

The logo features the letters 'TTV' in a bold, red, italicized font, followed by 'BIOPHARM' in a white, italicized font with a registered trademark symbol. The entire logo is set against a black diamond-shaped background.

TTV BIOPHARM®

台灣東洋藥品

WELCOME TO JOIN US

May, 2018

Safe Harbor Statement

This presentation contains certain forward-looking statements.

These forward-looking statements may be identified by words such as 'believes', 'expects', 'anticipates', 'projects', 'intends', 'should', 'seeks', 'estimates', 'future' or similar expressions or by discussion of, among other things, strategy, goals, plans or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this presentation, among others:

1. pricing and product initiatives of competitors;
2. legislative and regulatory developments and economic conditions;
3. delay or inability in obtaining regulatory approvals or bringing products to market;
4. fluctuations in currency exchange rates and general financial market conditions;
5. uncertainties in the discovery, development or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side-effects of pipeline or marketed products;

6. increased government pricing pressures;
7. interruptions in production
8. loss of or inability to obtain adequate protection for intellectual property rights;
9. litigation;
10. loss of key executives or other employees; and
11. adverse publicity and news coverage.

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You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. TTY Biopharm undertakes no obligation to update publicly or revise any forward-looking statements. Any statements regarding earnings growth is not a profit forecast and should not be interpreted to mean that TTY Biopharm's earnings or earnings per share for this year or any subsequent period will necessarily match or exceed published earnings or earnings per share forecasts of TTY Biopharm Company Limited.

Our Mission

We have been striving to extend liposomal & microsphere depot platform technologies for treatment of various diseases.

Our Target is to improve health and quality of life through innovative, cost-effective therapeutics and specialty drugs.

Our focus is on the **“Unmet Medical Needs”** in challenging diseases throughout the world, such as Cancer, CNS, Autoimmune, Diabetes Mellitus & Infectious Diseases.

Agenda

Company Overview

Product Strategy

Product Pipeline

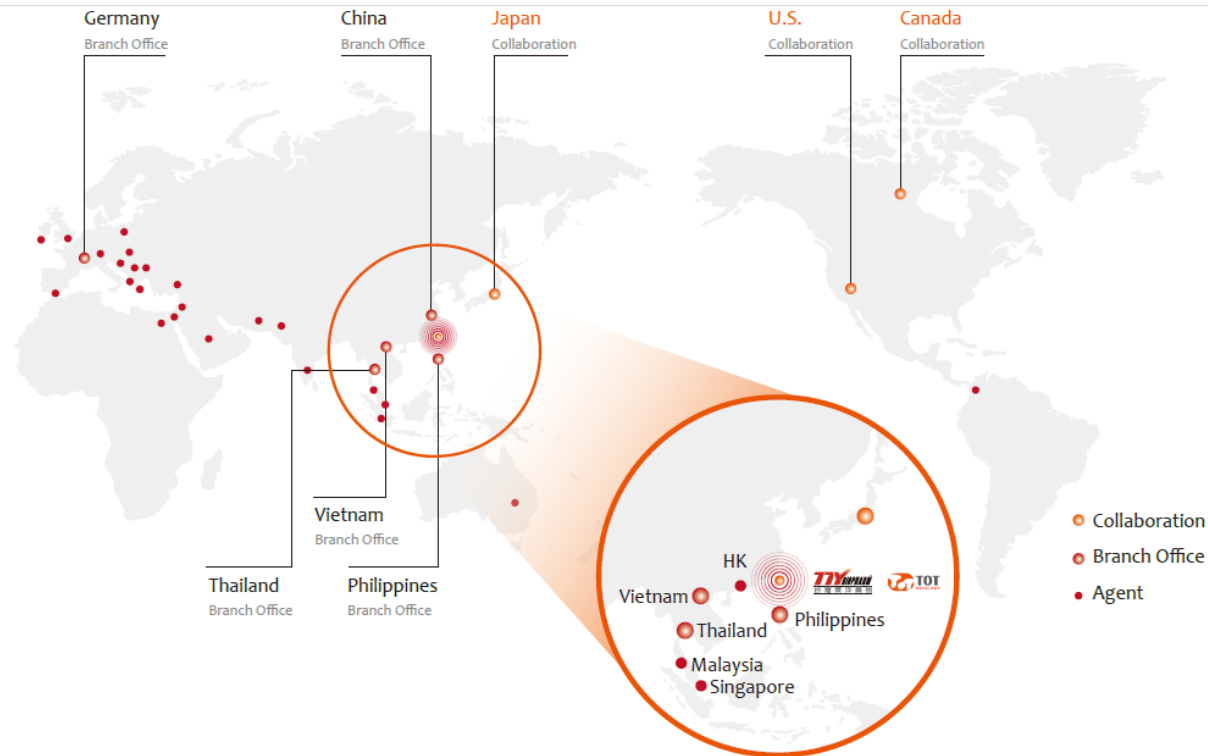
Manufacture Facilities

Successful Product Categories

In Progress Status

Biotech Success

Company Overview



- **Founded in 1960, restructured in 1996**
- **Traded in the Taiwan TPEX (2001, Code: 4105);**
Shares outstanding: 248 Million Shares
(December, 2017)

- **TTY Biopharm consolidated sales as of 2017- NTD 4.08 Billion, USD 138 Million**
- **Headquarters: Taipei, Taiwan**
Number of employees: 520



台灣東洋
TTY Biopharm

- 新藥及特殊學名藥開發
- 市值US\$856mn.

ROE 2011-2016: 19.5%.

ROE 2017: 24.5% (above industry average 11.13%).

Targets for 28%-35% in 2018-2020.

殷漢
EnhanX (67%)

- 研發及新藥開發
- 臨床試驗開發暨行銷業務推廣

東生華製藥
TSH (56.48%)

- 慢性病領域 (CV/GI/Immune) 之藥物開發暨行銷業務推廣
- 市值US\$78mn

智擎生技
PharmaEngine (17.92%)

- 新藥開發公司
- 市值US\$628mn

創益生技
CY Biotech (27.54%)

- 益生菌及減肥藥開發
- 市值US\$37mn

榮港生技
WorldCo (100%)

- 藥物開發(Liver/ID/CNS)
- 行銷暨業務推廣

ATB泰/ATB菲/越辦事處
40%/87%/100%

- 藥物開發暨行銷業務推廣

TTY 核心能力



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Product Strategy

Trends for Pharmaceutical Industry

Market Scope
(Risk)



Entry Barrier
(Profit)



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Manufacture Facilities

Successful Product Categories

In Progress Status

Biotech Success

New Drug Pipeline

產品組合	適應症	Preclinical	Phase I	Phase II	Phase III	
ENX-201	多發性硬化症/其他適應症： 葡萄膜炎/眼睛發炎，神經性疼痛， 骨關節炎，(ALS) 漸凍人—肌萎縮性 脊髓側索硬化症，(MPS) 黏多醣症， (MLD) 異染性腦白質失養症					
LGIA10 (505b2)	第二型糖尿病					

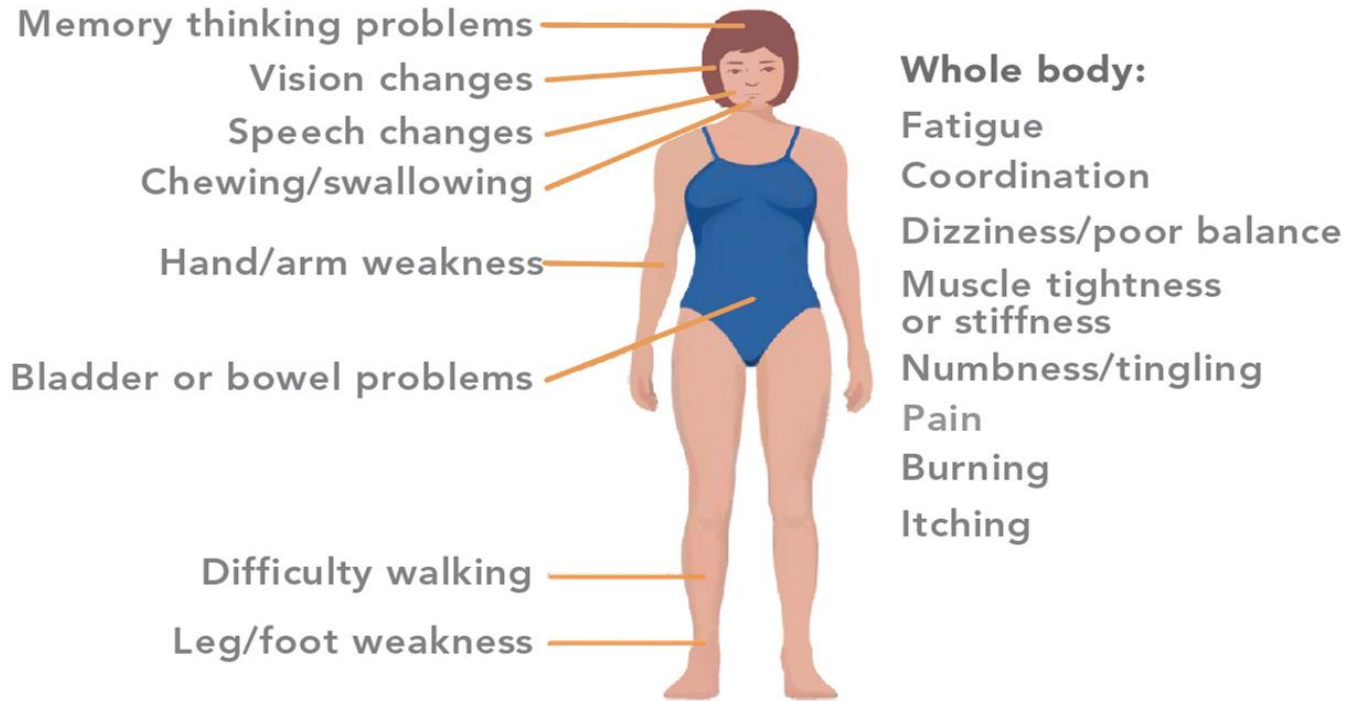
產品組合	World Market USD/M (est.)	核心技術	產品優勢
ENX-201	1,700	Liposome Technology	Penetrating Blood-Brain-Barrier (BBB) capability
LGIA10	910	Microsphere Formulation	Worldwide Manufacturing Patent Microsphere Deport Platform

Introduction of MS

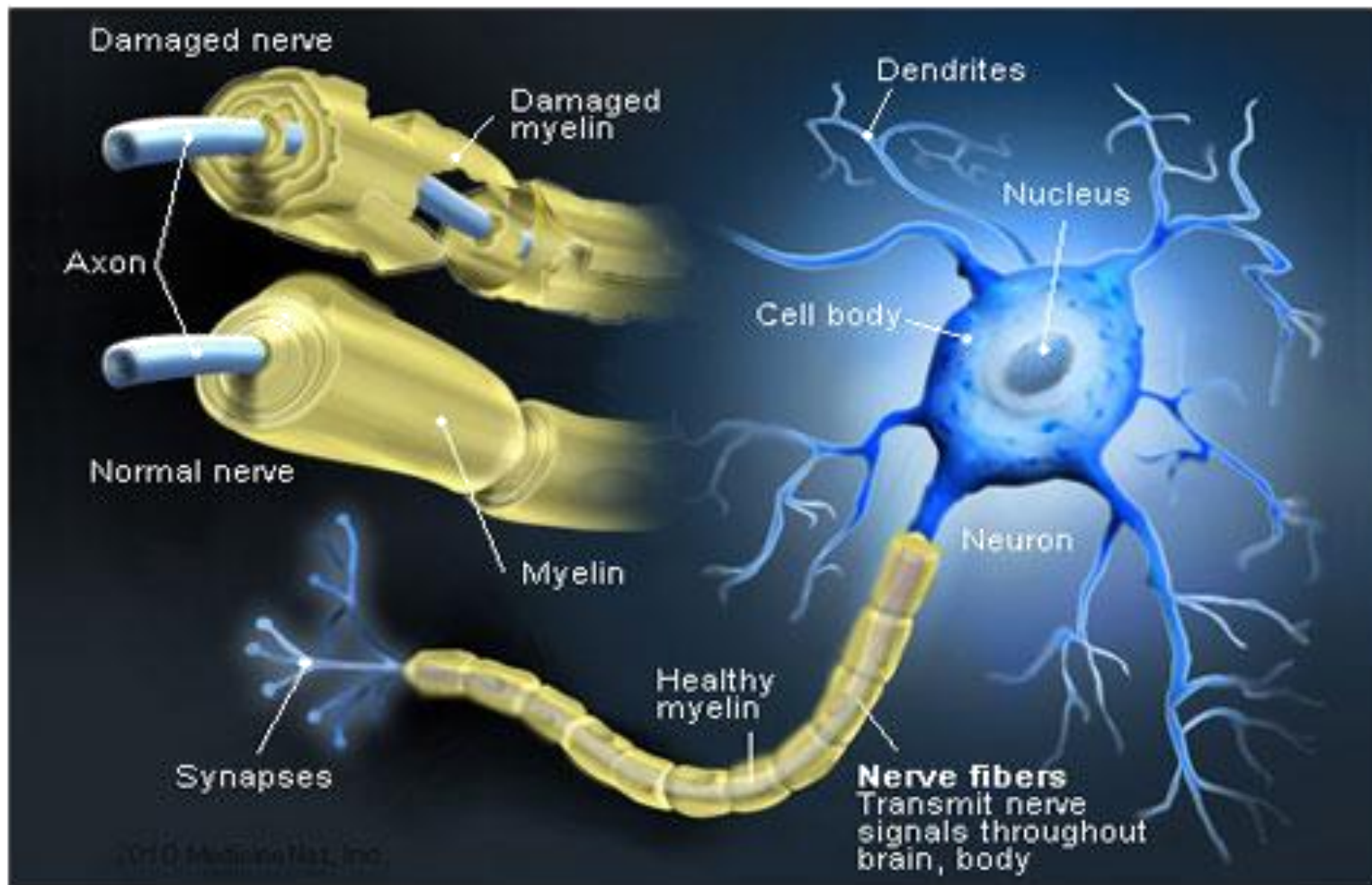
MS: a chronic, autoimmune & neurodegenerative disorder

