

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<sup>®</sup> BIOPHARM**

**台灣東洋藥品**

**WELCOME TO JOIN US**

April, 2017

# 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.

TTY Biopharm cautions that this foregoing list of factors is not exhaustive. There may also be other risks that management is unable to predict at this time that may cause actual results to differ materially from those in forward-looking statements.

**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

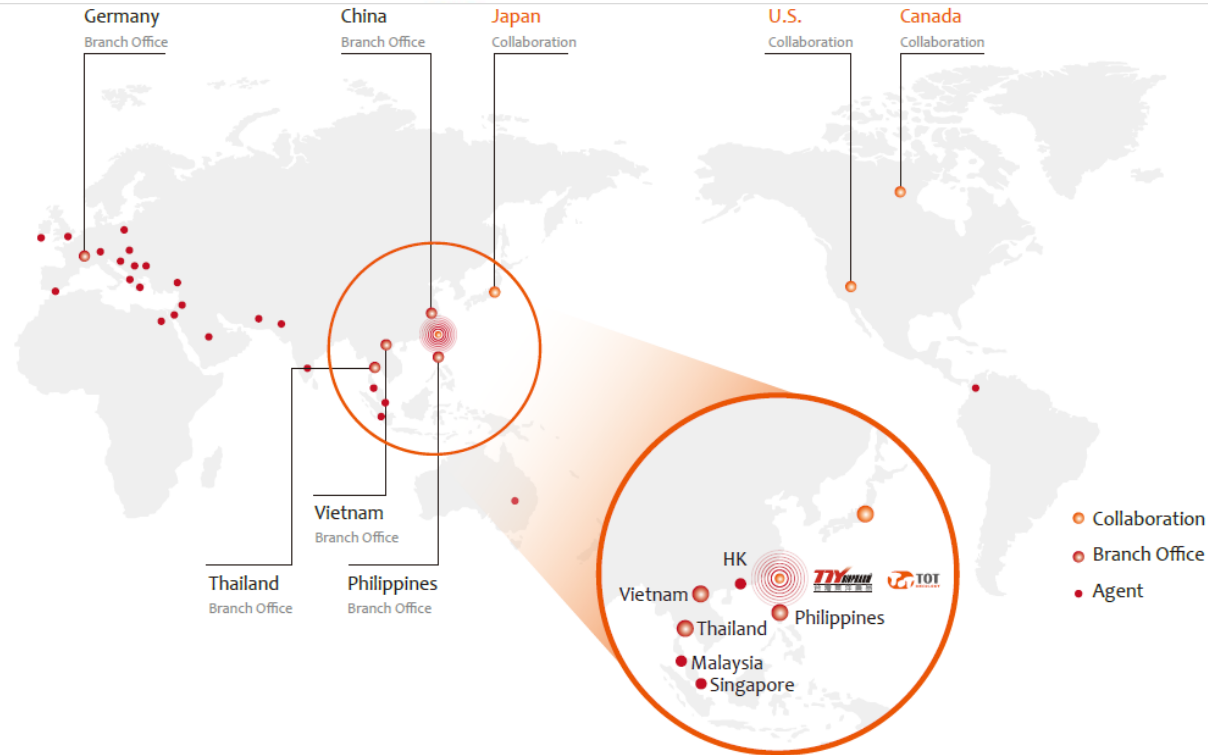
Manufacture Facilities

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 (March, 2017)**

- **TTY Biopharm consolidated sales as of 2016- NTD 3.80 Billion, USD 117 Million**
- **Headquarters: Taipei, Taiwan**  
**Number of employees: 508**





- TTY Biopharm is a global leader in Super-Generic Drugs and novel bio-drug development with strong growth potentials (targeting for 20% sales CAGR in 2014-19).
- TTY is Taiwan's largest biotechnology conglomerate with the most completed biotechnology products pipeline including oncology drugs, new formulations, ... etc.
- Market cap US\$906mn. As of 2/24/2017
- Currently has three major subsidiaries (base on 12/31/2016): PharmaEngine (listed), Market cap US\$689mn, 19.30% ; TSH Biopharm (listed), Market cap US\$85mn, 56.48%; CY Biotech, 27.54%
- Shareholder value creation-
  - TTY's ROE 19.5% in 2011-2016, ROE 21.4% in 2016 (above industry average 7.35%).
  - TTY targets for 28%-35% ROE in 2017-2020.
  - TTY aims to be a world-class biotechnology public listed company with multi-bn market capitalization in coming years.



## Major Investments

轉投資主要架構

Global  
Taiwan  
China  
Asia

殷瀚

EnhanX (67%)

- Clinical Trials Development
- R&D Development & Marketing

東生華製藥

TSH (56.48%)

- New Drug Development & Marketing of Chronic Diseases (CV/GI/Immune)

智擎生技

PharmaEngine (19.30%)

- New Drug Development

創益生技

CY Biotech (27.54%)

- Probiotics & Obesity Diseases

榮港生技

WorldCo (100%)

- New Drug Development (liver/ID/CNS)
- Marketing

ATB泰/ATB菲/越辦事處

40%/87%/100%

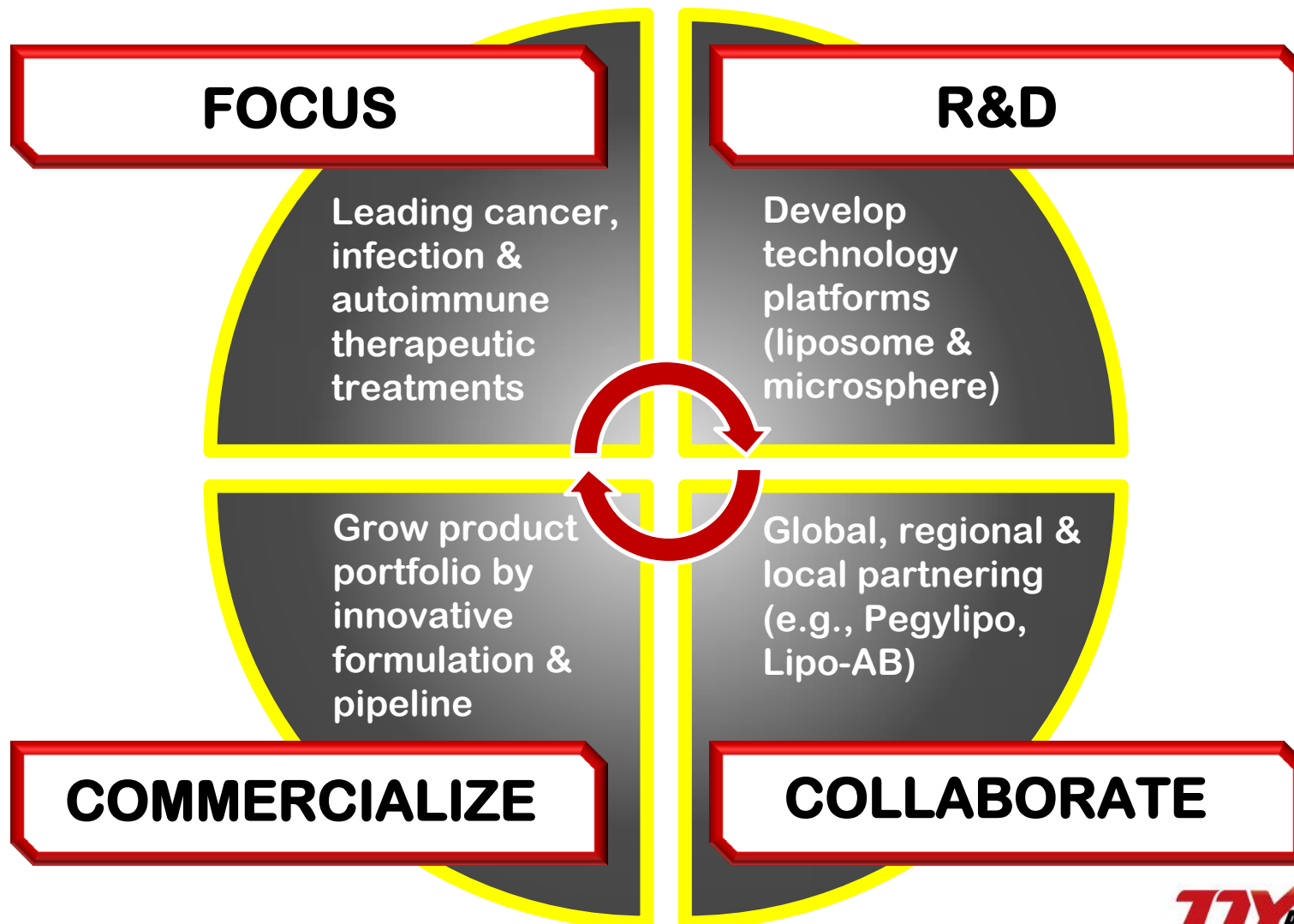
- New Drug Development & Marketing

# TTY Core Competences





# Corporate Strategy



# Agenda

Company Overview

**Product Strategy**

Product Pipeline

Manufacture Facilities

Successful Product Categories

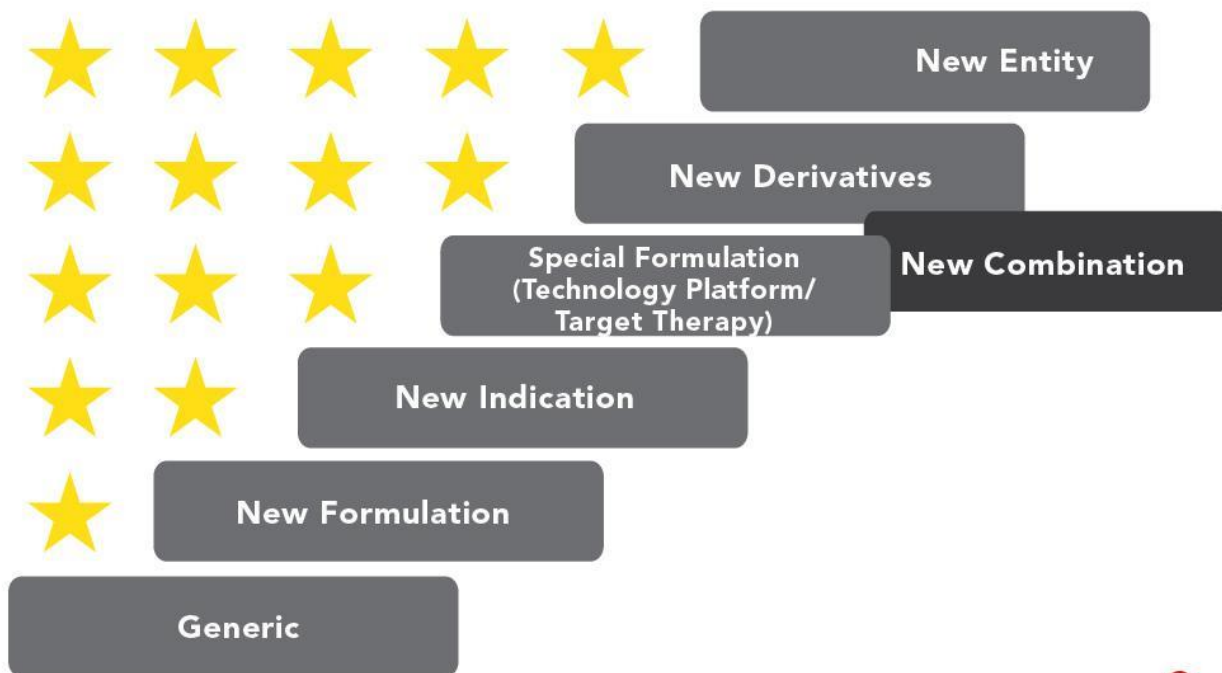
In Progress Status

Biotech Success

# Product Strategy

## Trends for Pharmaceutical Industry

Market Scope  
(Risk)







