary stroke prevention

Study	Study population	Trial design	Mean follow-up	Outcomes
CSPS (2000)	1095 with ischaemic stroke within 1–6 months in Japan	**Cilostazol 100 mg two times daily vs placebo**	1.5 years	Ischaemic stroke relative risk reduction (cilostazol vs placebo): 41.7% (95% CI 9.2% to 62.5%; p=0.015)
PRoFESS (2008)	20 332 patients with ischaemic stroke within 90 days of randomisation and an age of 50 years or older.	Aspirin/dipyridamole (25/200 mg) two times daily vs clopidogrel 75 mg daily	2.5 years	First recurrence of stroke (aspirin/dipyridamole vs clopidogrel): 9.0% vs 8.8%; p=NS. Risk of major haemorrhage: 4.1% vs 3.6%,p=NS.
CSPS-2 (2010)	2757 patients with a cerebral infarction within previous 26 weeks in Japan	**Cilostazol 100 mg two times daily vs aspirin 81 mg**	29 months	Recurrence of cerebral infarction (cilostazol vs aspirin): 2.76% vs 3.71%, p=0.0357. Haemorrhage: 0.77% vs 1.78; p=0.0004.
SOCRATES (2016)	13 199 patients with recent stroke or high-risk TIA within previous 24 hours	Ticagrelor 90 mg two times daily vs aspirin 100 mg daily	4 months	Rate of recurrent stroke, myocardial infarction or death (Ticagrelor vs aspirin): 6.7% vs 7.5%, p=0.07. Rate of ischaemic stroke: 5.8% vs 6.7%; p=0.046.
CSPS.com (2019)	1879 patients with recent ischaemic stroke and either at least 50% stenosis or more than two vascular risk factors	**Aspirin 81 mg or clopidogrel 75 mg and cilostazol 100 mg two times daily vs aspirin or clopidogrel**	1.4 years	Annual rate of recurrent stroke (DAPT vs SAPT): 2.2% vs 4.5%, HR 0.49 (95% CI 0.31 to 0.76; p=0.001)
CHANCE-2 (2021)	6412 patients with a minor ischaemic stroke or TIA and CYP2C19 loss-of-function alleles within 24 hours of symptom onset.	Ticagrelor 180 mg on day 1 followed by 90 mg two times daily or Clopidogrel 300 mg on day 1 followed by 75 mg daily. Both groups received aspirin 75 mg daily for 21 days.	90 days	New stroke (Ticagrelor plus aspirin vs clopidogrel plus aspirin): 6.0% vs 7.6%; HR 0.77, 95% CI 0.64 to 0.94, p=0.008. Severe or moderate bleeding: 0.3% vs 0.3%.

July, 2022. SVN

Dual Antiplatet Therapy Versus Aspirin in Minor Stroke or TIA

Meta-Analysis of Randomized Controlled Trials

4 trials, 21,459 patients with minor stroke or high-risk TIA

	Aspirin + P2Y12i	Aspirin + Placebo
	N = 10,737	N = 10,722
Recurrent Stroke (N)	626	827
	RR 0.76; 95% CI, 0.68-0.83; P <0.001	
Major Bleed (N)	71	29
	RR 2.2; 95% CI, 1.14-4.34; P =0.02	

In minor stroke or high-risk TIA, short term DAPT reduced the risk of recurrent stroke at the expense of a higher risk of major bleeds

27 Apr. 2021 Stroke

Cilostazol for Secondary Stroke Prevention History, Evidence, Limitations, and Possibilities

Comparison of the Mechanism of Action, Common and Major Adverse Events, and Out-of-Pocket Cost of Common Antiplatelet Medications Used in Stroke Prevention