Body's own defensive system attacks myelin

- Inflammatory damage in the brain and spinal cord
- Loss of myelin and axons (scars at multiple sites)
- Neurologic disability

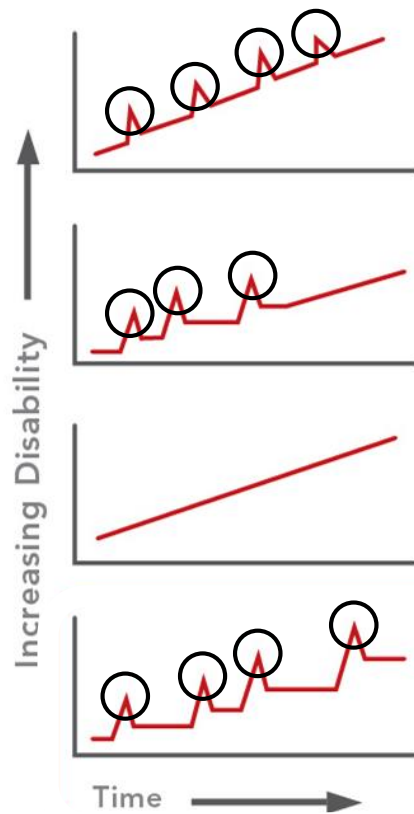


Introduction of MS's MoA



Introduction of MS

Four Classifications of MS



PRMS Progressive Relapsing MS
Steady decline since onset with super-imposed attacks.

SPMS Secondary Progressive MS
Initial RRMS that suddenly begins to decline without periods of remission and relapses.

PPMS Primary Progressive MS
Gradual progression of the disease from its onset with no relapses or remissions

RRMS Relapsing/Remitting MS
Unpredictable attacks which may or may not leave permanent deficits followed by periods of remission

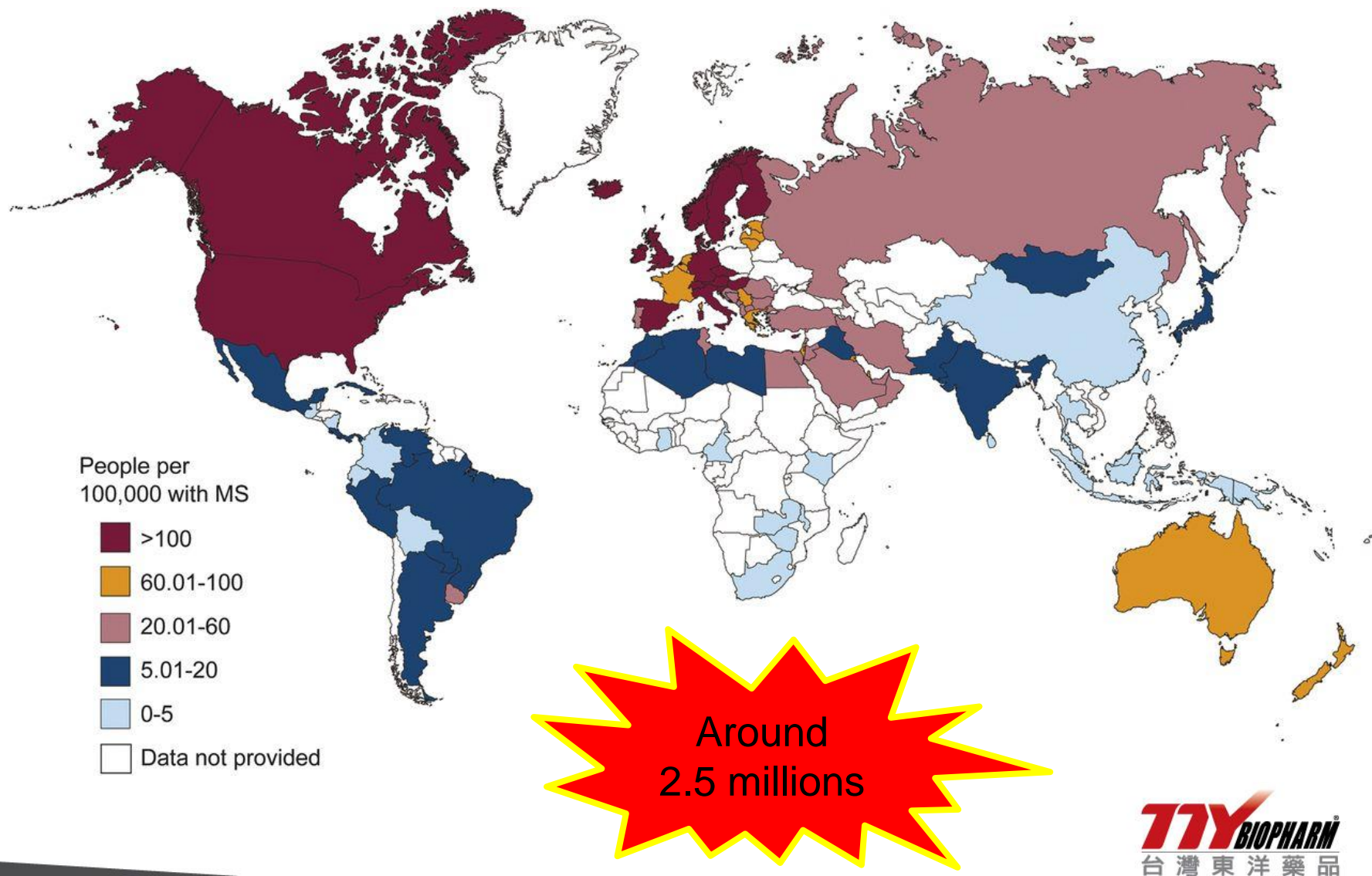
Either one of the four classifications occurs in acute is the target patient pool of ENX-201.
不管屬於哪一個發病類型，只要是急性復發，就是ENX-201的target 病患。

Introduction of MS 介紹

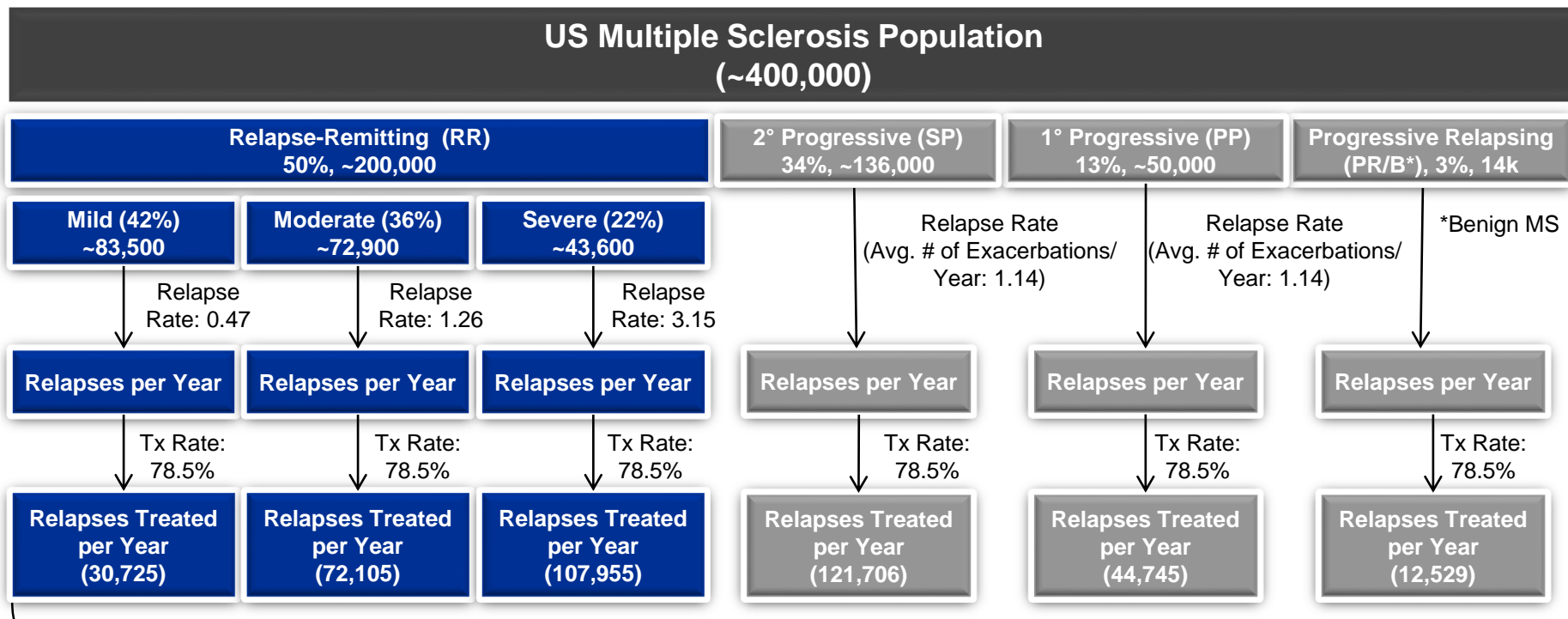


DH Primary Research, Ann Indian Acad Neurol. 2011 Jul.;14(Supp1 1):S65-9

Introduction of MS



Patients Distribution in US Market



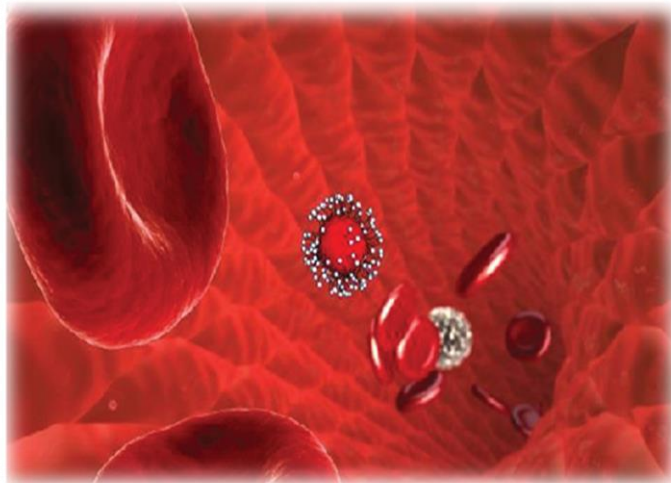
Minimum, Target, and Ideal Penetration Rates based on Use as First-Line or Second-Line Treatment from Physician Survey



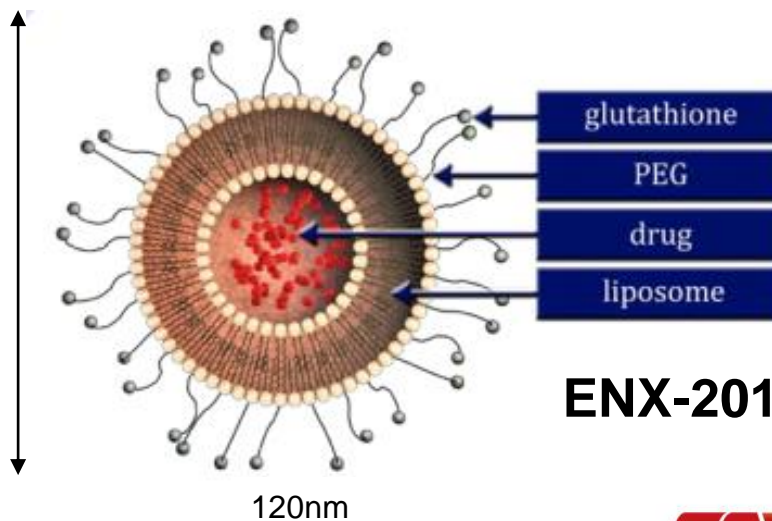
Relapses Treated with ENX-201 at Peak Under Minimum, Target, and Ideal 1st-Line/ 2nd-Line Penetration Scenarios



Introduction of the Product



Targeting Liposomal Methylprednisolone Injection (glutathione PEGylated liposomal methylprednisolone) is being developed for patients suffering from acute and chronic neuro-inflammatory diseases, with an initial focus on patients with acute MS relapses.