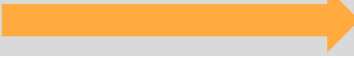





Entry Barrier  
(Profit)



# TTY Super Generics Pipeline

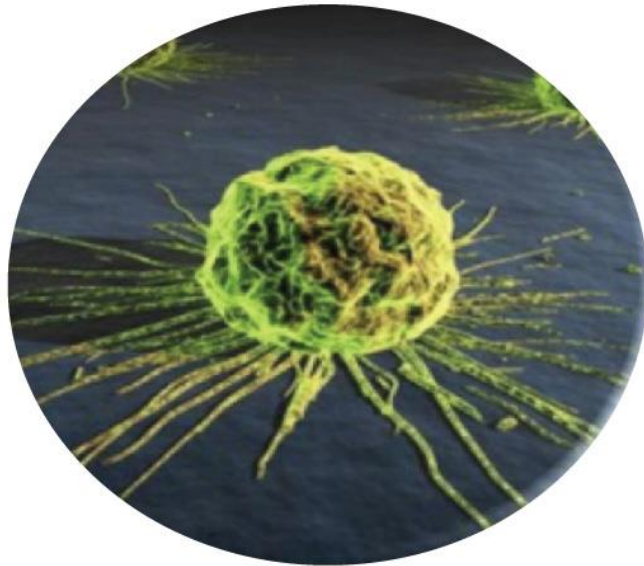
\* We had agreement in Feb. 2017 that the CMO price would be similar as 2016.

Products	Indication(s)	R&D (BE;BA+CT)	ANDA (EU/USA)
Caelyx/Doxil* (Lipo-Dox)	Metastatic breast cancer BC, AIDS-related Kaposi's sarcoma, Multiple myeloma, Overian cancer		Approved
Pegylipo			
Lipo-AB	Leishmaniasis, Concurrent renal toxicity invasive bacterial infection, The infected bursa meningitis HIV patients, Systemic Fungal Infection		TW Approved
			
Leuprolide Acetate Injection	Prostate cancer, Management of Endometriosis, Uterine Fibroids, Central Precocious Puberty		
Risperidone Injection	Schizophrenia		
SPL206	Functional gastric, intestinal, Pancreatic endocrine tumors		
LGIA10	Type II Diabetes Mellitus		505(b)2
Col103	Multidrug-resistant Gram-negative Bacteria Serious Infection		TW Approved
			China

# TTY Super Generics Pipeline

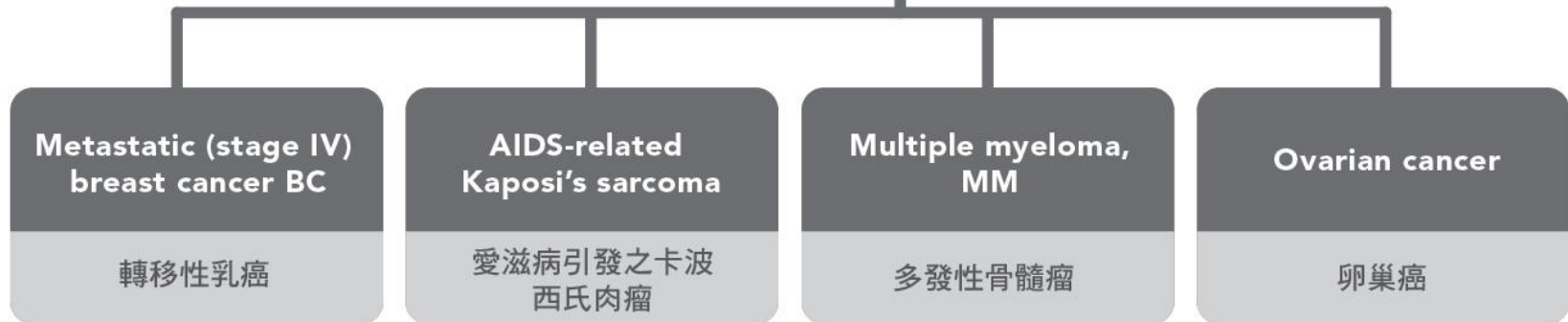
Programs 產品組合	Indication(s) 適應症	World Market (USD/M est.)	Core Technology 核心技術	Advantages 產品優勢
<b>Pegylipo</b>	Metastatic breast cancer BC、 AIDS-related Kaposi's sarcoma、 Multiple myeloma, MM、 Ovarian cancer	600	Pegylated Liposome Technology	Worldwide manufacturing patent
<b>Lipo-AB</b>	Systemic Fungal Infection	440	Liposome Technology	Worldwide manufacturing patent
<b>Leuprolide Acetate Injection</b>	Prostate Cancer、 Management of Endometriosis、 Uterine Fibroids、 Central Precocious Puberty	1,240	Lupron Depot Microsphere Formulation	Worldwide manufacturing patent
<b>Risperidone Injection</b>	Schizophrenia	960	Microsphere Formulation	Worldwide manufacturing patent
<b>SPL206</b>	Functional gastric, intestinal, pancreatic endocrine tumors	1,500	Microsphere Formulation	PLGA used for particular star polymers synthesized by TTY.
<b>LGIA10</b>	Type II Diabetes Mellitus	910	Microsphere Formulation	Worldwide manufacturing patent Microsphere Depot Platform
<b>Col103</b>	Multidrug-resistant Gram-negative Bacteria Serious Infection	150	Formulation	First Choice Irreplaceable Option, TWNIH

台灣東洋藥品

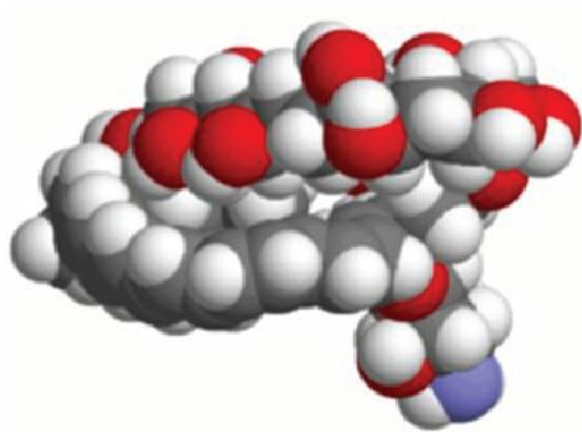


## Caelyx®/Doxil®/Pegylipo®

Global market: USD\$600 Million  
Taiwan: NTD\$200 Million



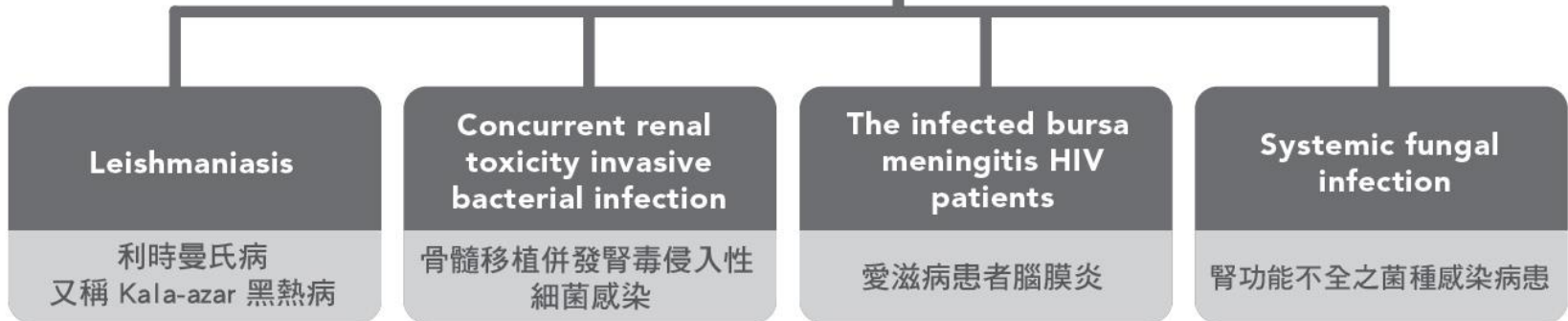
Source : Thomson Reuters Mar./2017

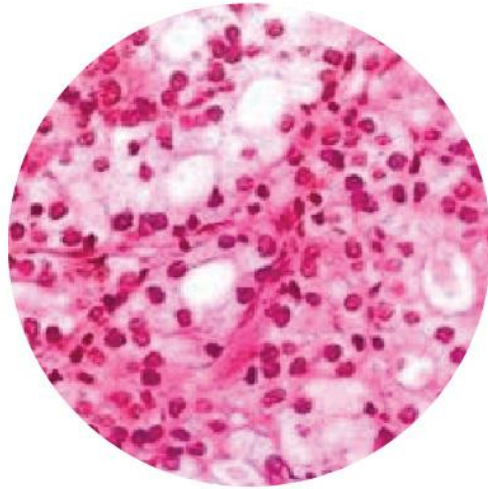


## Lipo-AB

Global Market: USD\$440 Million

Target: Worldwide 35~50%

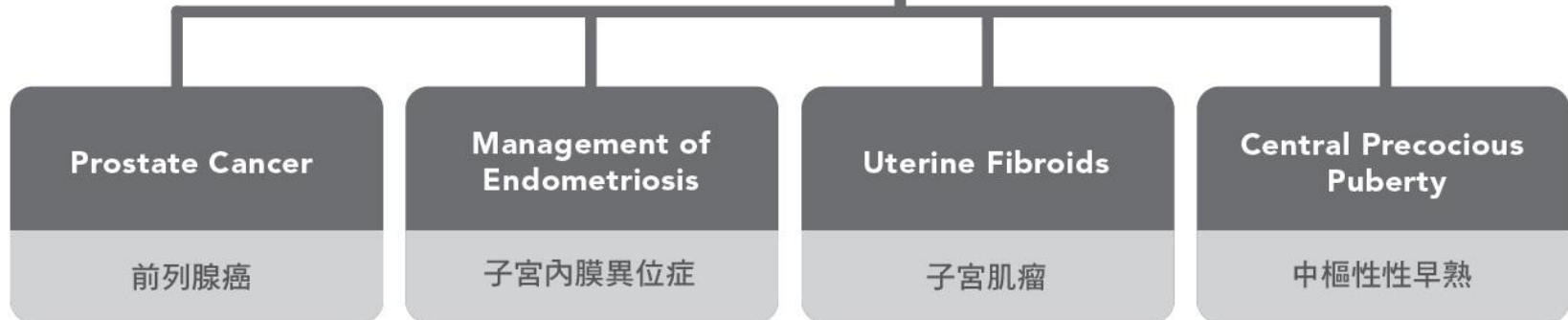




## Specialty- Leuprolide Acetate Injection

Global 2014 Lupron/Leuprolide  
Market: USD\$1.24 Billion

Target: Worldwide 20~35%

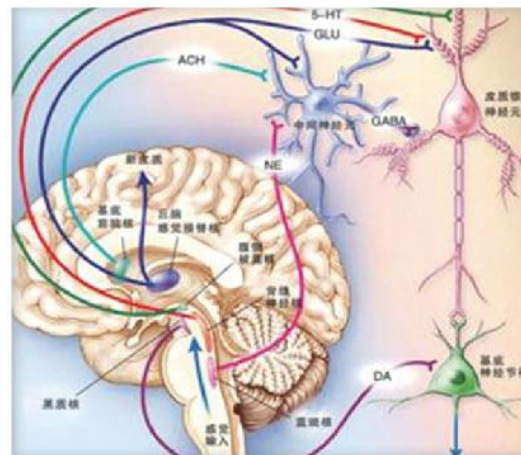
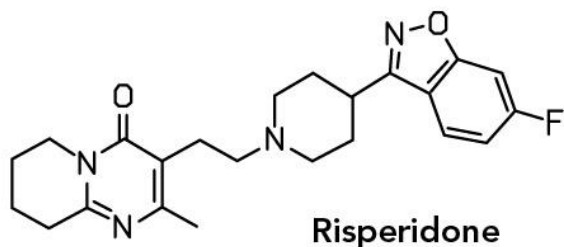