Medication	Mechanism of action	Most common adverse events	Major adverse events	Monthly cost
Cilostazol	**Reversible intracellular PDE3 inhibition**	**Headache, diarrhea, palpitation, dizziness, tachycardia**	**Contraindicated in patients with heart failure**	**$9.00**
Dipyridamole	Reversible intracellular PDE3 inhibition	Headache, dizziness, abdominal distress, angina pectoris, nausea	Major bleeding (when combined with aspirin)	$22.2(MR)
Aspirin	**Irreversible inhibition of COX**	**Dyspepsia, rash, minor bleeding, epistaxis**	**Major bleeding, upper gastrointestinal ulcers**	**$2.47**
Clopidogrel	**Irreversible extracellular inhibition of P2Y12**	**Bruising, minor bleeding, epistaxis**	**Major bleeding**	**$15.00**
Ticagrelor	Irreversible extracellular inhibition of P2Y12	Dyspnea, ventricular pause, nausea, dizziness, transient creatinine increase, minor bleeding	Major bleeding, bradyarrhythmia, thrombotic thrombocytopenic purpura	$373.90
Prasugrel	Irreversible extracellular inhibition of P2Y12	Hypertension, headache, nausea, minor bleeding, epistaxis	Fatal bleeding, thrombotic thrombocytopenic purpura	$32.36

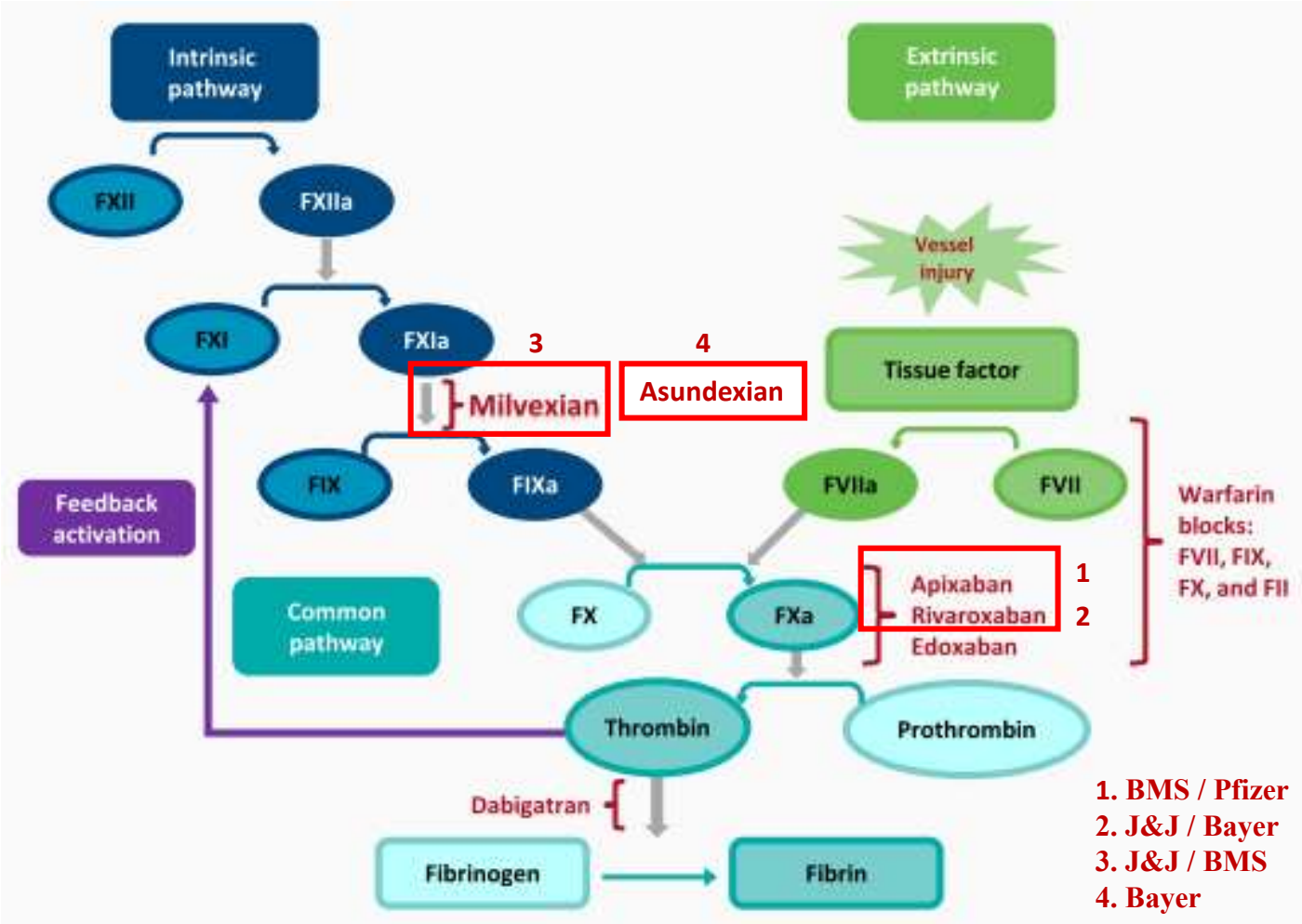
Top 20 best-selling pharmaceuticals of 2022-(1/2)