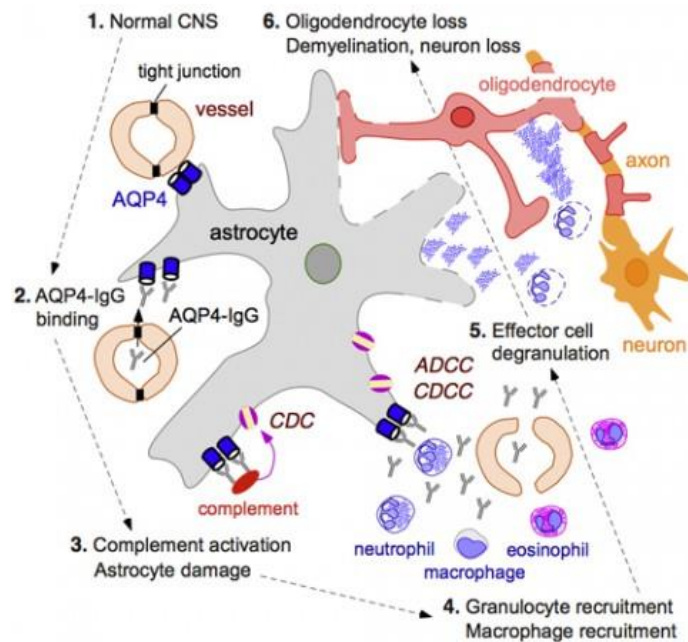


ENX-201

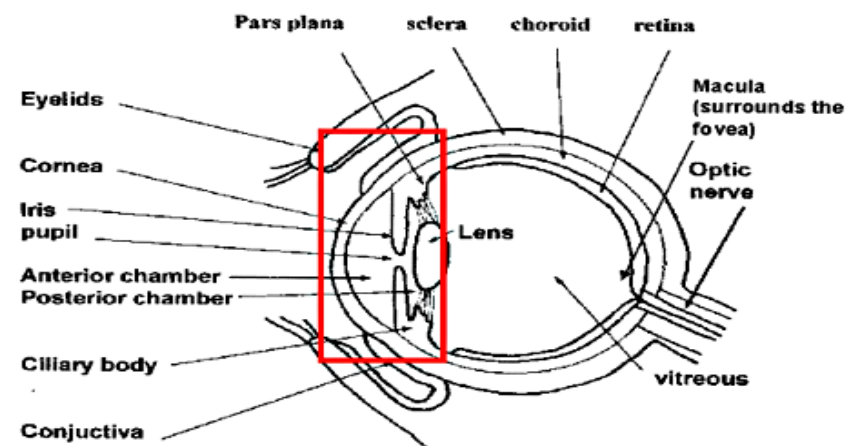
Introduction of the Product

ENX-201's potential indications

Neuromyelitis Optica



Uveitis

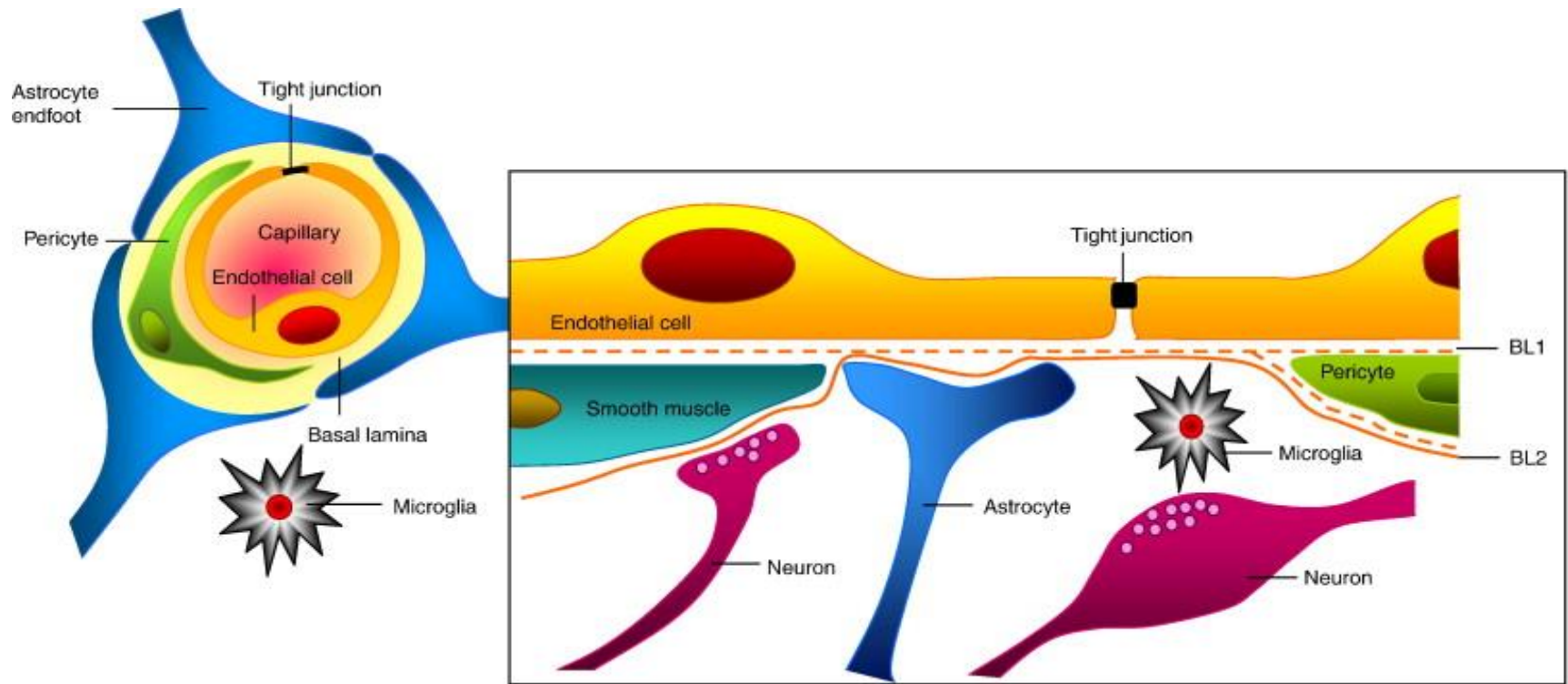


Neuro-inflammation is associated with a wide range of CNS diseases, including multiple sclerosis (MS), optic neuritis, non-infectious uveitis, acute disseminated encephalomyelitis (ADEM), neuromyelitis optica (NMO), as well as neuropathic pain, amyotrophic lateral sclerosis (ALS) and Parkinson's disease.

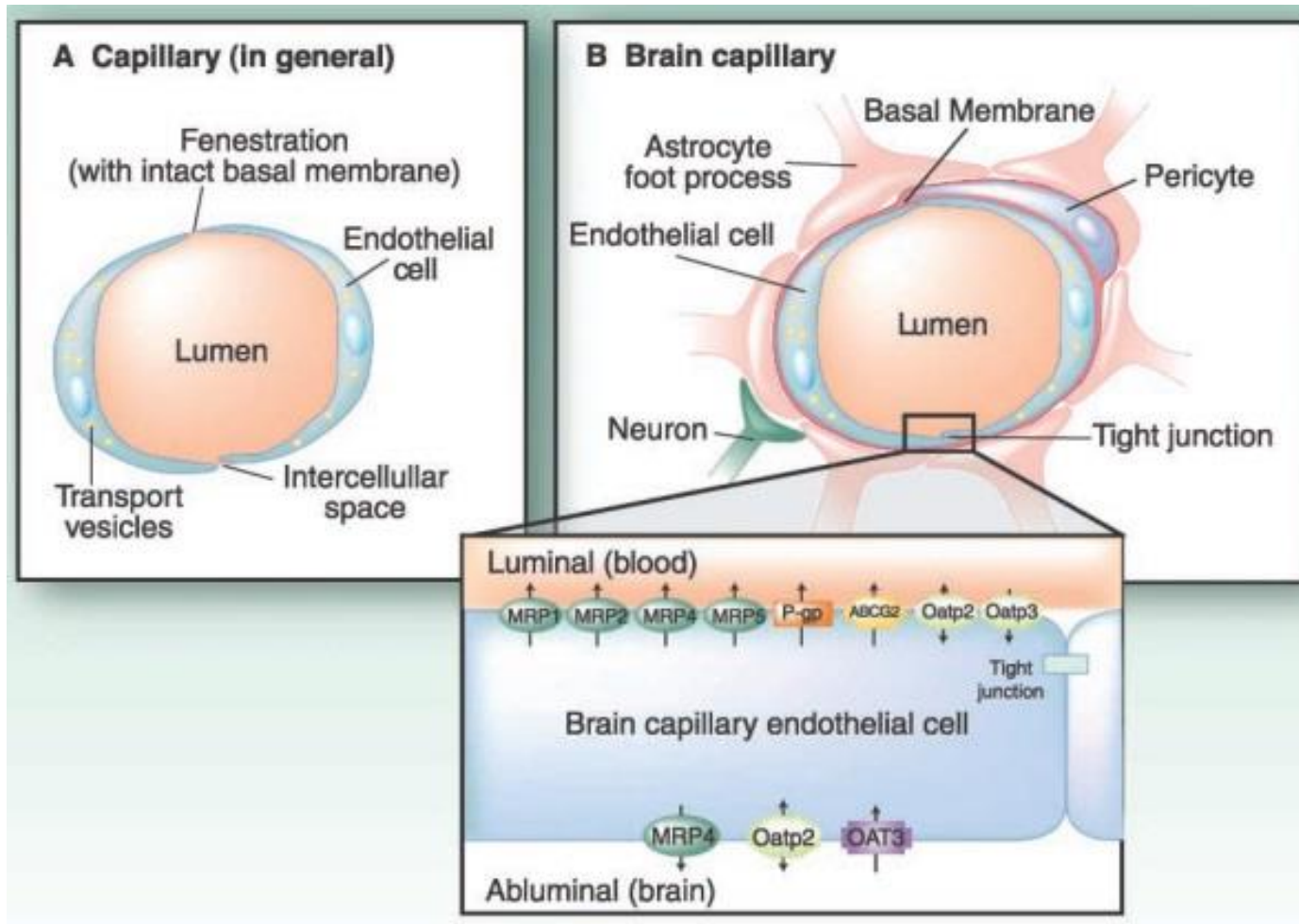
Source: http://www.msdiscovery.org/news/news_synthesis/8147-neuromyelitis-optica-part-2-pathogenesis