# Specialty- Risperidone Injection

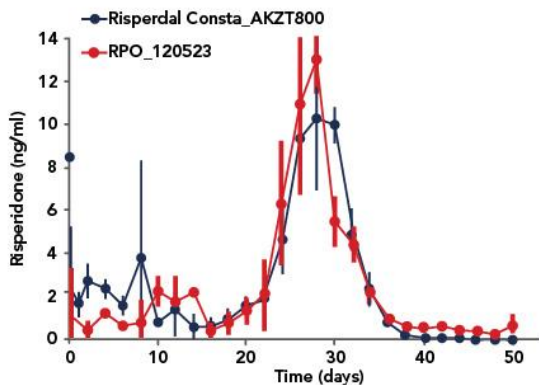
Indication: Schizophrenia

Global market: USD\$960 Million

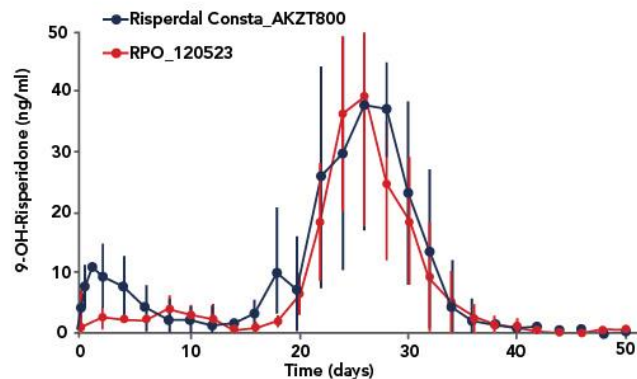


Beagle in vivo release

Risperidone



9-OH-Risperidone



**TTV** BIOPHARM  
台灣東洋藥品

# Specialty- SPL206

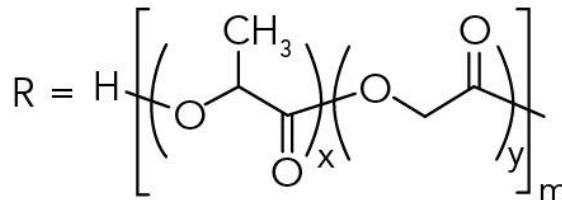
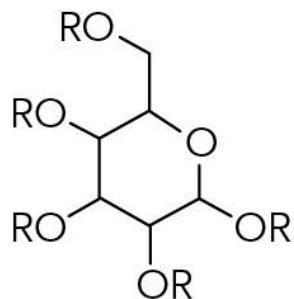


## Indications:

- 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!!**

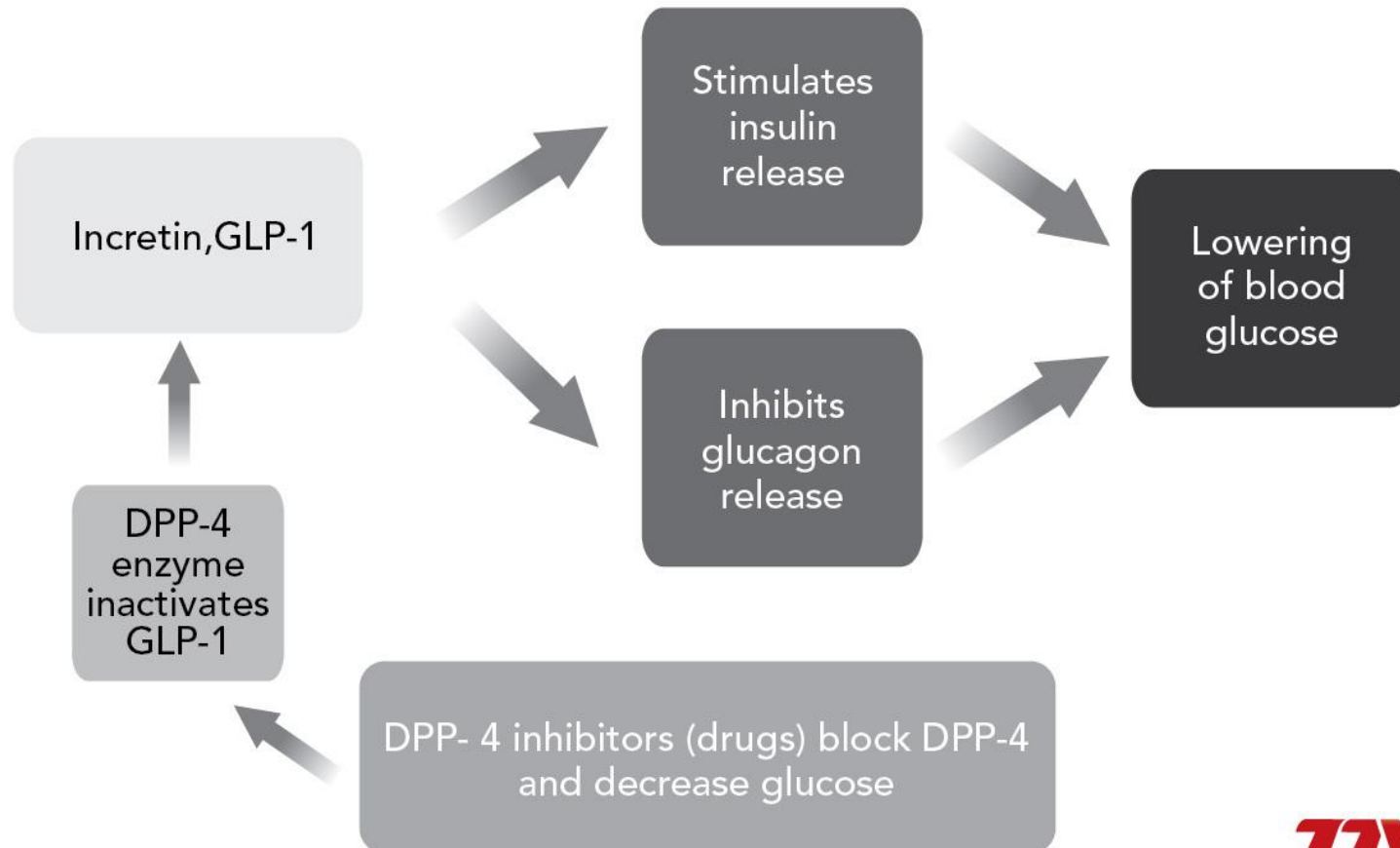


Polymer	Lot	MW(K Da)	PI
Poly(lactide-co-glycolide) star, glucose core LA:GA=1:1	TTY#783053	53	1.67