Drug name	Manufacturer(s)	2022 Sales
1. Comirnaty COVID-19 vaccine	Pfizer/BioNTech	$55,918,791,640
2. Humira (adalimumab)	AbbVie	$21,237,000,000
3. Keytruda (pembrolizumab)	Merck	$20,937,000,000
4. Paxlovid	**Pfizer**	**$18,933,000,000**
5. Spikevax COVID-19 vaccine	Moderna	$18,435,000,000
6. Eliquis (apixaban)	**Bristol Myers Squibb and Pfizer**	**$18,269,000,000**
7. Eylea (aflibercept)	Regeneron Pharmaceuticals, Bayer	$12,721,221,200
8. Biktarvy (bictegravir, emtricitabine, and tenofovir alafenamide)	**Gilead Sciences**	**$10,390,000,000**
9. Revlimid (lenalidomide)	**Bristol Myers Squibb (Celgene)**	**$9,978,000,000**
10.Stelara (ustekinumab)	Janssen (Johnson & Johnson)	$9,723,000,000

Top 20 best-selling pharmaceuticals of 2022-(2/2)

Drug name	Manufacturer(s)	2022 Sales
11.Dupixent (dupilumab)	Sanofi Genzyme, Regeneron Pharmaceuticals	$8,735,846,200
12.Imbruvica (ibrutinib)	**Pharmacyclics (AbbVie) and Janssen (Johnson & Johnson)**	**$8,352,000,000**
13.Opdivo (nivolumab)	Bristol Myers Squibb	$8,249,000,000
14.Darzalex (daratumumab)	(Janssen) Johnson & Johnson	$7,977,000,000
15.Trikafta/Kaftrio	**Vertex Pharmaceuticals**	**$7,686,800,000**
16.Xarelto (rivaroxaban)	**Janssen (Johnson & Johnson)/Bayer**	**$7,460,849,000**
17.Trulicity (dulaglutide)	Eli Lilly	$7,439,700,000
18.Gardasil/Gardasil 9 (human papillomavirus 9-valent vaccine)	Merck	$6,897,000,000
19.Prevnar family (pneumococcal vaccine)	Pfizer	$6,337,000,000
20.Ocrevus (ocrelizumab)	Roche	$5,764,380,000