Source: <https://www.uveitis.net/patient/anterior.php>

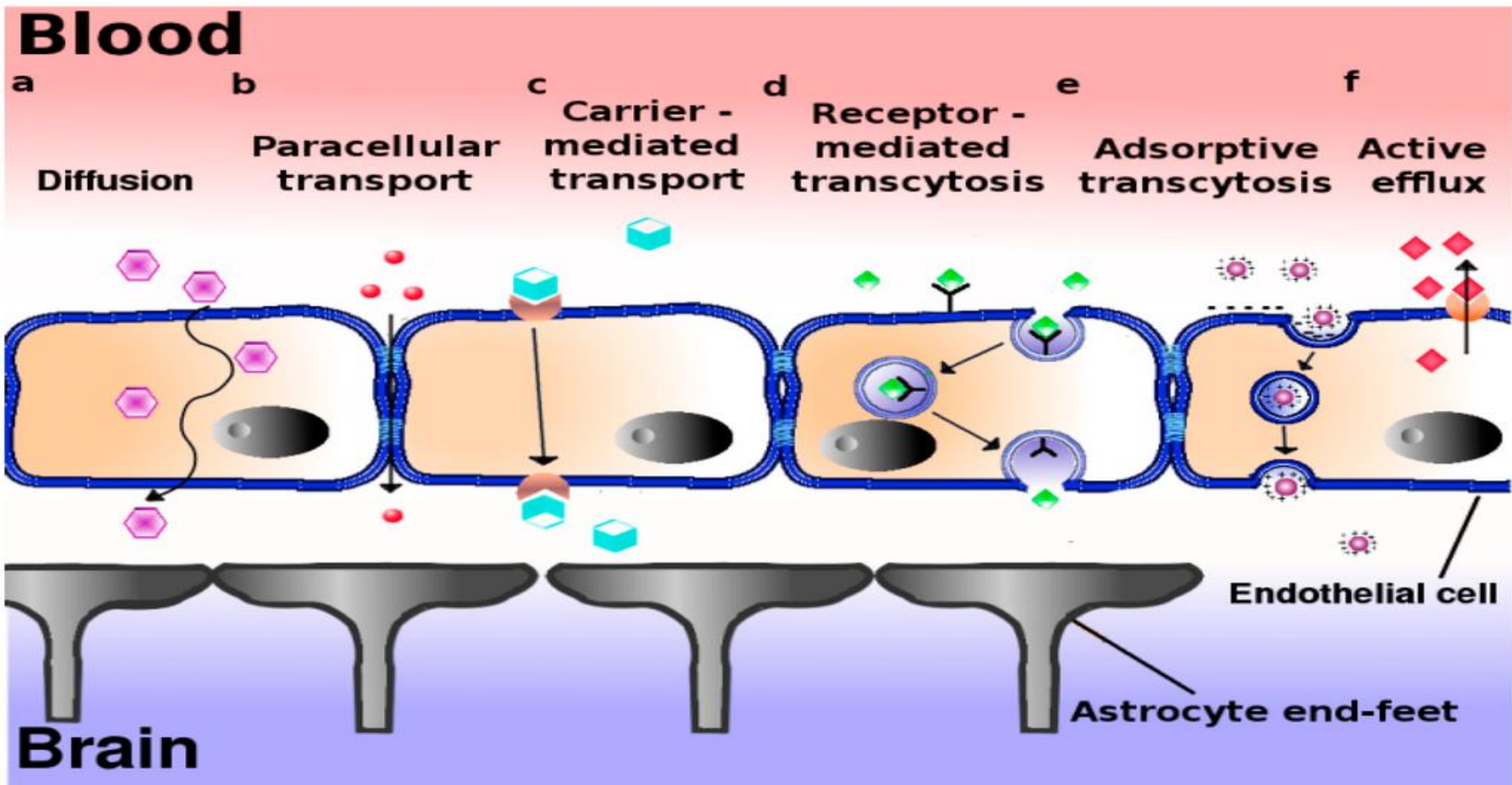
Introduction of BBB



Introduction of BBB



Introduction of BBB

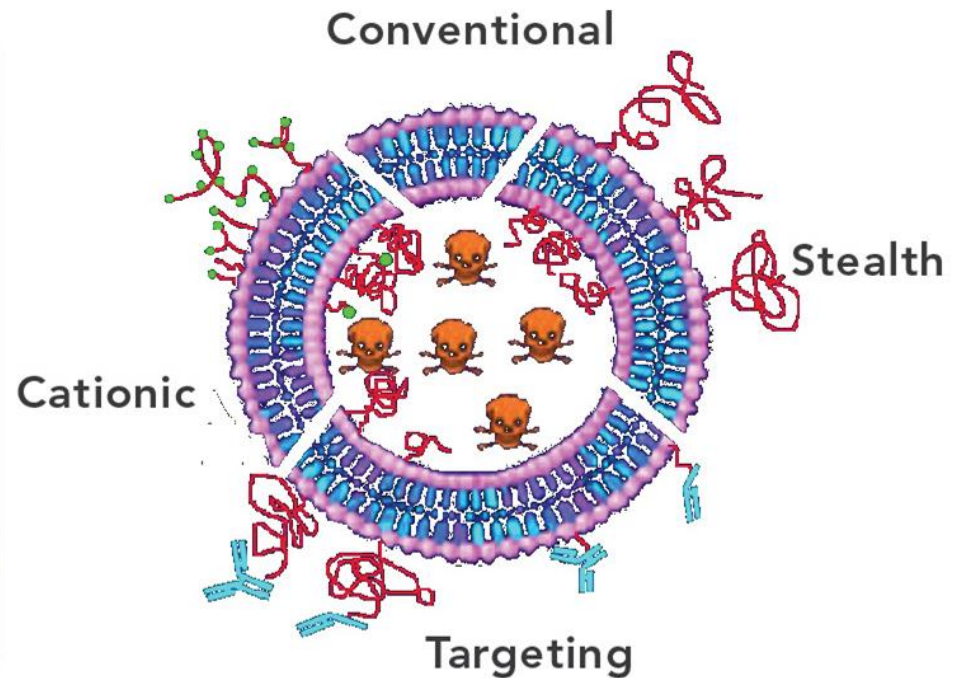
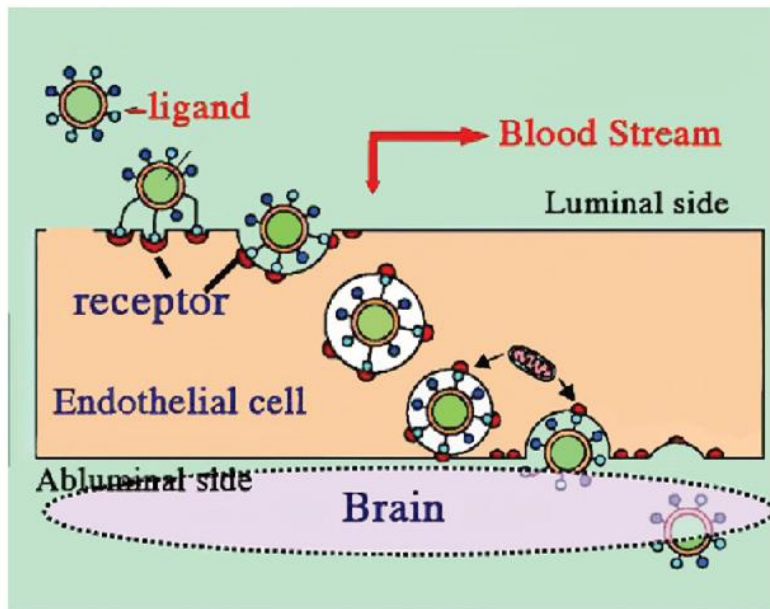


Introduction of BBB

NO.	TARGETING LIGANDS	NOTE
1	Transferrin	MBP-426, MBP-Y003
2	Melanotransferrin	
3	Insulin	
4	LDL	
5	Angiopeps	
6	Leptin	
7	Thiamine	
8	Glutathione	2B3-101, ENX-201
9	Synthetic Opioid Peptides	
10	RVG Peptide	
11	Tetanus Toxin, Tet1 and G23	
12	Diphtheria Toxin	
13	TAT peptide	

ENX-201 Introduction

Effective drug delivery to across the blood-brain barrier (BBB)



Preclinical Study

在大鼠實驗的結果顯示，在注射8小時後，在腦中MP的量，ENX-201超過非微脂體的MP6倍以上。

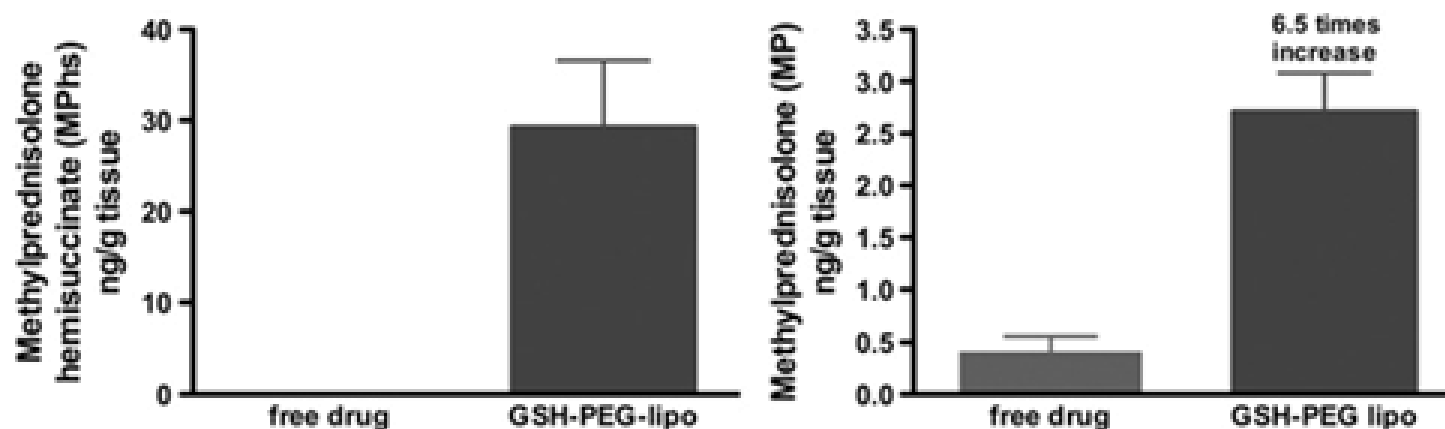
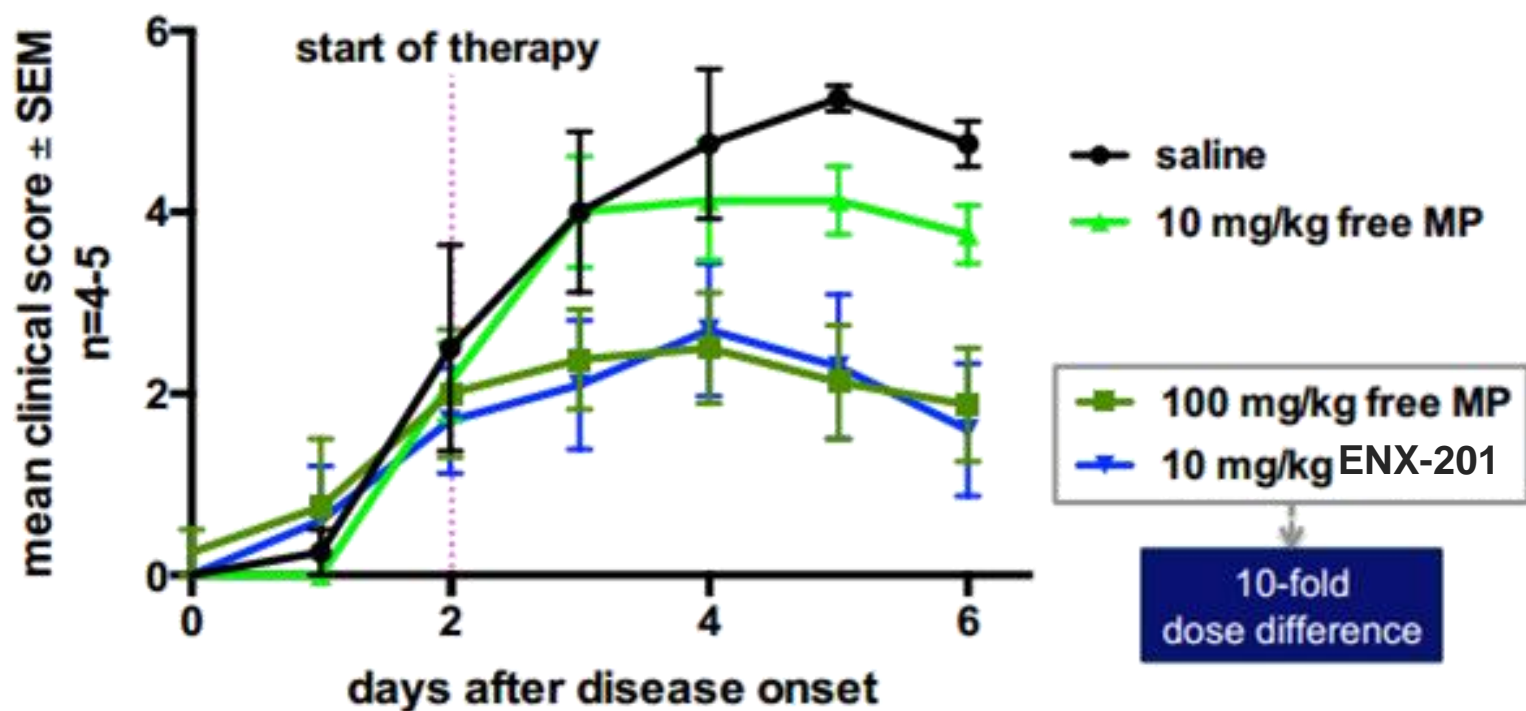


Fig. 3. Brain uptake of methylprednisolone hemisuccinate (left) and methylprednisolone (right). Rats ($n=4$ /group) received 1 bolus i.v. administration of 10mg/kg glutathione pegylated liposomal methylprednisolone (GSH-PEG lipo) or free methylprednisolone (free MPHs, 10mg/kg). Brain uptake was determined 8h after administration.