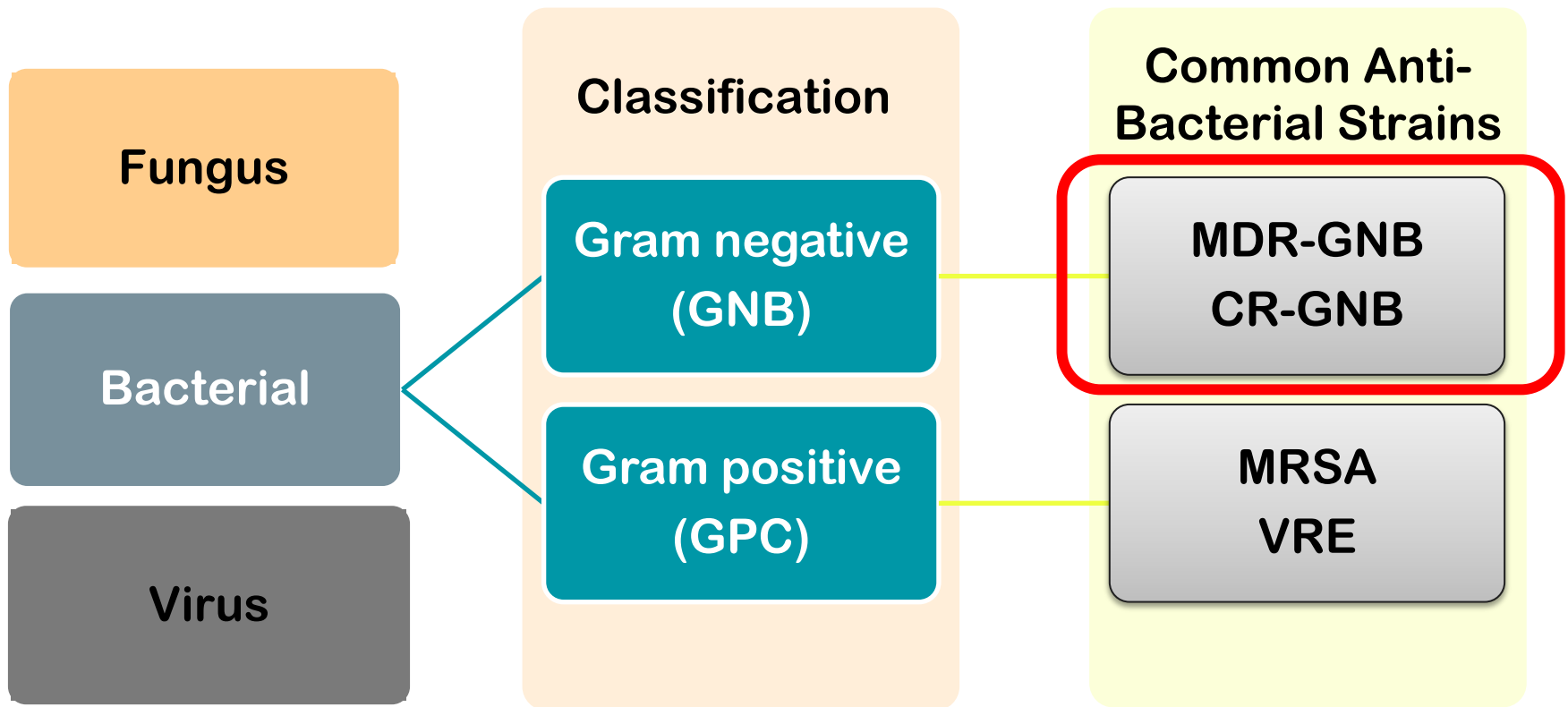
# Mechanism of LGIA10

## GLP-1 and Diabetes

Indication: Type II Diabetes Mellitus



# Specialty – Col103

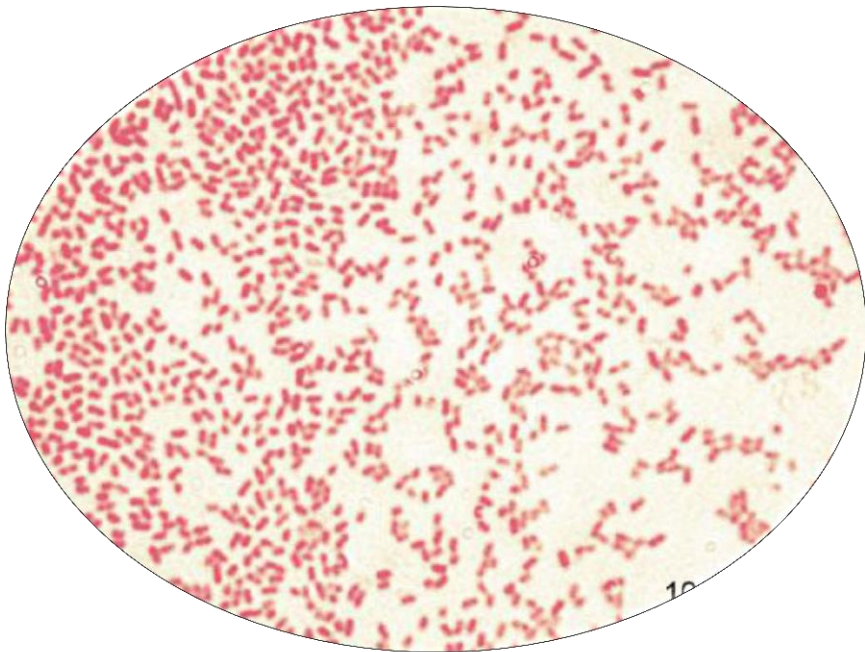


MDR-: multi-drug resistant  
CR-: carbapenem resistant

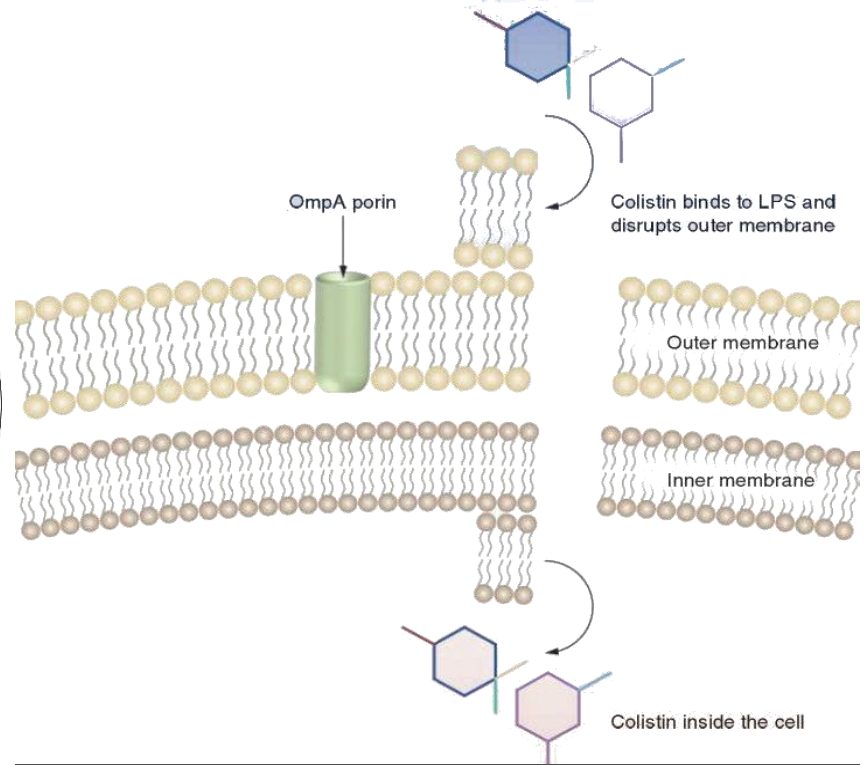
MRSA: methicillin resistant *Staphylococcus aureus*  
VRE: vancomycin resistant *Enterococcus*

# Col103

Global Market: 150M



Multidrug-resistant  
Gram-negative Bacteria  
Serious Infection



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

By Y\_tambe - Y\_tambe's file, CC BY-SA 3.0,  
<https://commons.wikimedia.org/w/index.php?curid=49535>