Novel Anticoagulants with less bleeding



ESC Congress 2022 Barcelona

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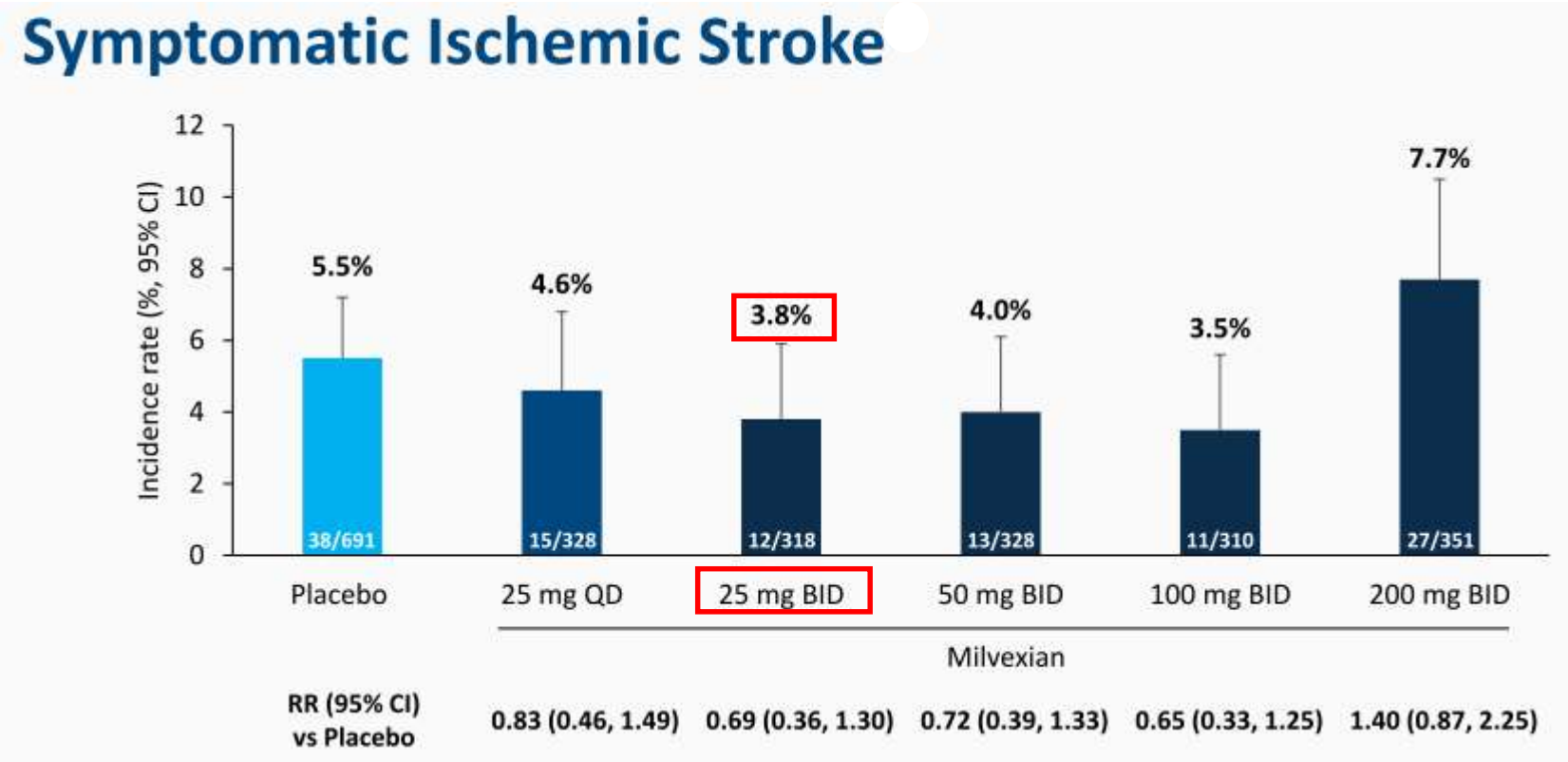
Efficacy and Safety of the FXIa Inhibitor Milvexian for Secondary Stroke Prevention : Final Results of the AXIOMATIC-SSP Dose-finding Randomized Trial



All participants on 100mg aspirin and/or 75mg clopidogrel

28 August 2022

ESC Congress 2022 Barcelona

Genovate

Efficacy and Safety of the FXIa Inhibitor Milvexian for Secondary Stroke Prevention : Final Results of the AXIOMATIC-SSP Dose-finding Randomized Trial