Preclinical Study

ENX-201: 藥效驗證試驗

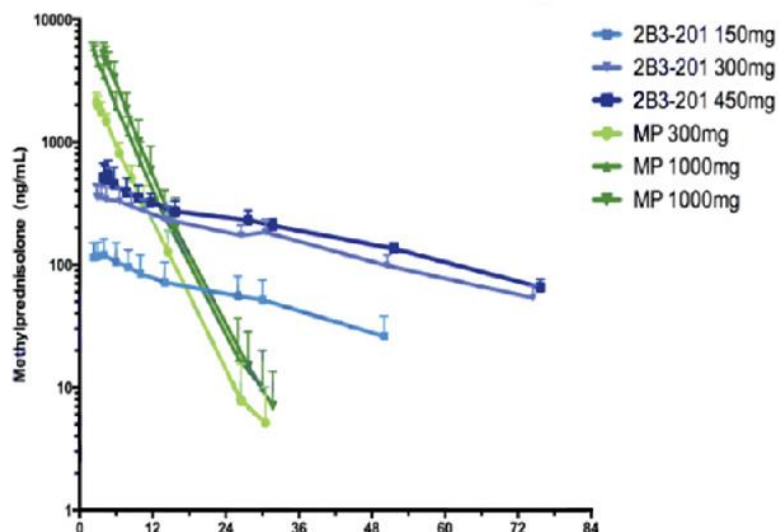
EAE-MOG mouse model of MS



Phase I Study (Solution)

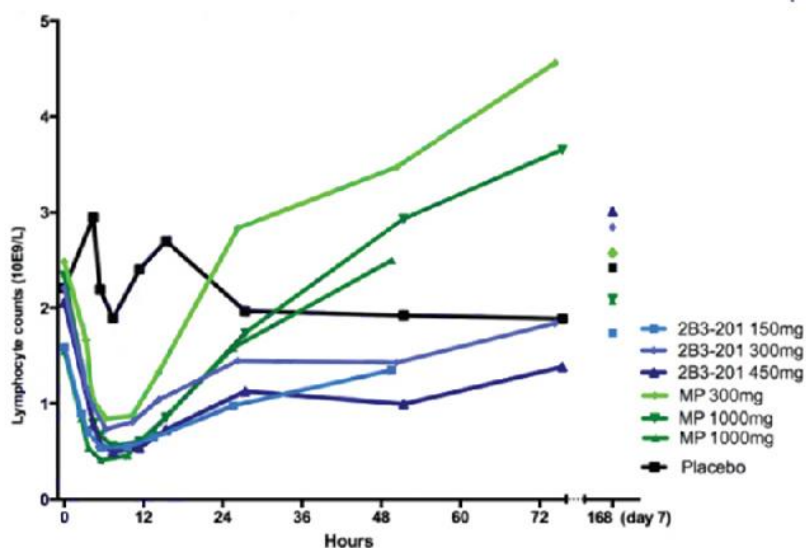
Phase I dose-escalation results Pharmacokinetics

- Long circulation half-life of ENX-201 (23~28 hrs) vs. MP (2.5 hrs)
- Reduced high peak exposure



Phase I dose-escalation results Effect on lymphocytes

- Rapid and sustained immunosuppressive effect
- Lymphocyte count crossed baseline within 7 days in all groups



Introduction of MS

Major existing choices for MS treatments

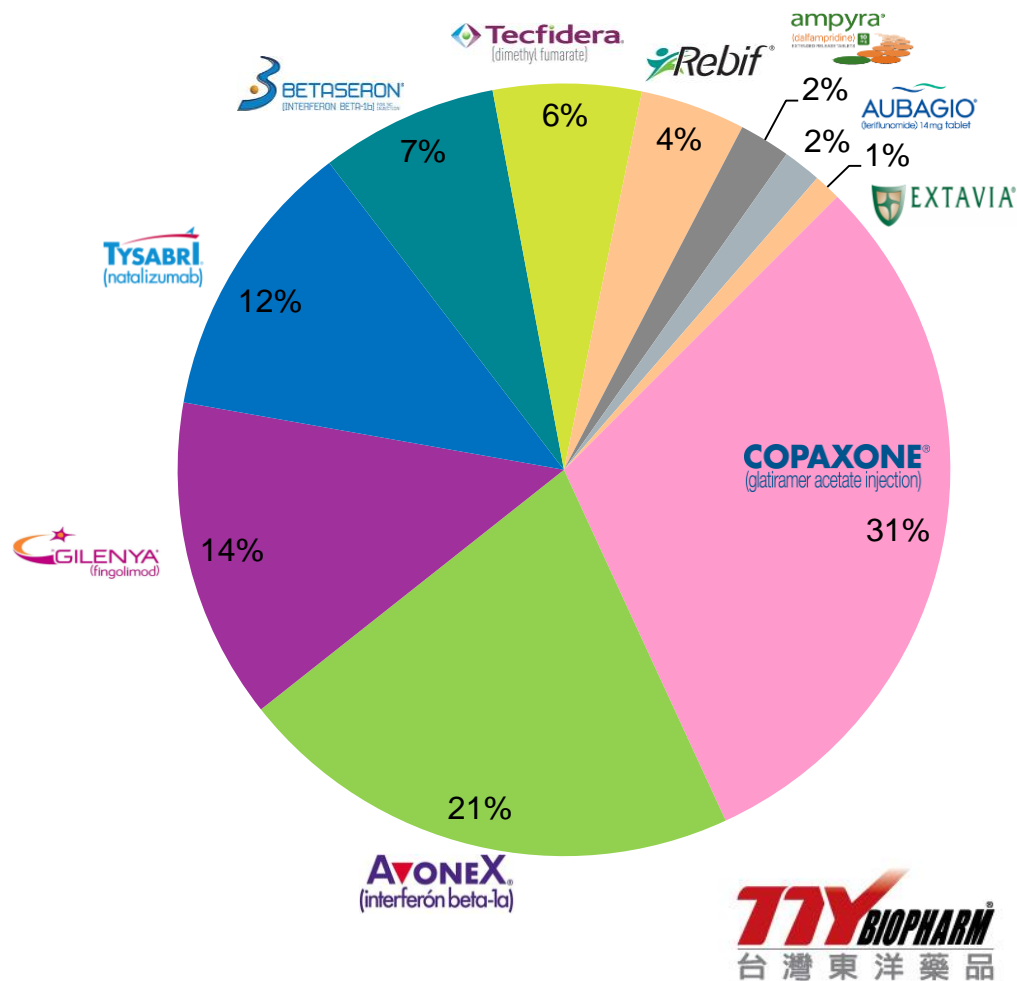
(2014 Sales & Market Share in Value)

MS Therapies

- “ABCRES” products represented 64% of the global MS market in value in 2014
 - Moderate efficacy and patients continue to relapse on therapy
 - Require frequent injections
- Latest entrants represent treatment alternatives
 - Drives the benefit vs. risk discussion

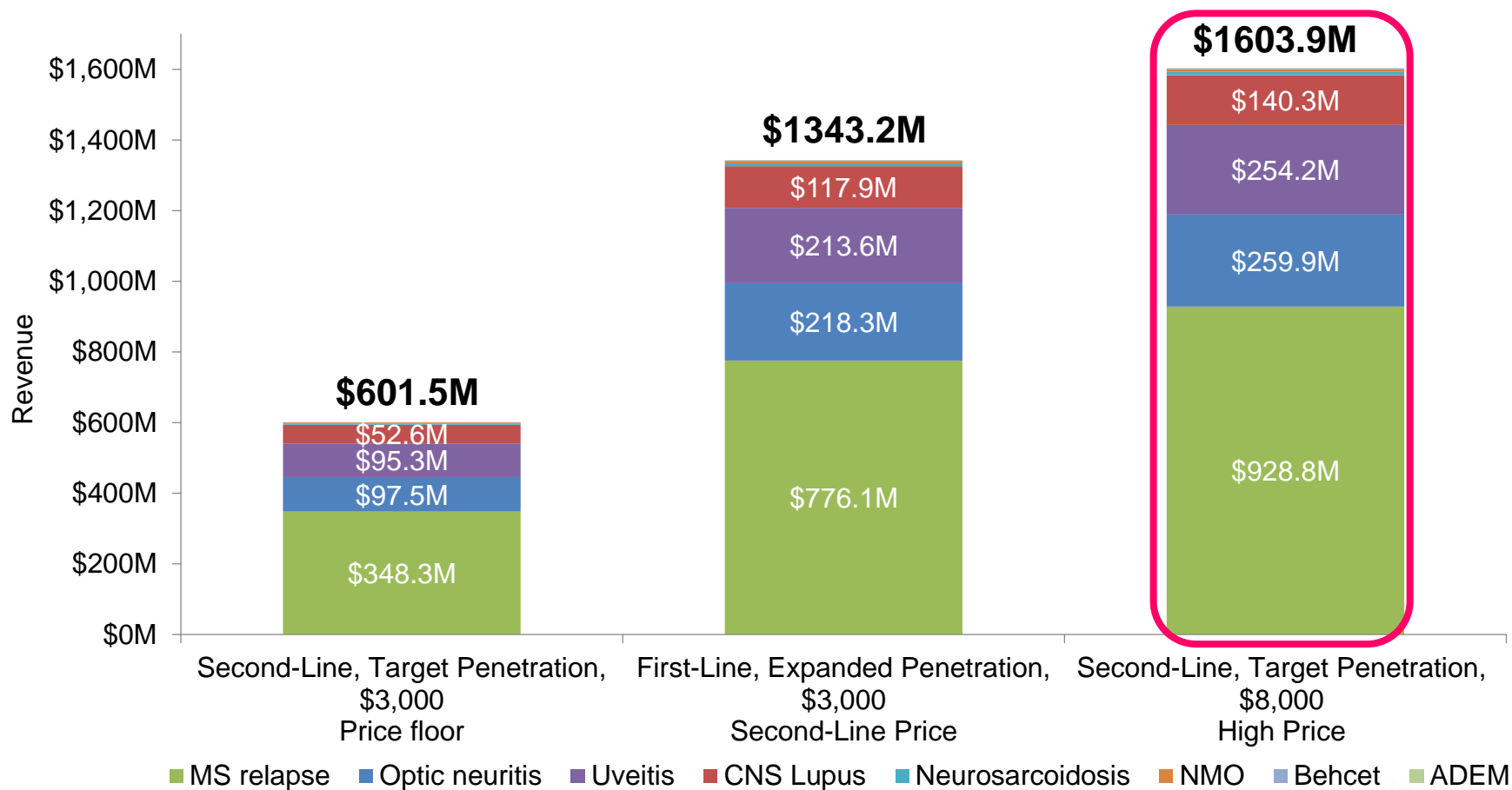
Unit: USD

4.328B	■ Copaxone
3.0B	■ Avonex
1.9B	■ Gilenya
1.67B	■ Tysabri
1.05B	■ Betaseron
876M	■ Tecfidera
622M	■ Rebif
302M	■ Ampyra/ Fampyra
266M	■ Aubagio
159M	■ Extavia



Potential Market Size

ENX-201 US Peak Year Revenue – MS & Other Inflammatory Indications



Potential Market Size

Global estimation

MS treatment market rising from \$17.2 billion to \$20 billion (YoY) from 2014 to 2024 (approx.), at a Compound Annual Growth Rate (CAGR) of 1.5%.