# Agenda

Company Overview

Product Strategy

**Product Pipeline**

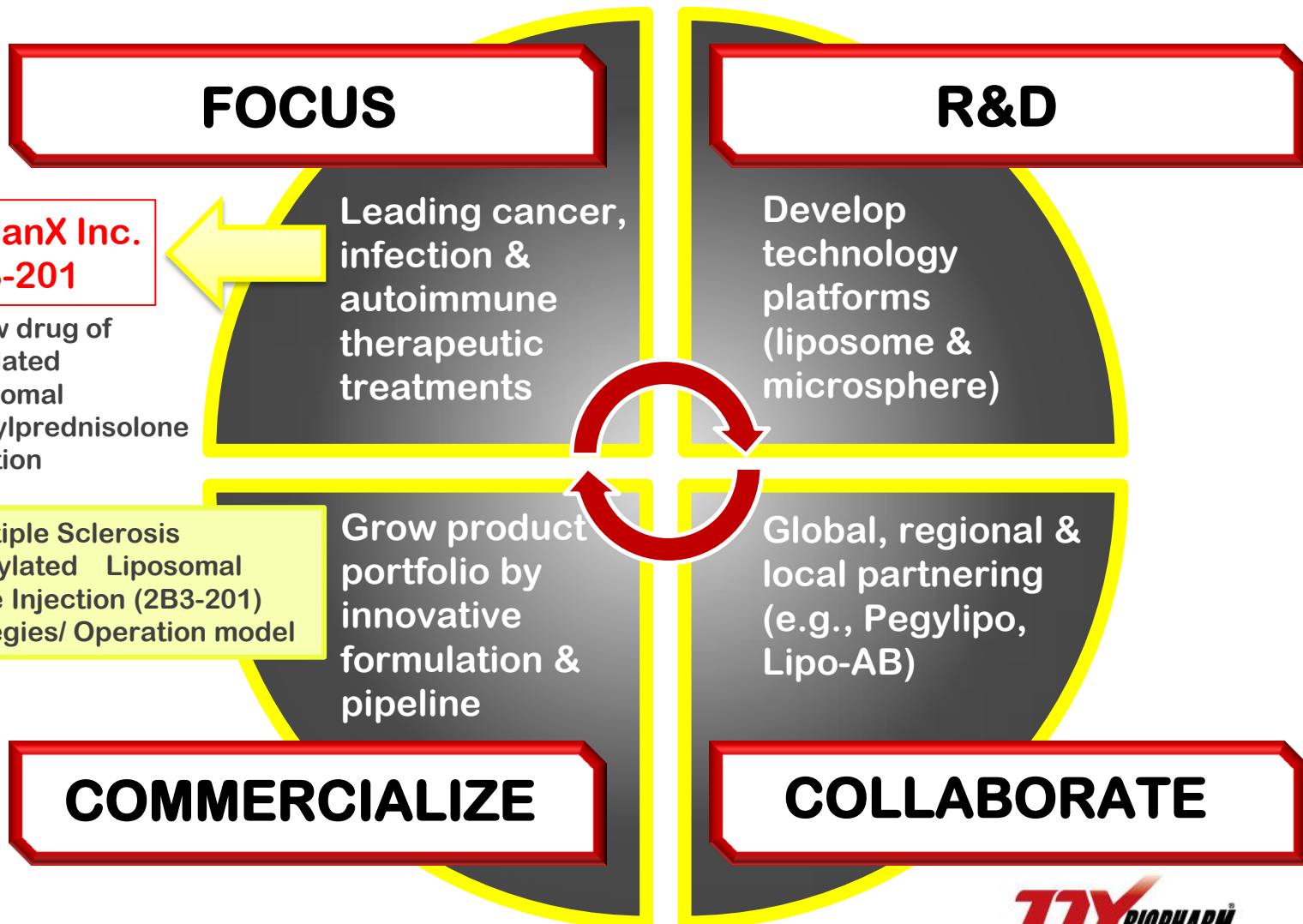
Manufacture Facilities

Successful Product Categories

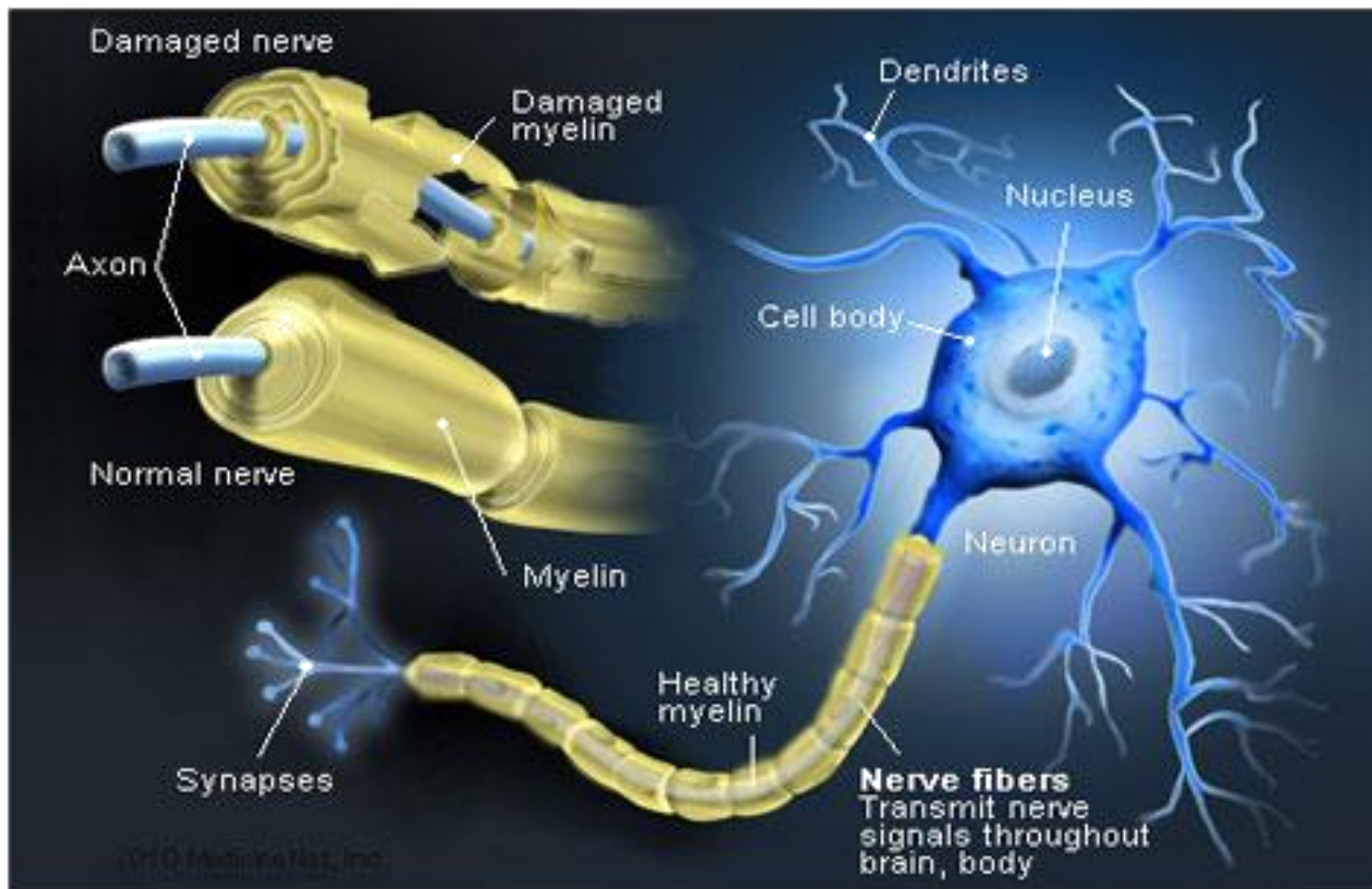
In Progress Status

Biotech Success

# Corporate Strategy



# Introduction of MS's MoA



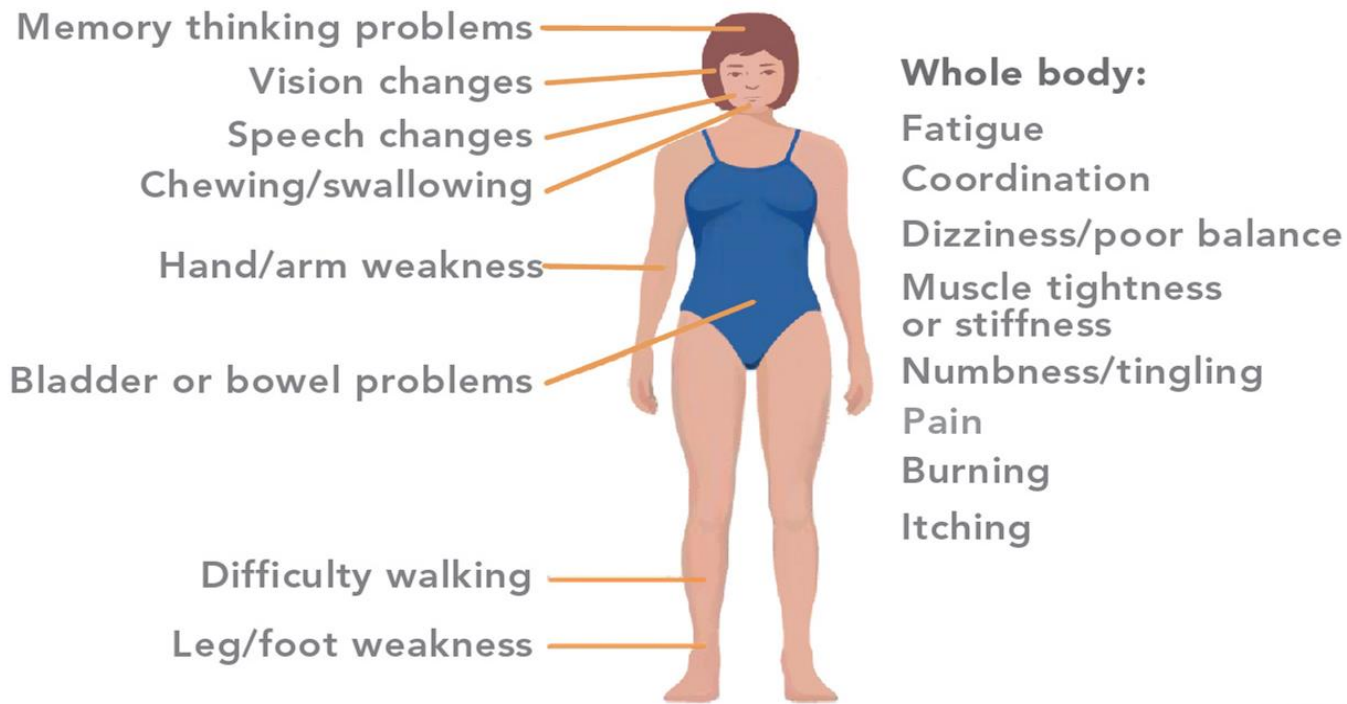


# Introduction of MS

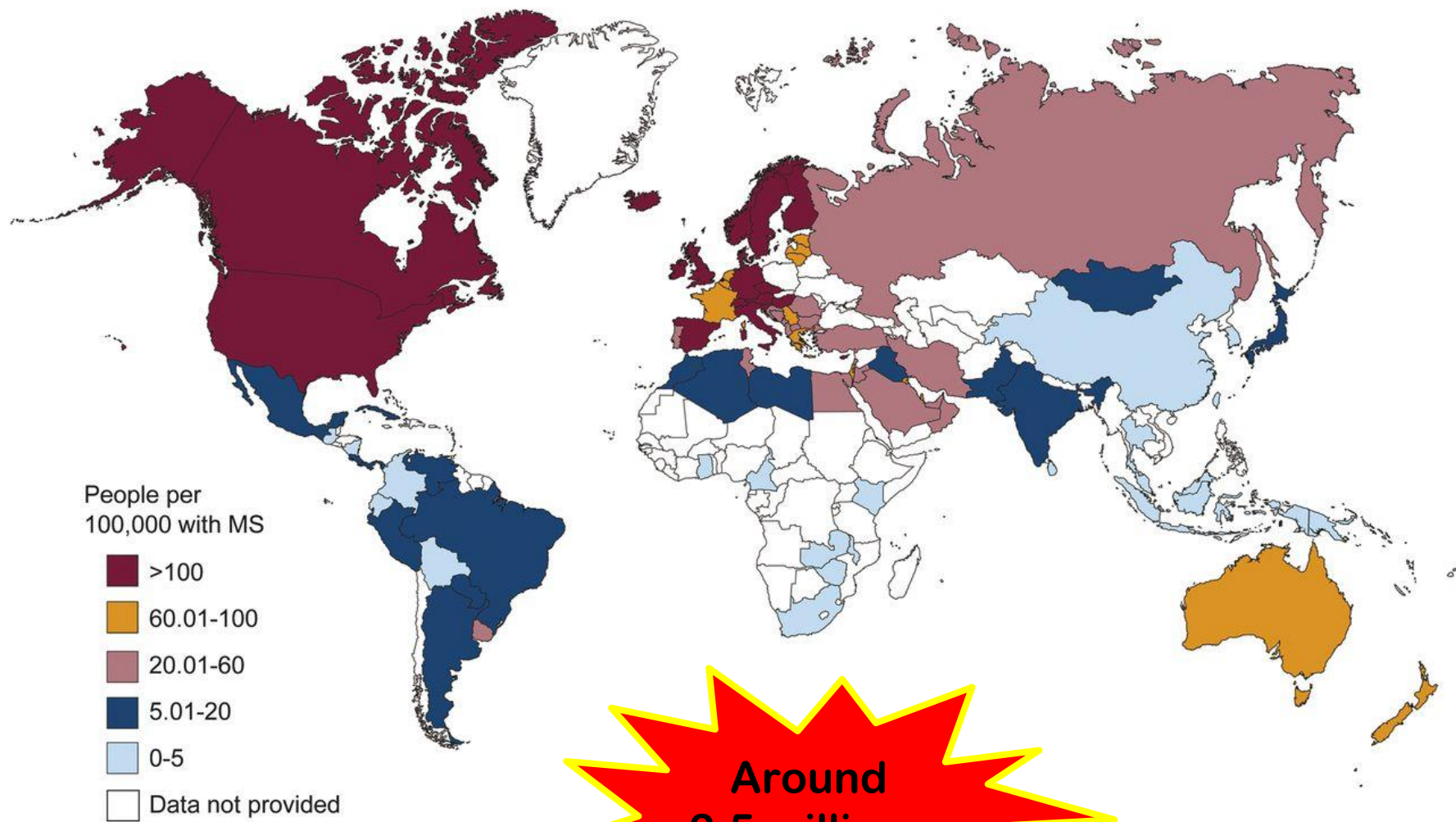
## MS: a chronic, autoimmune & neurodegenerative disorder

### 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



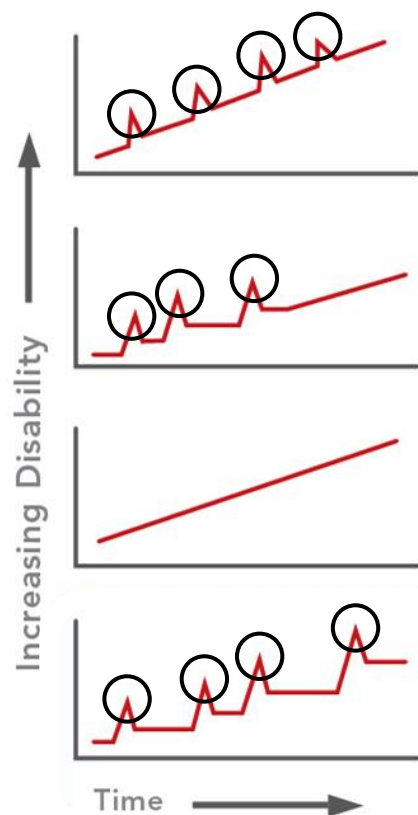
# Introduction of MS



**Around  
2.5 millions**

# Introduction of MS

## Four Classifications of MS



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

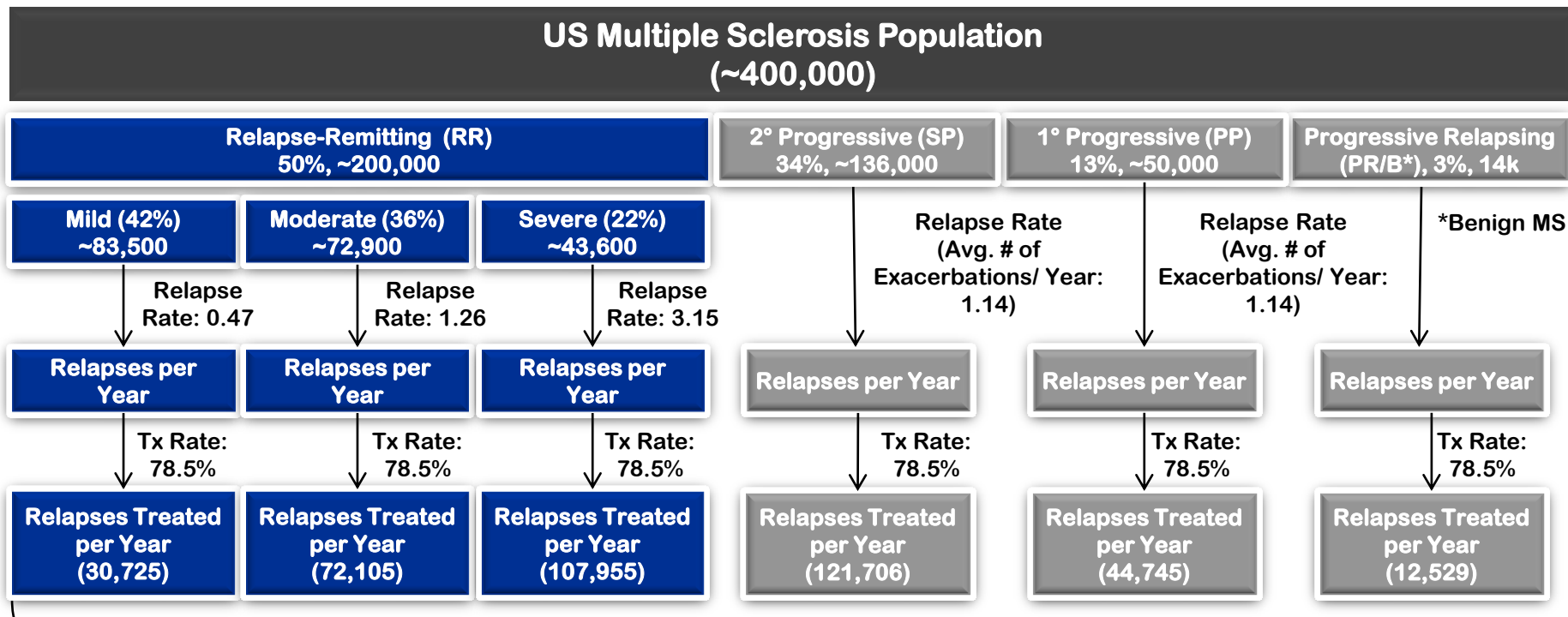
**SPMS** Secondary Progressive MS  
Initial RRMS that suddenly begins to decline without periods of remission and relapses.