Adverse Events

		Milvexian				
		QD regimen	BID regimen			
	Placebo (n = 682)	25 mg (n = 325)	25 mg (n = 313)	50 mg (n = 325)	100 mg (n = 306)	200 mg (n = 344)
AE, n (%)	399 (58.5)	190 (58.5)	186 (59.4)	192 (59.1)	193 (63.1)	211 (61.3)
SAE, n (%)	94 (13.8)	37 (11.4)	39 (12.5)	41 (12.6)	42 (13.7)	54 (15.7)
Bleeding AE, n (%)	66 (9.7)	31 (9.5)	27 (8.6)	48 (14.8)	41 (13.4)	42 (12.2)
Discontinuation due to AE, n (%)	83 (12.2)	44 (13.5)	47 (15.0)	46 (14.2)	51 (16.7)	79 (23.0)
Death, n (%)	0	1 (0.3)	1 (0.3)	1 (0.3)	2 (0.7)	0

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Next generation blockbuster for stroke treatment
Combination of Antiplatelet Agents and Anticoagulants

A Study of Milvexian in Participants After an Acute Ischemic Stroke or High-Risk Transient Ischemic Attack- LIBREXIA-STROKE (LIBREXIA-STROKE)

ClinicalTrials.gov ID NCT05702034
Sponsor Janssen Research & Development, LLC
Information provided by Janssen Research & Development, LLC
All participants on aspirin and/or clopidogrel
Enrollment (Estimated) 15000
Phase 3

A Study to Test Asundexian to Prevent a Clot-related Stroke in Participants After an Acute Ischemic Stroke or High-risk TIA/Mini-stroke (Transient Ischemic Attack) (OCEANIC-STROKE)

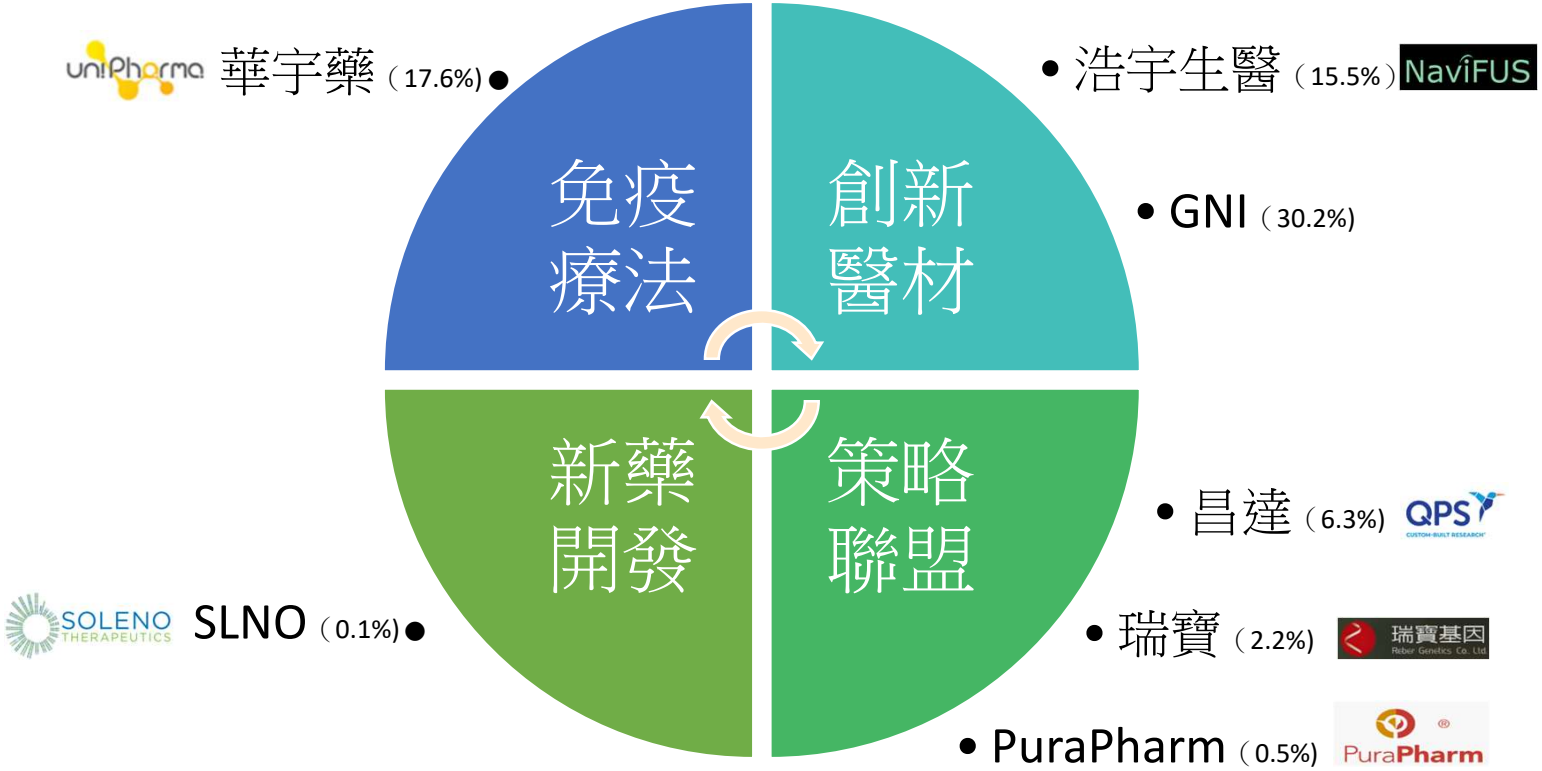
ClinicalTrials.gov ID NCT05686070
Sponsor Bayer
Information provided by Bayer
All participants on aspirin and/or clopidogrel
Enrollment (Estimated) 9300
Phase 3