Global existing MS treatment market value

2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
17.20B	17.46B	17.72B	17.99B	18.26B	18.53B	18.81B	19.09B	19.38B	19.67B	19.96B

■ ENX-201's strengths

- *ENX-201 is a pegylated liposome which glutathione is attached on its lipid, while methylprednisolone as the main substance is encapsulated inside.*
- *Compared with the standard of care, i.e., a free methylprednisolone, ENX-201 is an **one-shot** intravenous injection which brings **home-care convenience** and **better tolerance** to patients suffering acute multiple sclerosis relapses.*

ENX-201 Pipeline

ENX-201 : Liposomal Methylprednisolone Injection (glutathione PEGylated liposomal methylprednisolone)

	2014 - 2016			2017			2018			2019			2020			2021			2022			
Phase I	█	█	█	█	█	█																
Phase I bridging study (lyophilized injection)							█	█	█	█	█	█										
Scientific advice from FDA & EMA							█	█	█	█	█	█										
Phase II/III in MS relapses (vs placebo)							█	█	█	█	█	█	█	█	█	█						
Phase II/III in MS relapses (vs MP)							█	█	█	█	█	█	█	█	█	█	█	★	→	→	→	
US NDA indication #1																	█	█	█	█		
EU MAA indication #1																	█	█	█	█		

Multiple Indications to Go (Pipeline)

	Indications to Develop	Market Potential Size	Competitors
1	Multiple Sclerosis (多發性硬化症)	>21.5B	Teva (2014) Biogen EMD Serono Novartis
2	Uveitis (葡萄膜炎) (眼睛發炎)	>0.531B	Humira (2016)
3	Neuropathic Pain (神經性疼痛)	>5.7B	Pfizer (2011)
4	Osteoarthritis (骨關節炎)	>5.335B	Anika (2014)
5	ALS (漸凍人—肌萎縮性脊髓側索硬化症)	>25M (a negative CAGR of 16.10%)	Biogen Idec Inc. Avanir Pharmaceuticals Inc. Isis Pharmaceuticals Inc. Sanofi Bristol-Meyers Squibb Co.
6	Mucopolysaccharidoses (MPS, 黏多醣症)	>300M	Vimizim
7	Metachromatic leukodystrophy (MLD, 異染性腦白質失養症)	1B	Shire Plc Nuo Therapeutics GlaxoSmithKline Plc Zymenex A/S RegenxBio Inc. Novartis AG

Unit: USD/Billion

ENX-201 Management Team



Yu-Fang Hu



Pieter J. Gaillard



Yuan-Yi Chou



ENX-201 Scientific Advisory Board

蔡清標
Taipei, Taiwan



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臺北榮民總醫院
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Medical Center
Amsterdam

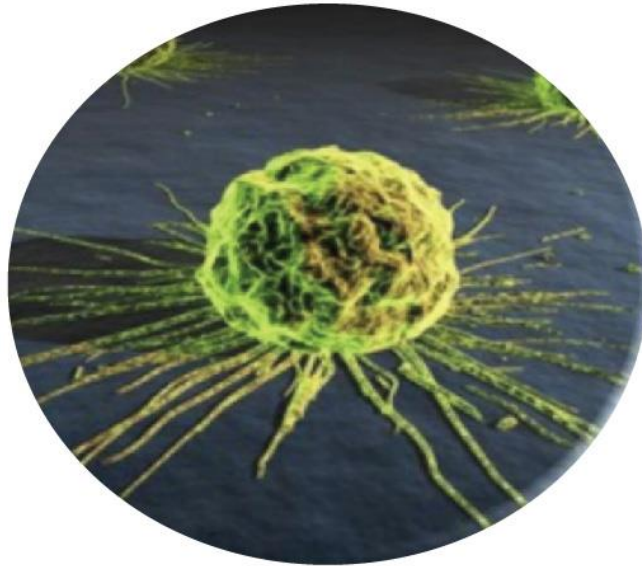
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Super Generics Pipeline

產品組合	適應症	R&D (E)	
Caelyx/Doxil* (Lipo-Dox)	轉移性乳癌、 愛滋病引發之卡波西氏肉瘤、 多發性骨髓瘤、卵巢癌	←	Pegylipo's license fee US\$3,500,000 = US\$500,000 (Upfront Fee) + US\$ 1,000,000 *3 (Milestone payment) Pegylipo's sales – profit sharing
Pegylipo		→	
Lipo-AB	利時曼氏病(黑熱病)、骨髓移植 併發腎毒侵入性細菌感染、 愛滋病患者腦膜炎、腎功能不全 之菌種感染病患	←	Lipo-AB's license fee US\$3,500,000 = US\$500,000 (Upfront Fee) + US\$ 1,000,000 *3 (Milestone payment) Lipo-AB's sales – profit sharing
Leuprolide Acetate Injection	前列腺癌、子宮內膜異位症、 子宮肌瘤、中樞性早熟	→	
Risperidone Injection	精神分裂	→	
Octreotide	肢端肥大症、功能性胃、腸、 胰臟內分泌腫瘤	→	
Colimycin	非一般抗生素，多重抗藥性 之革蘭氏陰性菌之嚴重感染	→	TW Approved China

產品組合	World Market USD/M (est.)	核心技術	產品優勢
Caelyx/Doxil* (Lipo-Dox)	600	Pegylated Liposome Technology	Worldwide Manufacturing Patent
Pegylipo			
Lipo-AB	440	Liposome Technology	Worldwide Manufacturing Patent
Leuprolide Acetate Injection	1,240	Lupron Depot Microsphere Formulation	Worldwide Manufacturing Patent
Risperidone Injection	960	Microsphere Formulation	Worldwide Manufacturing Patent
Octreotide	1,500	Microsphere Formulation	PLGA, Star Polymers Synthesized by TTY.
Colimycin	150	Formulation	First Choice Irreplaceable options, TWNIH