**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; it's the target patients of 2B3-201.  
不管屬於哪一個發病類型，只要是急性復發，就是2B3-201的target 病患。

# Patients Distribution in US Market

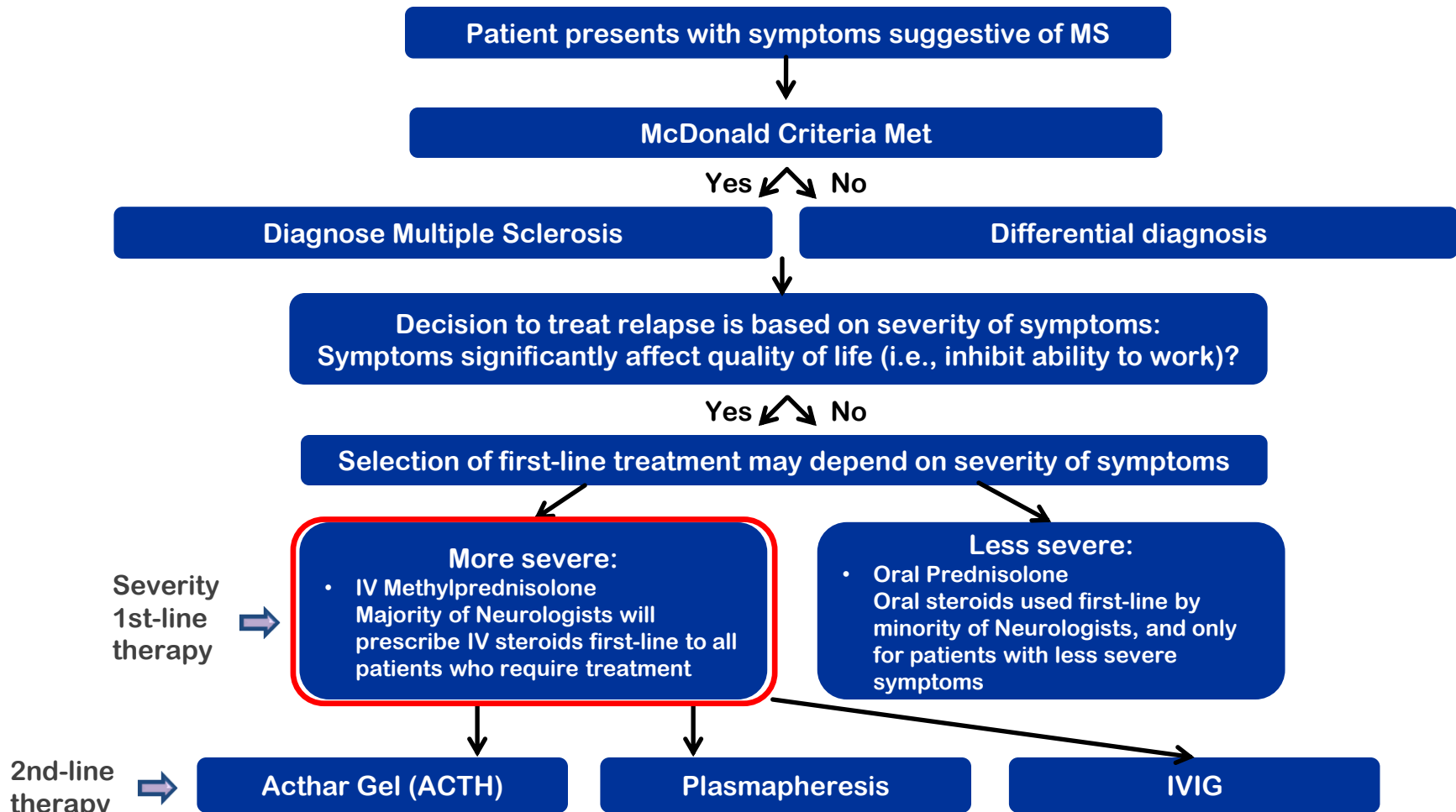


**Minimum, Target, and Ideal Penetration Rates based on Use as First-Line or Second-Line Treatment from Physician Survey**



**Relapses Treated with 2B3-201 at Peak Under Minimum, Target, and Ideal 1st-Line/ 2nd-Line Penetration Scenarios**

# Introduction of MS

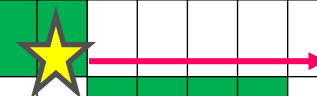


DH Primary Research, Ann Indian Acad Neurol. 2011 Jul.;14(Supp1 1):S65-9

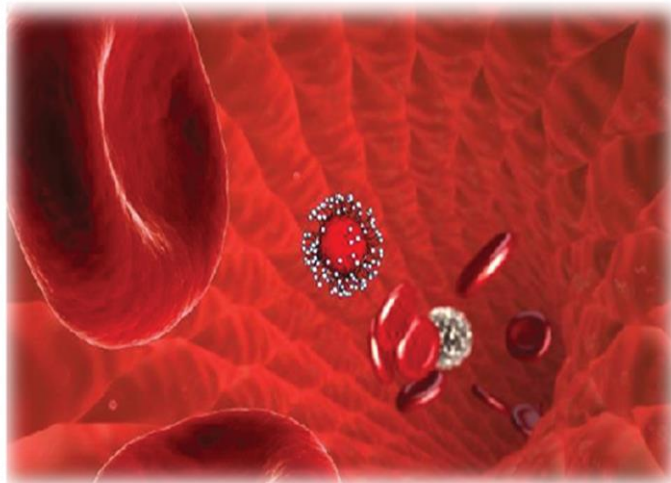
# 2B3-201 Pipeline

## 2B3-201 : Liposomal Methylprednisolone Injection (glutathione PEGylated liposomal methylprednisolone)

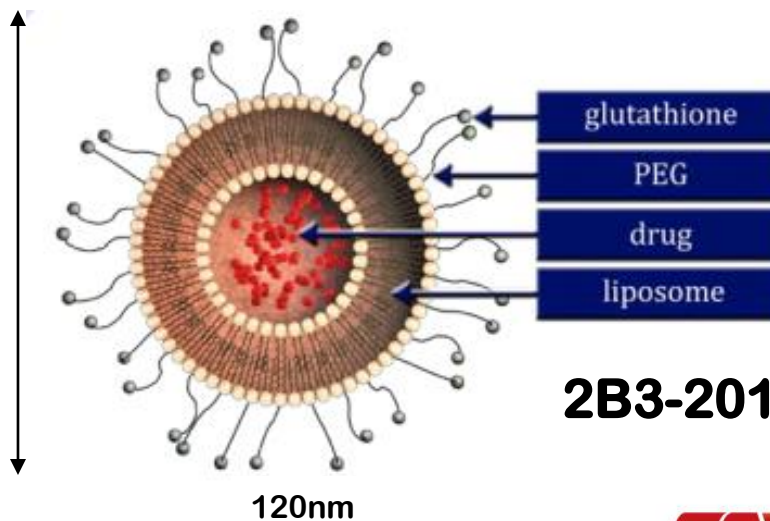
	2014 - 2016			2017			2018			2019			2020			2021			2022				
Phase I	█	█	█	█	█	█																	
Phase I bridging study (lyophilized injection)							█	█	█	█	█	█											
Scientific advice from FDA & EMA											█	█	█										
Phase II/III in MS relapses (vs placebo)													█	█	█	█	█	█	█				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



# Introduction of the Product



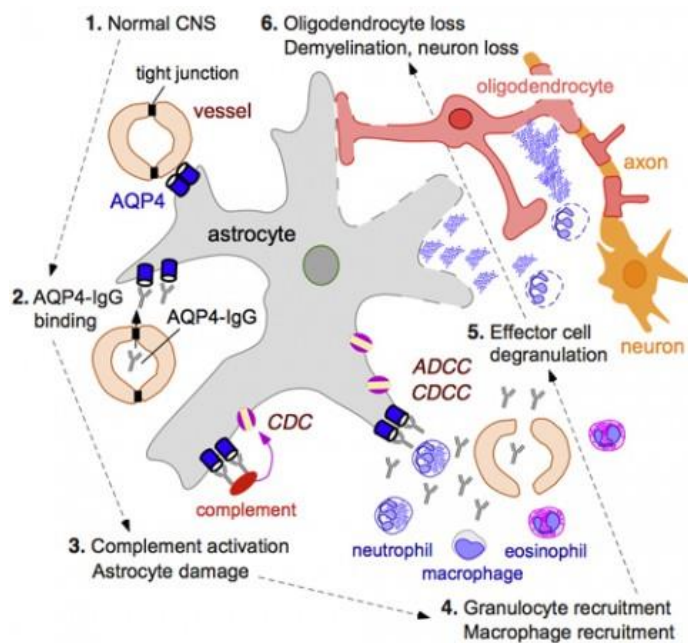
Targeting Liposomal Methylprednisolone Injection (glutathione PEGylated liposomal methylprednisolone) is being developed for patients suffering from acute and chronic neuro-inflammatory diseases, with an initial focus on patients with acute MS relapses.