預防二次中風：黃金組合

FXIa Inhibitor + PMR

With or without Aspirin

投資策略



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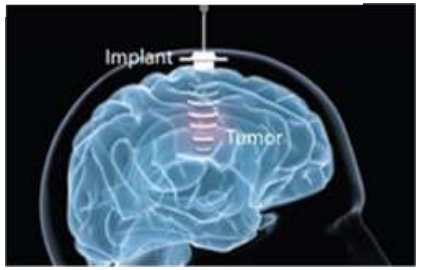
NaviFUS is the 1st system that could do treatment in OPC

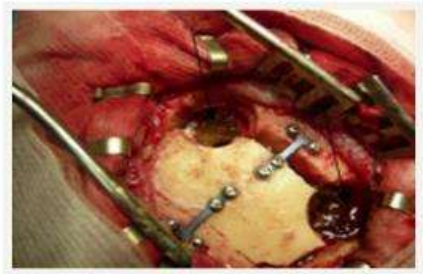
- NaviFUS does not require MRI guidance to do the FUS treatment during the operatun procedure, which saves treatment time and greatly reduces operation costs.

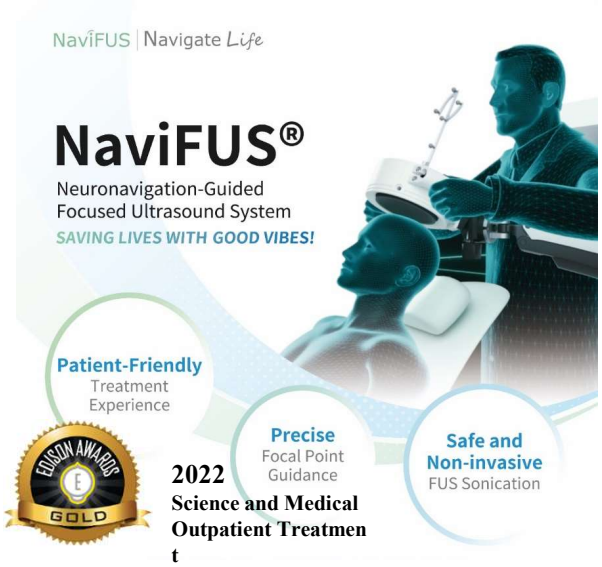
INSIGHTEC

CARTHERA
Advanced Brain Therapy Through Innovation

Nature Reviews (2021.10)
DOI: 10.1038/s41582-020-00418-z







➢**NaviFUS®** uses a neuronavigator to guide the FUS. The patient only needs to sit on the chair to receive FUS treatment for **less than 0.5hours** and requires **no implants or incisions**