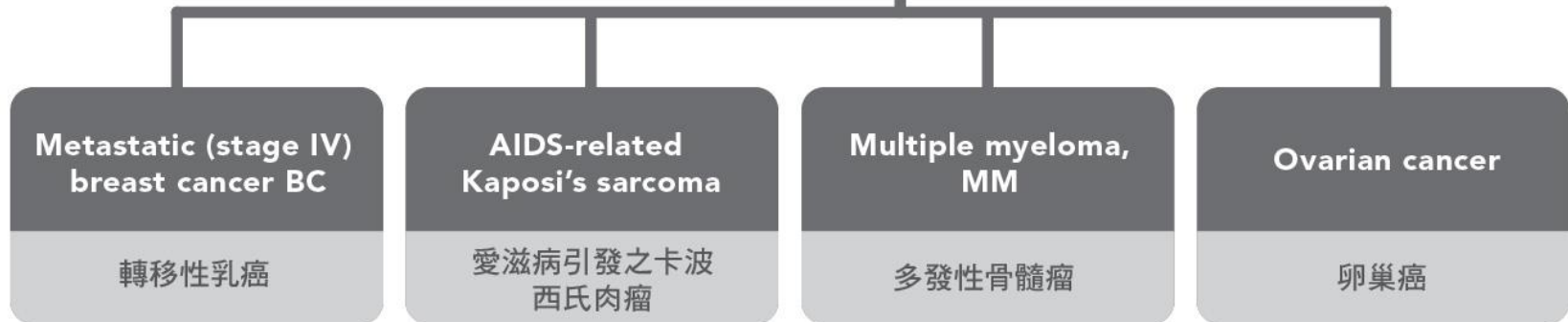
Specialty- Caelyx®/Doxil®/Pegylipo®



Caelyx®/Doxil®/Pegylipo®

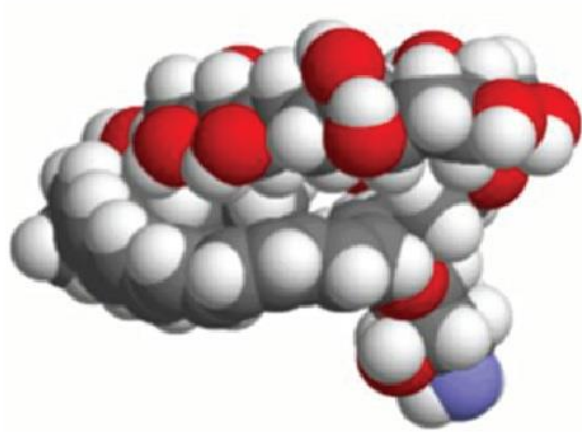
Global market: USD\$600M

Taiwan NTD\$200M



Source : Thomson Reuters Mar./2017

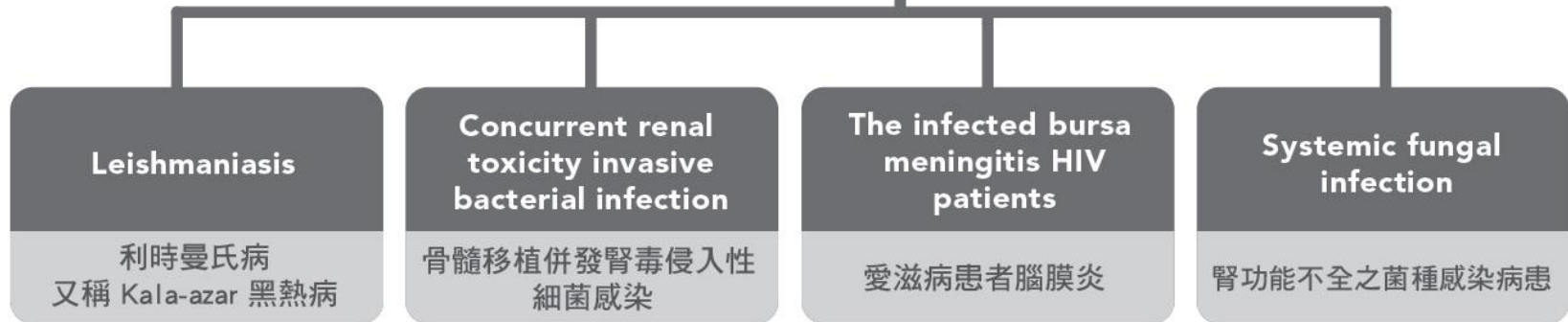
Specialty- Lipo-AB



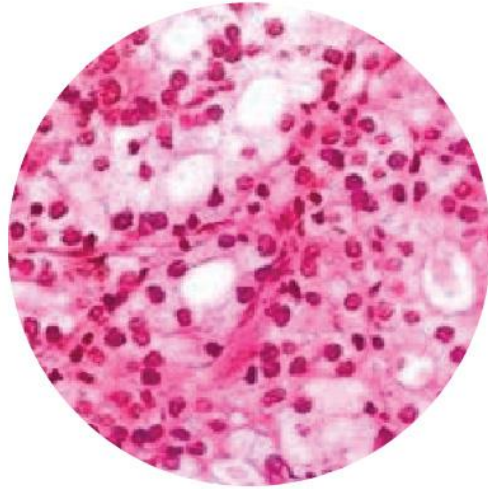
Lipo-AB

Global market: USD\$440M

Target: worldwide 35~50%



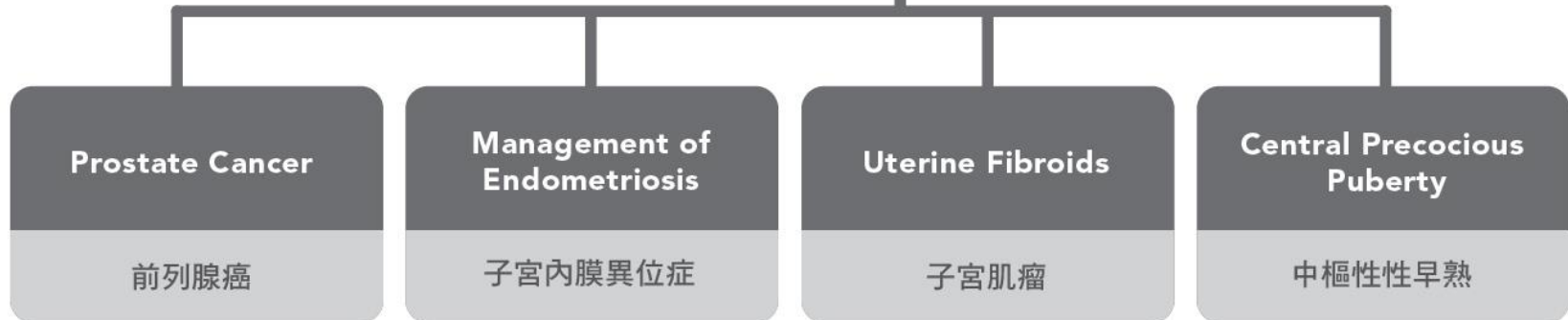
Specialty- Leuprolide



Leuprolide Acetate Injection

Global market: USD\$1,240M

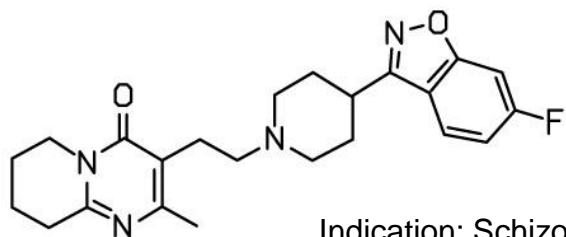
Target: worldwide 20~35%



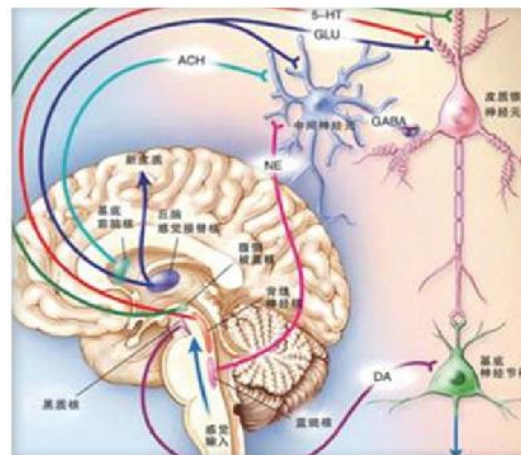
Specialty- Risperidone Injection

Risperidone Injection

Global market: USD\$960M

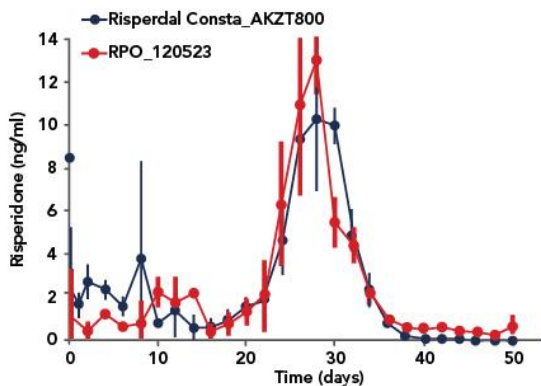


Indication: Schizophrenia

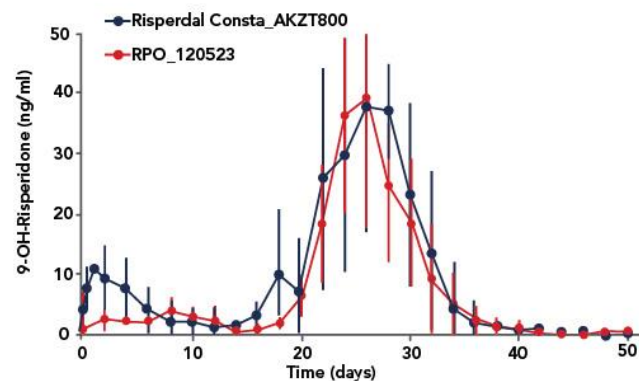


Beagle in vivo release

Risperidone



9-OH-Risperidone



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Specialty- Octreotide

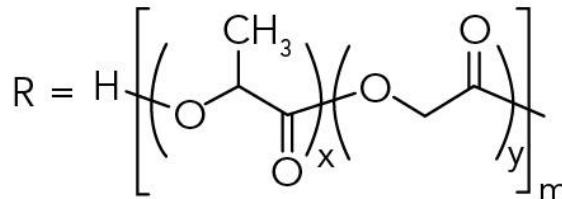
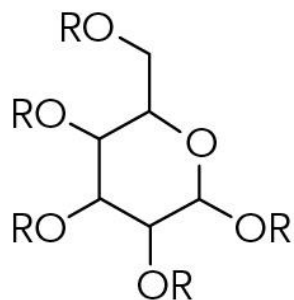


Indications:

- Acromegaly
- Severe diarrhea/flushing episodes associated with metastatic carcinoid tumors
- Profuse watery diarrhea associated with VIP-secreting tumors

Synthesized by TTY

TTY synthetic star polymers as a carrier!!



Polymer	Lot	MW(K Da)	PI
Poly(lactide-co-glycolide) star, glucose core LA:GA=1:1	TTY#783053	53	1.67

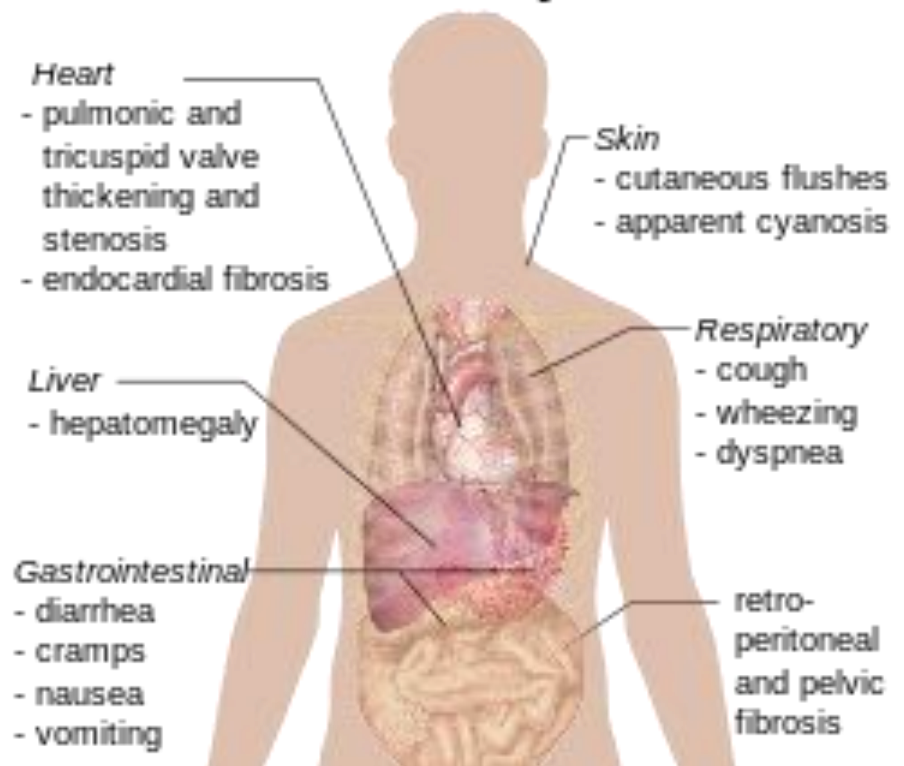
Introduction of Octreotide

Symptoms-

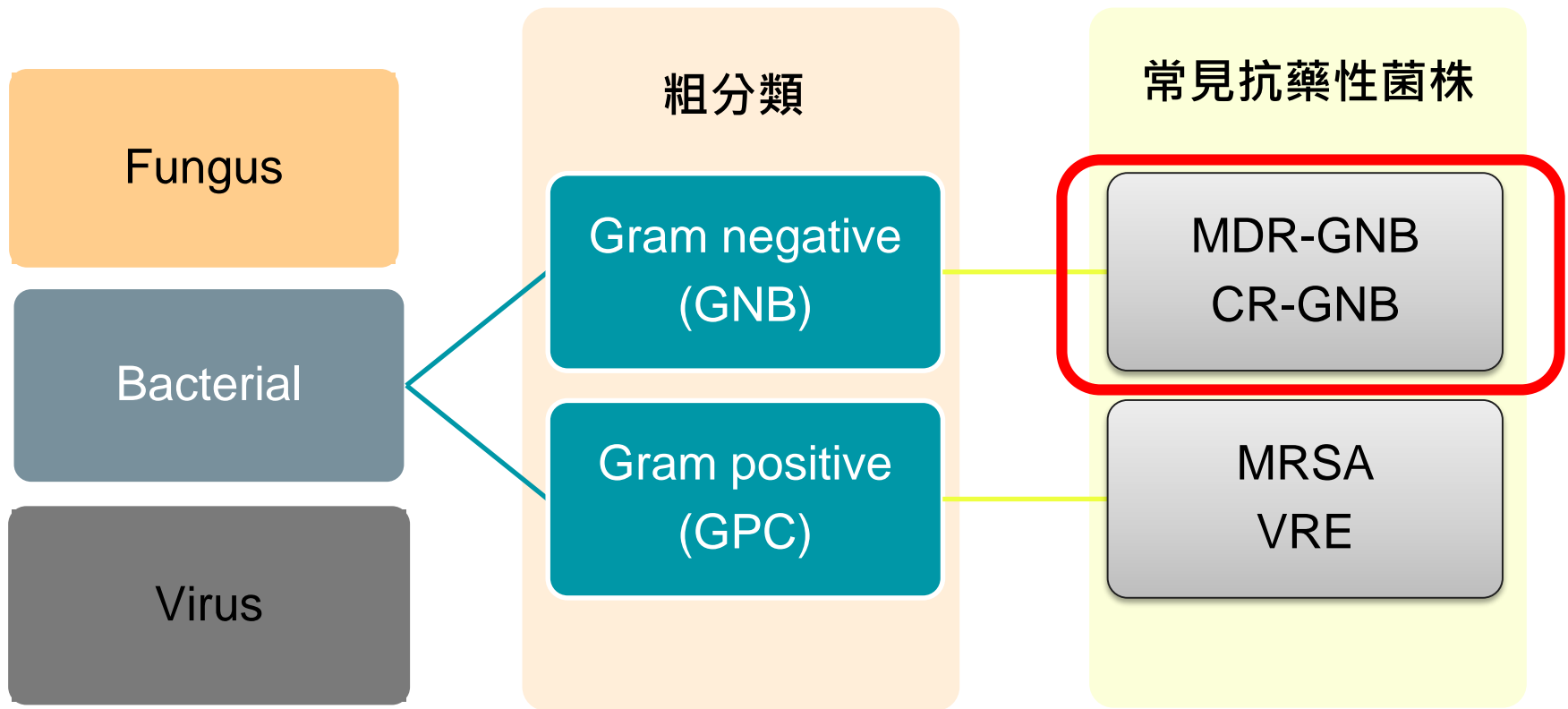
- Acromegaly
- Metastatic Carcinoid tumors
- VIP-secreting tumors



Carcinoid syndrome



Colimycin



MDR-: multi-drug resistant
CR-: carbapenem resistant

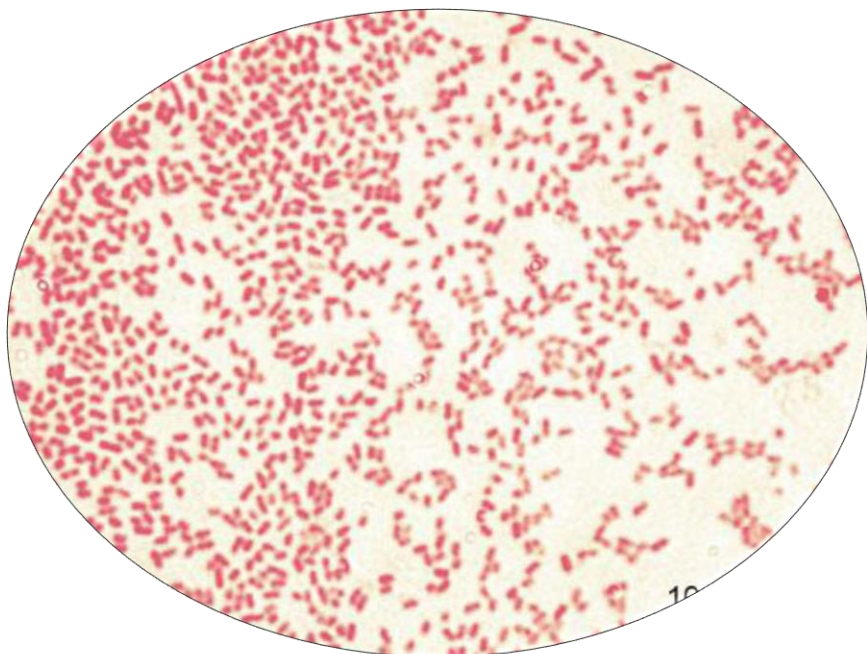
MRSA: methicillin resistant *Staphylococcus aureus*
VRE: vancomycin resistant *Enterococcus*