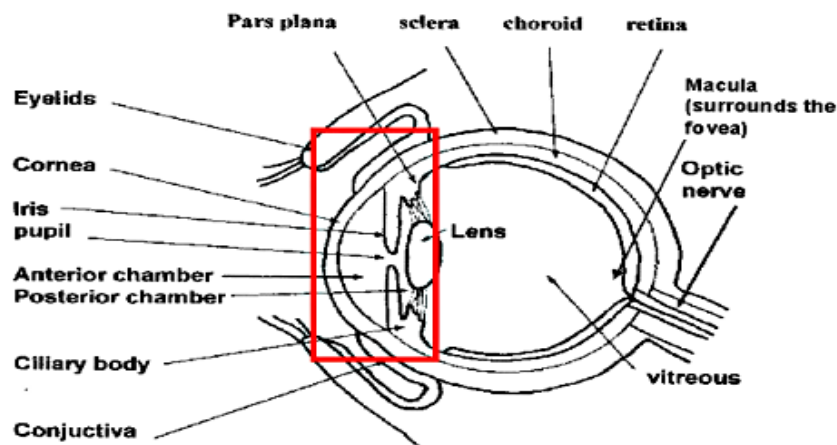
# Introduction of the Product

## 2B3-201'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.

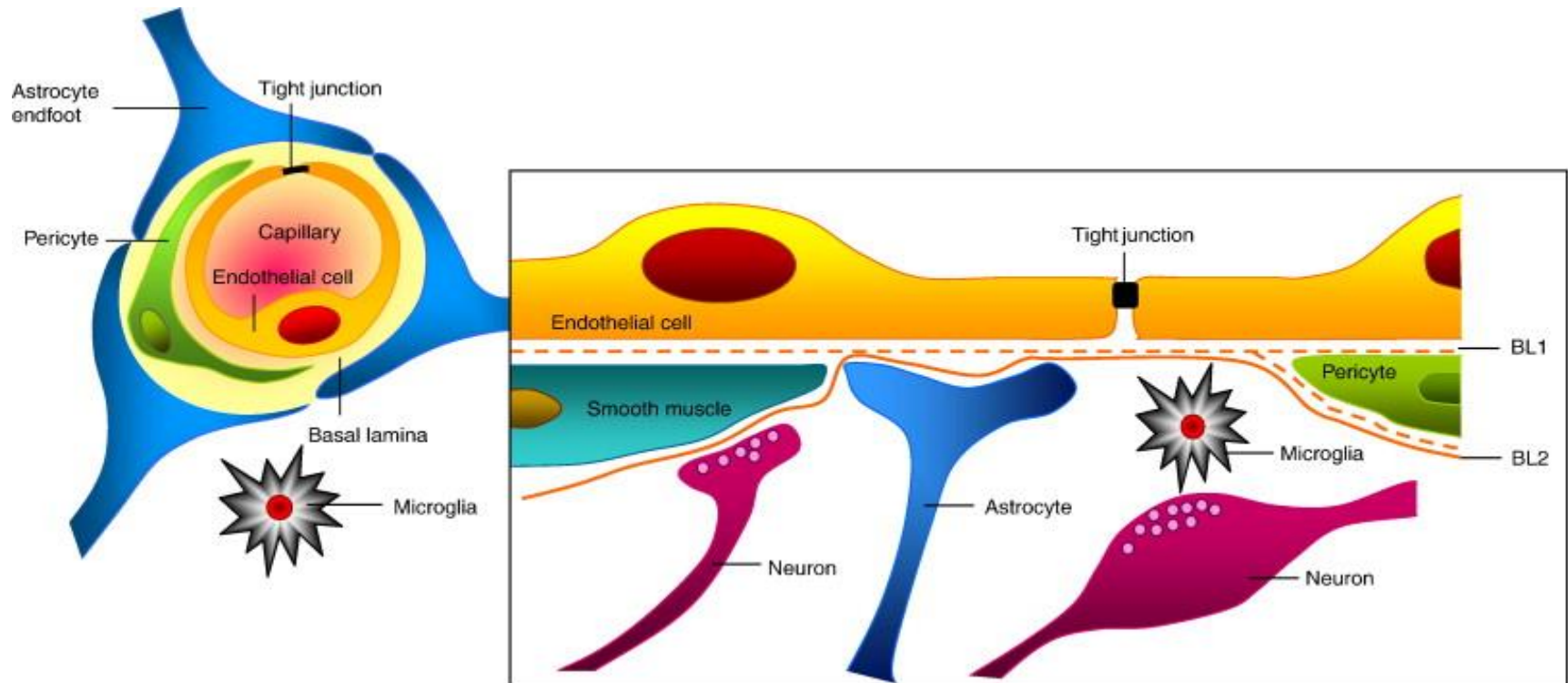
Source: [http://www.msdiscovery.org/news/news\\_synthesis/](http://www.msdiscovery.org/news/news_synthesis/)

8147-neuromyelitis-optica-part-2-pathogenesis

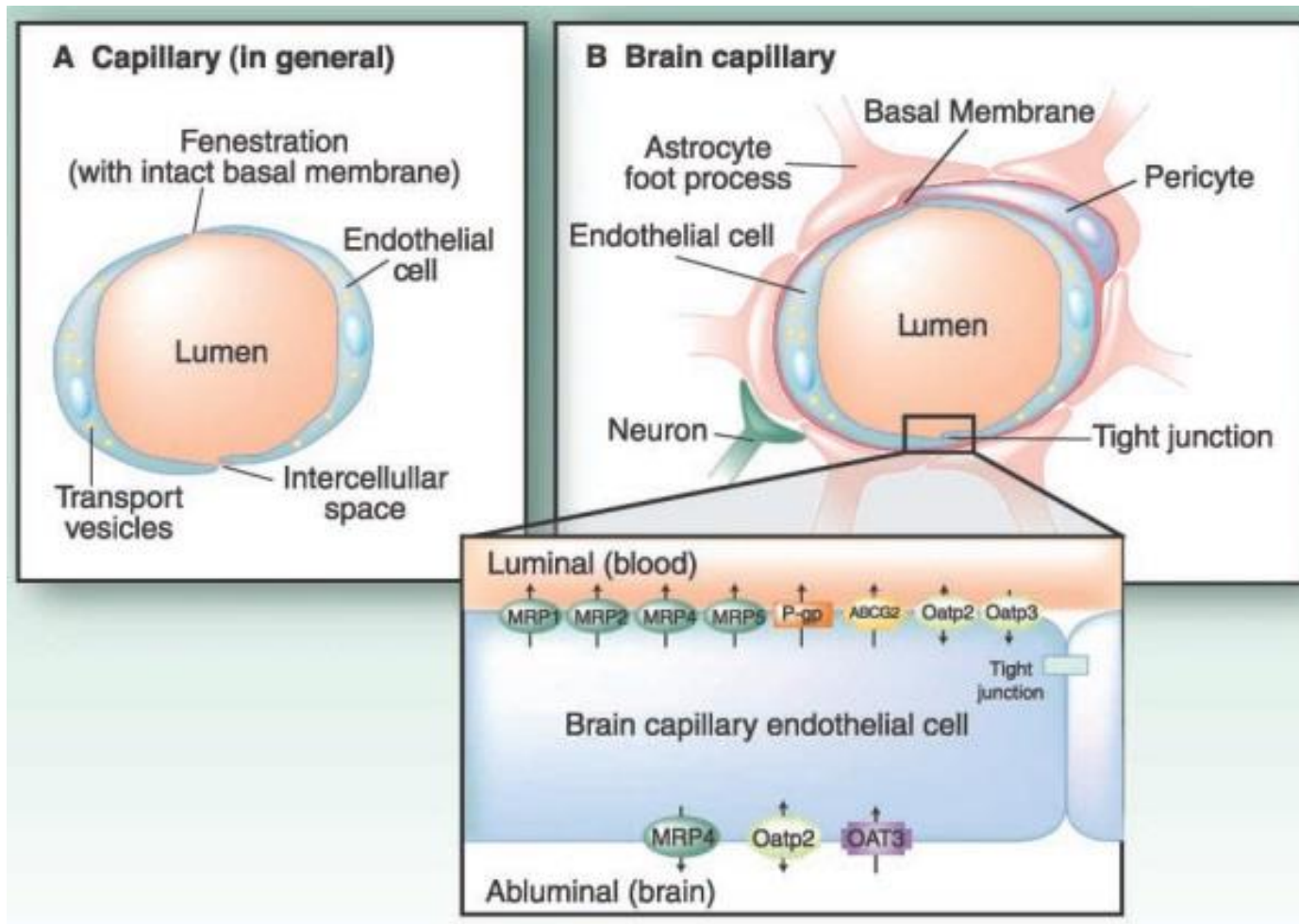
Source: <https://www.uveitis.net/patient/anterior.php>