Therapeutic evidence: PFS for Avastin+FUS in treatment of rGBM

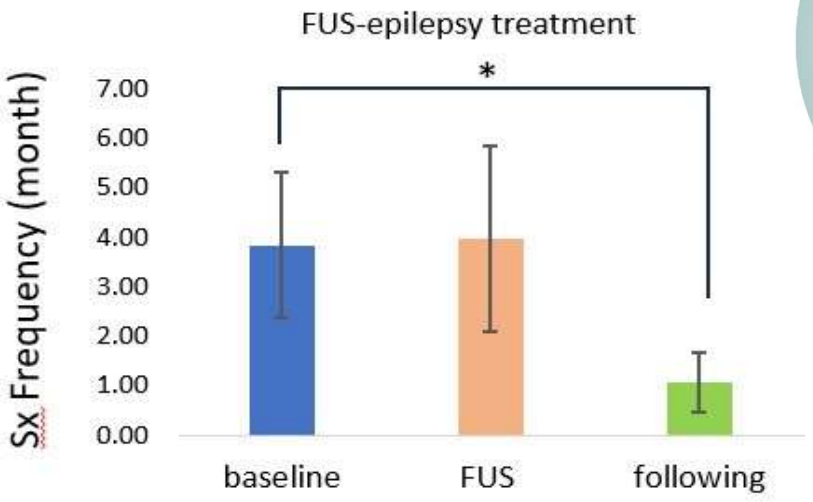
	Median PFS (Month)	Median OS (Month)	Patients No.	CT Location	Intervention Model	Allocation
NaviFUS, 2022	**9.5 (4-9.5)**	**20.5*(5-24)**	**6**	Taiwan	Single	-
Fried et al., 2009 (Ph2: Irinotecan+AVA/ AVA; 1:1)	4.2 (2.9-5.8)	9.2 (8.2-10.7)	167	Multicenter	Parallel	Randomized
Cloughesy, et al., 2020 (Ph3: VB-111+AVA/ AVA; 1:1)	3.7 (3.7-4.3)	7.9 (7.0-9.7)	256	57-centers in 3 countries (US/Canada/Israel)	Parallel	Randomized
Reardon et al., 2020 (Ph3: Nivolumab/ AVA , 1:1)	3.5 (2.9-4.6)	10.0 (9.0-11.8)	369	57-centers in 12 countries	Parallel	Randomized
Lee et al., 2020 (Ph2: Trebananib+AVA/ Placebo+AVA, 1:1)	4.8 (3.8-7.1)	11.5 (8.4-14.2)	115	41-centers in 2 countries (US/Canada)	Parallel	Randomized

Focused Ultrasound: Lesions and Neuromodulation in Epilepsy

- Speaker: Hsiang-Yu Yu (尤香玉主任)

  35th International Epilepsy Congress, 2-6. Sep. 2023@Dublin Ireland

- 初步看出五位患者於治療期後，癲癇發作頻率於術後6個月內下降



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Current status of Product Pipeline

Indications/Country	Phase Ⅰ/Ⅱ(Feasibility)	Phase Ⅱ (efficacy)	Phase III (Pivotal)
rGBM/Avastin/TW	Clinical data published in 2021	Clinical data submitted to top journals	IDE Submitted
	2018/01~2020/04	2020/03~2023/07	2023/04~Now
rGBM/Avastin/USA		Received FDA IDE approval on 2023/07	
		2022/04~now	
Epi/Neuromodulation/TW (1 x 1month)	Clinical data published in 2022	10 pt	
	2019/02~2021/05	2021/07~now	
Epi/Neuromodulatio/USA (2 x 3weeks)	Pre-Clinical data published in 2022/2023	FDA IDE Submitted on 2023/08	
		2022/10~Now	
Epi/Neuromodulation/Aus (2 x 2weeks)&(2 x 3weeks)		Under recruitment	
		2023/06~now	
rGBM/ 5-ALA(SDT)/USA	Pre-clinical Data submitted	Ready for the first pt	
	2021/10~2022/12	2023/07~now	