Colimycin

Colimycin

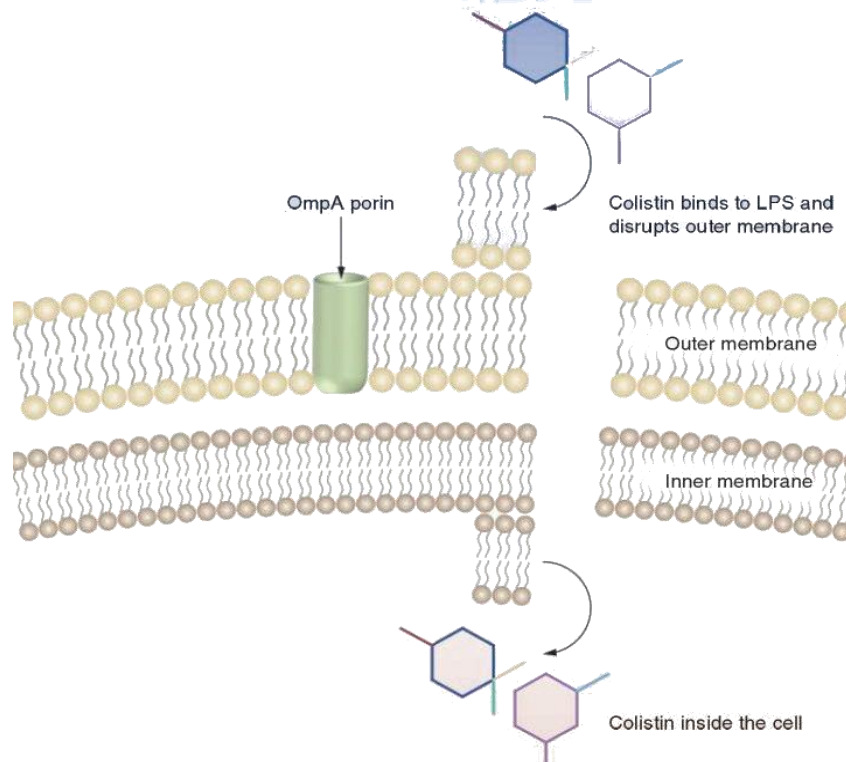
Global Market: US\$150M

China Market: RMB\$1.0B



限用於一般抗生素無效，
且具多重抗藥性之革蘭氏
陰性菌之嚴重感染。

Medscape



Source: Expert Rev Anti Infect Ther. 2012;10(8):917-934

From: Y_tambe's file, CC BY-SA 3.0,
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TTV BIOPHARM
台灣東洋藥品

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Product Pipeline

Manufacture Facilities

Successful Product Categories

In Progress Status

Biotech Success

Manufacture Facilities

- The only PIC/S GMP certified manufacture sites for high potency oncology, 2008/2013/2016 EMA, 2010/2014 Japan, 2013/2016 US FDA, 2013 Brazil, Australia
- High standard Validation of
 - Equipment qualification/ Laboratory instruments qualification/ HVAC system/ Water system/ Compressed air system/ Nitrogen system/ Cleaning/ Analytical method/ Process/ Computer/ Logistic
- Individual flow management
 - Air flow/ Man flow/ Material flow/ Product flow/ Waste flow
 - To prevent cross contamination and environmental pollution

HVAC System



Work Safety



Environmental Protection



中壢廠



2008
EMA
Arabian
Official



2009
EMA
Official



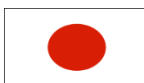
2010
Jordan
Official



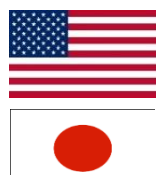
2011
Germany
Official
Brazil
Official



2012
Japan
Official



2013
US FDA
Japan
Official



2014
EMA
Turkey
MOH



2015
Korea
Kazakhstan
EMA



2016
US FDA



2017
Belarus/
Indonesia



六堵廠



- Comply with PIC/S GMP and Taiwan FDA inspection for **non-cytotoxic or non-hormone**



TTY BIOPHARM[®]
台灣東洋藥品

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Biotech Success

Oncology/Successful Products for Global

TTY has successfully registered **47** oncology product licenses in **9** countries.

Country	UFur	Oxalip	Lipo-Dox	Irino	Asadin	Gemis	Tynen	Epicin	Thado	Anazo	Folina	Sulfin	Algycon	Colimycin	Maxtam	Total
Thailand	1	1	1	1	1				1		1	1	1	1	1	11
Philippines			1	1	1			1		1		1	1			7
Vietnam	1	1	1	2	1		2		1							9
Hong Kong	1	1		1		2	2	3								10
Malaysia	1		1		1		1		1		1					6
Singapore				1												1
India	1															1
Sri Lanka										1						1
Guatemala			1													1
Total	5	3	5	6	4	2	5	4	3	2	2	2	2	1	1	47

國際代工合作廠商擁有Lipo-Dox在美國(Doxil)及歐洲(Caelyx)之藥證。

Successful Oncology Products

Asadin
(伸定注射劑)



TS-1
(愛斯萬膠囊)



Epicin
(益彼欣注射液)



Tynen
(汰能注射劑)



Anazo
(安納柔膜衣錠)



Gemmis
(建仕注射劑)



Zobonic
(抑骨凍晶靜脈
注射劑)



Ivic
(癌微可膜衣錠)



UFUR
(友復膠囊)



Pexeda Inj.
(派癌休注射劑)



Lipo-Dox
(力得微脂體
注射劑)



Painkyl
(平舒疼口頰溶片)



Oxalip
(歐力普注射劑)



Thado
(賽得膠囊)



Irino
(益立諾)



Lonsurf
(朗斯弗膜衣錠)



Megest
(麥格斯口服
懸液劑)



Otril
(嘔速停靜脈
注射劑)



Folina
(芙琳亞錠)

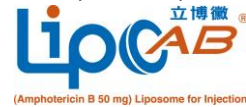


Successful Products of Intensive Care

Brosym C+S
(博益欣)



Lipo-AB
(立博儻)



Colimycin
(克痢儻素注射劑)



Cubicin
(救必辛注射劑)



Flusine
(弗路欣錠)



Exacin
(依克沙)



Maxtam
(抑酉每靈注射劑)



Agrippal
(安爾保流感疫苗)



Successful Healthcare Products

Algitab
(艾胃逆服)



Cepiro
(希比洛靜脈乾粉注射劑)



Alginos
(胃逆舒)



METACIN
(西腹黴素注射劑)



BIO-CAL PLUS
(滋骨咀嚼錠)



Sulfin
(速復利錠)



R&D Investment 研究及臨床

Subject \ Year	2013	2014	2015	2016	2017
Revenue (NTD,000)	2,307,540	2,384,220	2,738,956	3,344,262	3,672,040
R&D Expense (NTD,000)	289,530	283,470	236,398	230,192	219,126
Total Staff	484	494	450	508	520
R&D Manpower	111	105	97	105	98
R&D Expense/ Revenue	12.55%	11.89%	8.63%	6.88%	5.97%
R&D Total Staff	22.93%	21.26%	21.56%	20.67%	18.85%

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Financial Disclosure

歷年財務報表 (個體)

NTD in Thousands

Item	2013		2014		2015		2016		2017	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
Net Sales	2,292,163	100%	2,384,207	100%	2,738,956	100%	3,344,262	100%	3,672,040	100%
Gross Profit	1,404,003	61%	1,411,875	59%	1,777,941	65%	2,217,286	66%	2,347,809	64%
Operating Expenses	-1,121,548	-49%	-1,144,400	-48%	-1,035,412	-38%	-1,063,104	-32%	-1,135,595	-31%
Operating Profit	282,455	12%	267,475	11%	742,529	27%	1,154,182	34%	1,212,214	33%
Non-Operating Income and Expenses	413,685	18%	596,585	25%	705,211	26%	277,855	9%	351,484	10%
Income before Tax	696,140	30%	864,060	36%	1,447,740	53%	1,432,037	43%	1,563,698	43%
Net Income	587,440	26%	779,645	33%	1,211,018	44%	1,193,324	36%	1,344,731	37%
EPS	2.52		3.14		4.87		4.80		5.41	

歷年財務報表 (合併)

NTD in Thousands

Item	2015		2016		2017		1Q/18	
	Amount	%	Amount	%	Amount	%	Amount	%
Net Sales	3,195,218	100%	3,760,717	100%	4,078,760	100%	1,040,455	100%
Gross Profit	2,183,144	68%	2,559,220	68%	2,668,845	65%	697,820	67%
Operating Expenses	-1,393,357	-44%	-1,379,533	-36%	-1,411,855	34%	387,207	37%
Operating Profit	789,787	24%	1,179,687	32%	1,256,990	31%	310,613	30%
Non-Operating Income and Expenses	735,808	23%	332,372	8%	338,077	8%	33,818	3%
Income before Tax	1,525,595	47%	1,512,059	40%	1,595,067	39%	344,431	33%
Net Income (Consolidated)	1,246,592	38%	1,254,724	33%	1,368,314	33%	267,664	26%
Net Income (TTY)	1,211,018	37%	1,193,324	31%	1,344,731	32%	255,944	25%
EPS	4.87		4.80		5.41		1.03	

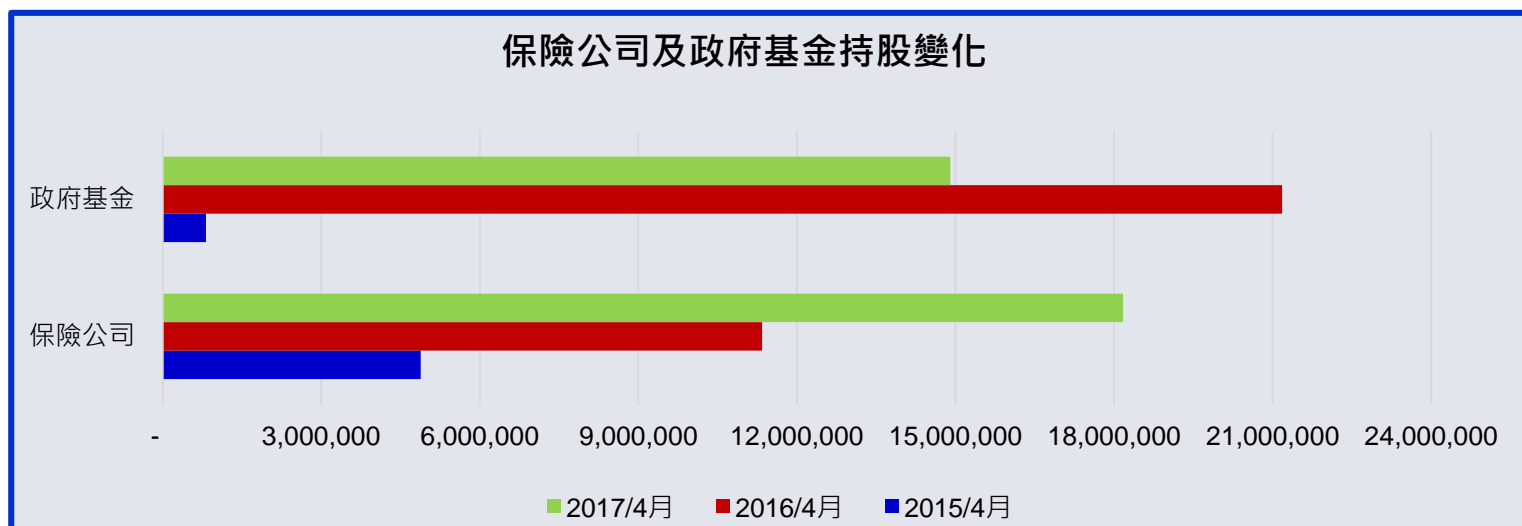
Dividend Payout 股息配發

Item \ Year	Year				
	2013	2014	2015	2016	2017
Yield Rate (%)	1.91	2.39	3.86	3.42	4.52
P/E	41.65	33.23	18.61	23.16	18.39
Cash Dividend	2.00	2.50	3.50	3.80	4.50 (note)
Cash Payout Ratio	79.4%	79.6%	71.9%	79.2%	83.2%
Stock Dividend	0.67	-	-	-	-
Total Dividend	2.67	2.50	3.50	3.80	4.50

Note: Board of Directors proposed dividend payout and would be further approved by Annual General Meeting.

保險公司及政府基金持股

機構 \ 持股情形	2015/4月		2016/4月		2017/4月	
	持有股數	持股比例	持有股數	持股比例	持有股數	持股比例
保險公司	4,880,800	1.96%	11,339,000	4.56%	18,169,000	7.31%
政府基金	817,021	0.33%	21,177,843	8.52%	14,904,000	5.99%
合計	5,697,821	2.29%	32,516,843	13.08%	33,073,000	13.30%





Let's share and grow together
in this big family



東生華製藥
tsh biopharm



PharmaEngine

智擎生技製藥股份有限公司