NaviFUS—Global Partnerships (Contract Signed)

- **FUS Foundation:**
  1) Invest 0.8M USD as the stakeholder to sponsor the trials in Taiwan
  2) Sponsor ≒ 3M USD for Sonodynamic trial at UVA
- **BrainLab:**
  1) Provide ≒ 2M USD neuronavigators to do the trials in TW & USA
- **Bracco:**
  1) Provide ≒1M USD microbubble for global clinical trials
  2) Co-develop new BBBO products
- **Hospitals & Research Site:**
  1) Purchase/Loan the NaviFUS research devices for different clinical studies
- **2024 ISTU Symposium @ Taipei**
  - Seek collaboration with global pharmas and KOLs

華宇發展計畫主題

人類肝癌
NAVIRFA+DC細胞治療

人類DR-70 2.0早期癌症篩檢

寵物癌症產品鍊

2024年產品開發與預期成果(1/2)

產品	目標概述與預期成果	現行初步成果	潛在市場規模與競爭力
人類肝癌NAVIRFA+DC細胞治療	● 創新的肝癌聯合療法 ● 與萬芳醫院、台大醫院皆有合作計畫	● 特管法審查中，已回復第三次審查意見。 ● 明年Q1通過特管法	● 肝癌治療市場規模龐大，全球估計價值為28億美元，預計年增率為17.39%。 ● 創新聯合療法提供創新且有商機的治療方式。
人類DR-70 2.0早期癌症篩檢	● 全新專利製程 ● 更加精準穩定 ● 國內增加使用量 ● 國外推廣至全球市場	● 創新抗體製備完成 ● 明年Q2完成許可證變更 ● 抗體專利提出申請	● 預計上市後一年內可貢獻國內市場千萬以上營收 ● 智慧財產權保護確保市場獨佔性

2024年產品開發預期成果(2/2)

產品	目標概述與預期成果	現行初步成果	潛在市場規模與競爭力
寵物癌症產品鍊	● 全新寵物癌症檢測、治療與照護 ● 全球市場未見之寵物癌症產品鍊 ● 寵物癌症市場之領導品牌	● 研究論文發表至頂尖獸醫國際期刊 ● 治療反應率可達80%以上 ● 香港、馬來西亞代理商主動接洽	● 切入全球數百億台幣之寵物癌症市場 ● 與領先的研究機構 (東大、台大)策略合作，加速發展
犬癌症檢測晶片開發計畫	● 開發至少三種以上的犬腫瘤標記 ● 以半導體生醫晶片提高檢測準確性 ● 實現診所院內分析	● 包含DR70，已有至少四種可能潛在標的蛋白 ● 半導體生醫晶片 良率大於90%，確認DR70用於晶片的可行性，可同時於機器上檢測多個晶片 ● 單株抗體生產測試完成	● 伴侶動物診斷市場於2024年將增長到30億美元 ● 目前國際上可用之犬腫瘤標記約僅4種，且因價格或準確性不足導致競爭力薄弱，多重腫瘤標記可以提高檢測的準確性

應用於寵物多重腫瘤標誌之高敏晶片創新應用開發計畫成果

計畫內容	補助單位	計畫期間	開發經費	自籌款	補助款	共同開發公司	合作學術單位
進行腫瘤癌症指標蛋白篩選，開發多重標誌檢測晶片及其量測系統模組，應用於寵物檢體。	經濟部產業發展署	**2022/07/01至2025/06/30**	**2,120萬**	**1,423萬**	**697萬**	矽基分子電測科技股份有限公司	台灣大學、陽明交通大學
補助款：**2022年271萬、2023年267萬、2024年151萬、2025年8萬**							