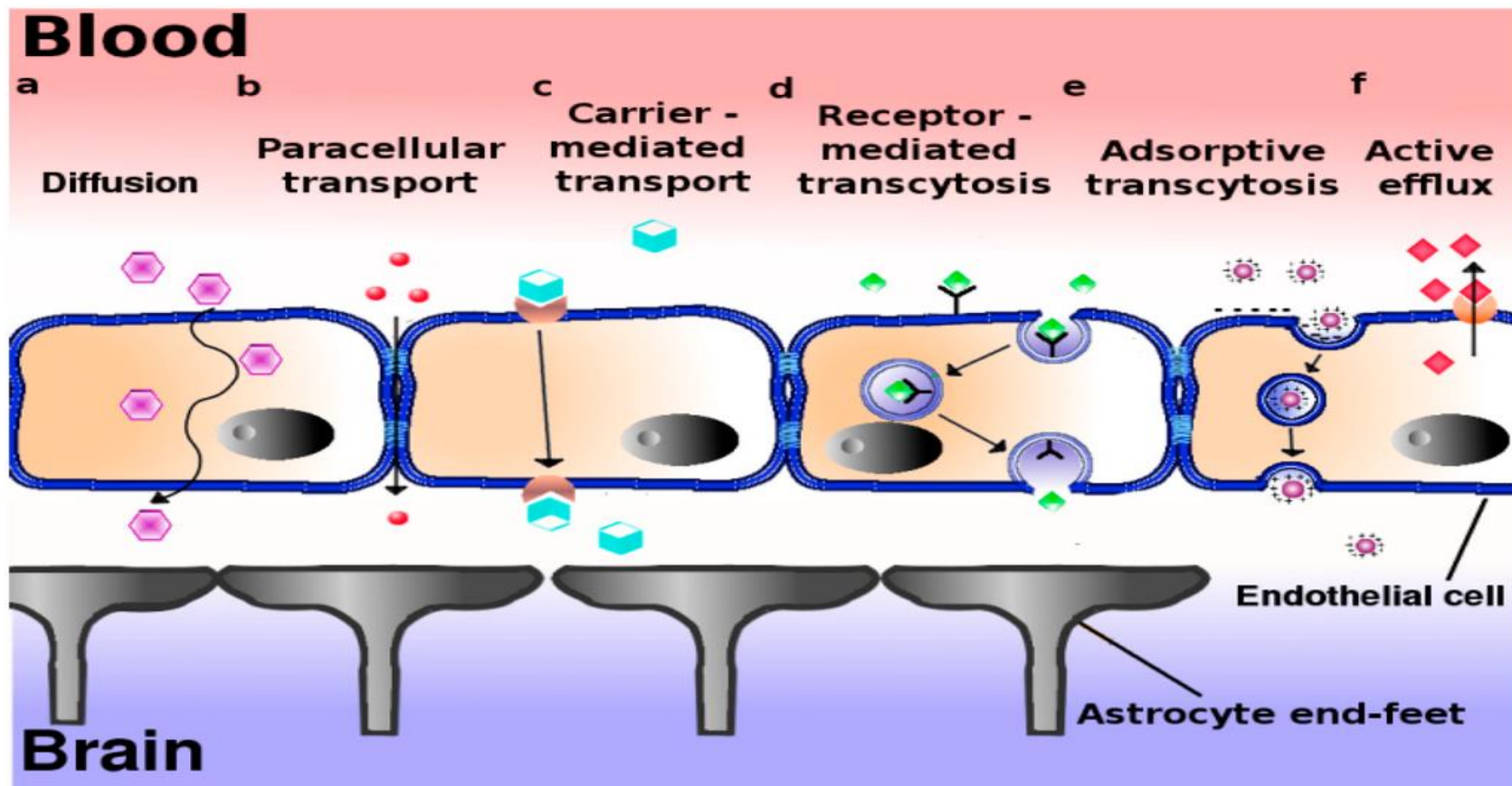
# Introduction of BBB



# Introduction of BBB



# Introduction of BBB

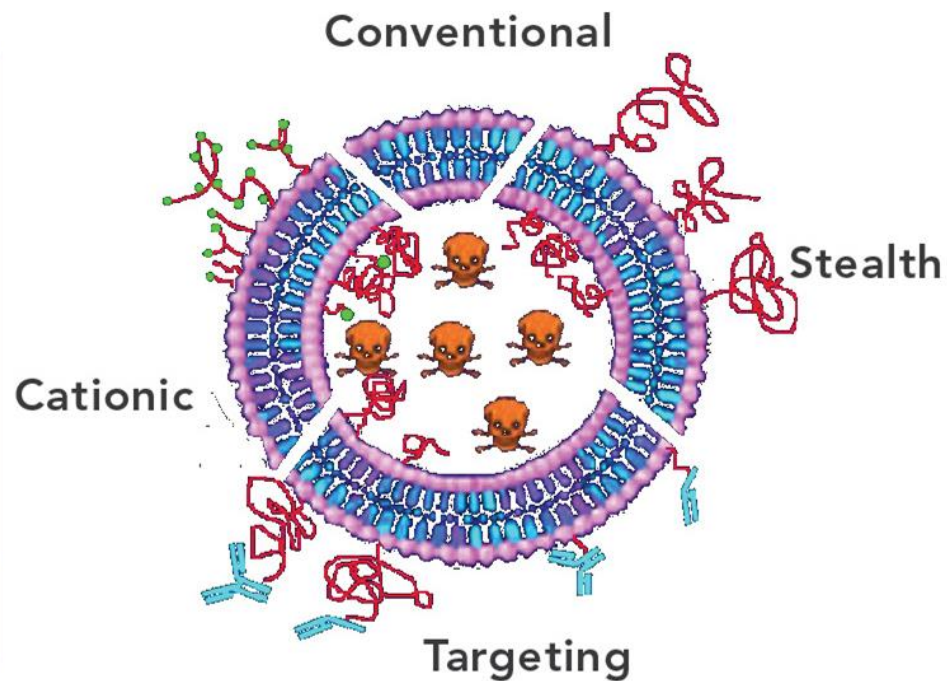
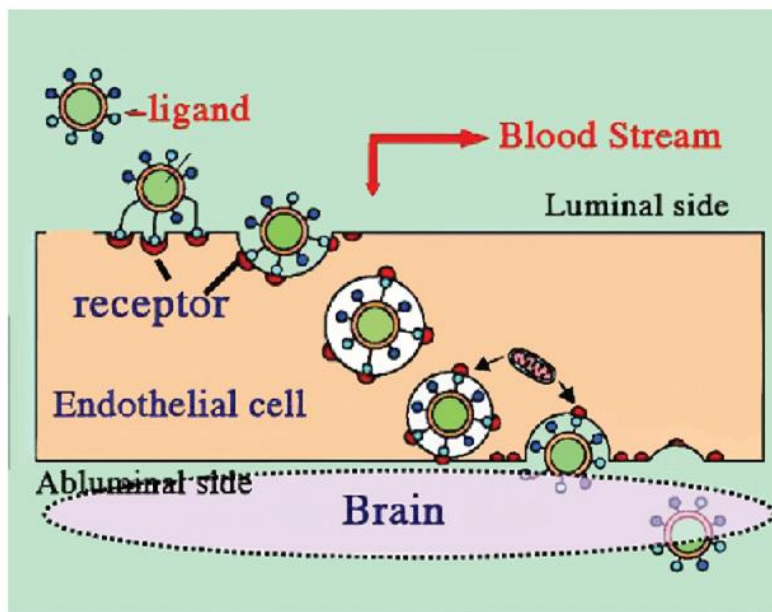


# Introduction of BBB

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, 2B3-201
9	Synthetic Opioid Peptides	
10	RVG Peptide	
11	Tetanus Toxin, Tet1 and G23	
12	Diphtheria Toxin	
13	TAT peptide	

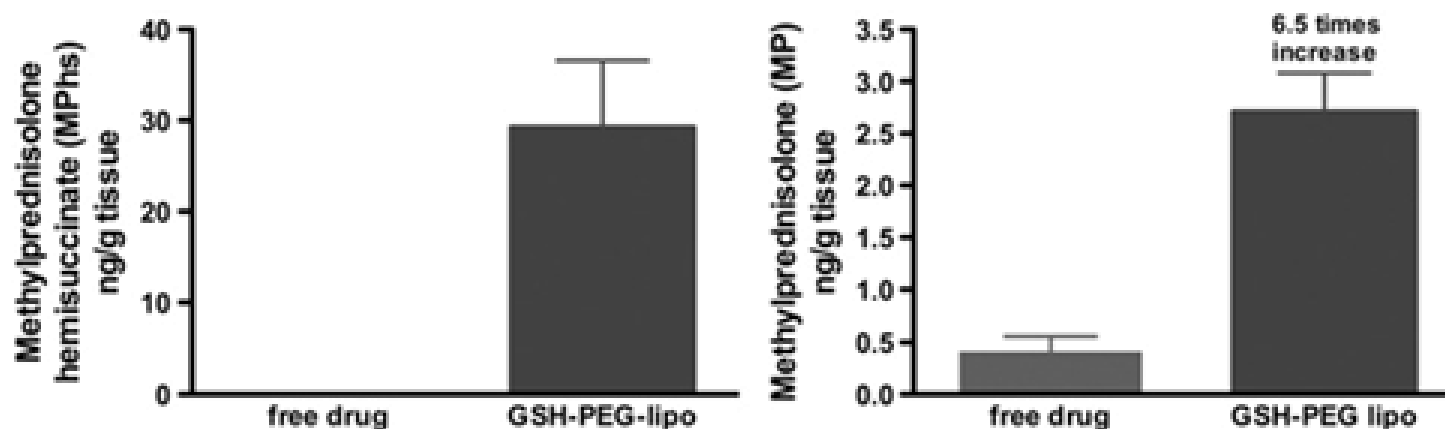
# Introduction of 2B3-201

## 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，2B3-201超過非微脂體的MP6倍以上。

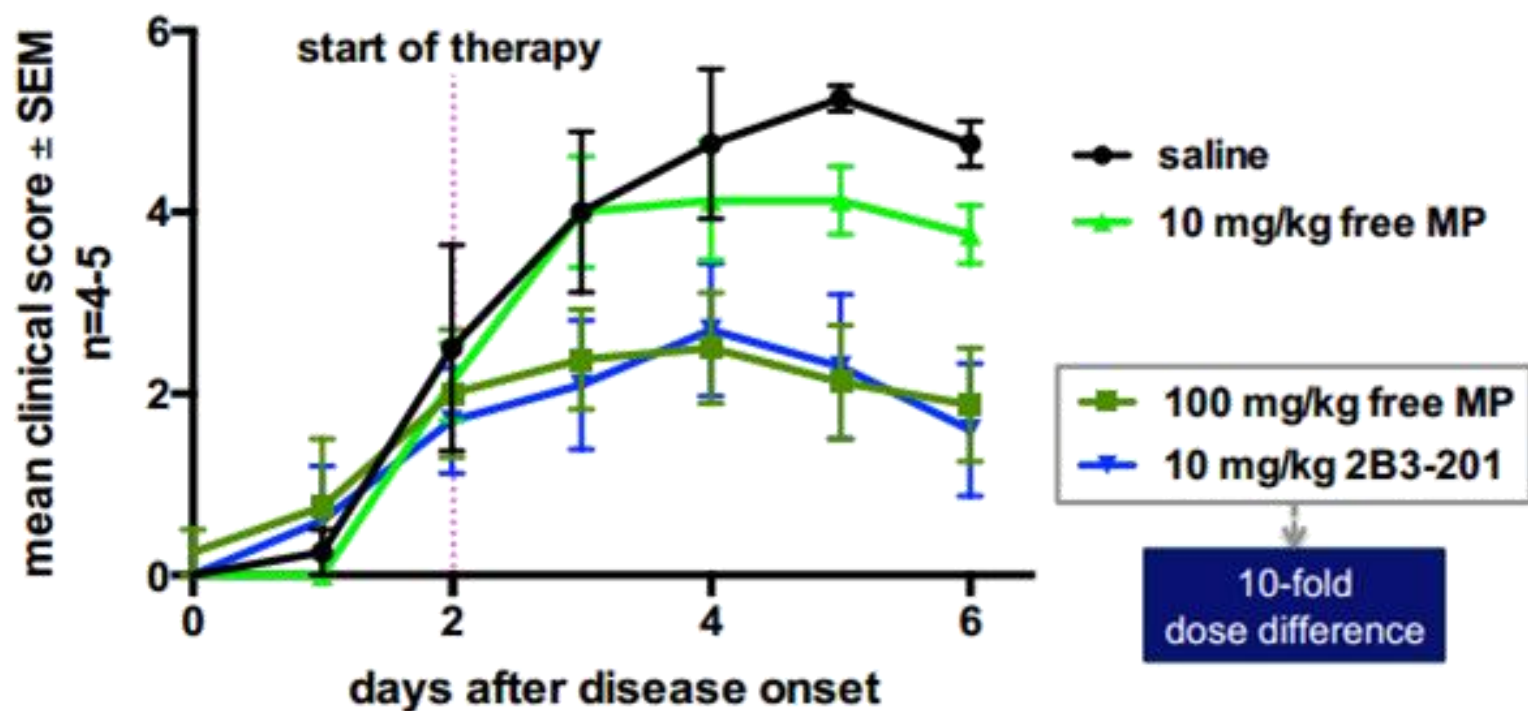


**Fig. 3.** Brain uptake of methylprednisolone hemisuccinate (left) and methylprednisolone (right). Rats ( $n=4$ /group) received 1 bolus i.v. administration of 10mg/kg glutathione pegylated liposomal methylprednisolone (GSH-PEG lipo) or free methylprednisolone (free MPHs, 10mg/kg). Brain uptake was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

# Preclinical Study

2B3-201: 藥效驗證試驗

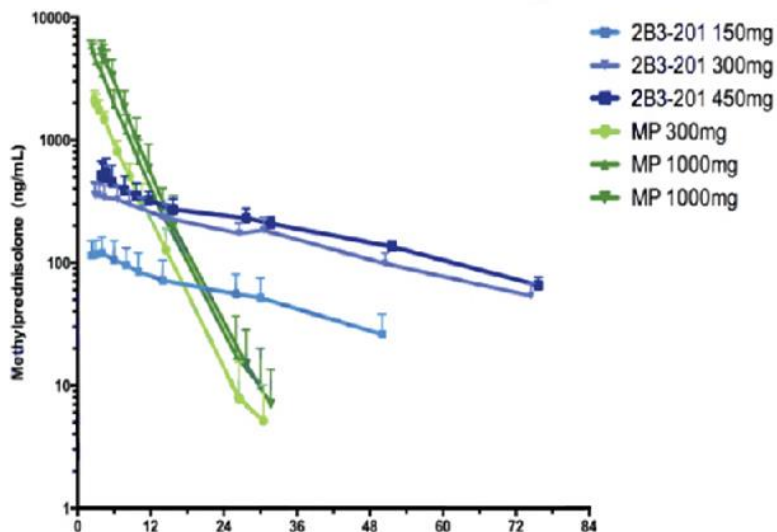
EAE-MOG mouse model of MS



# Phase I Study (Solution)

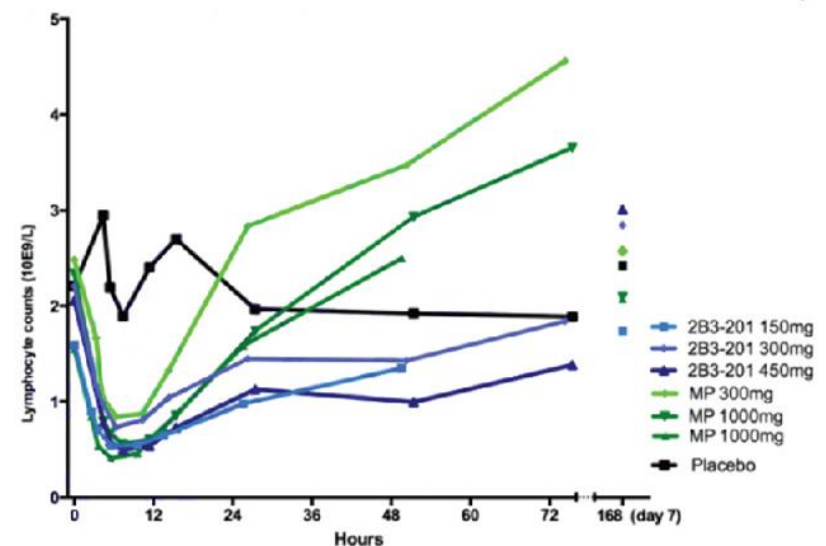
## Phase I dose-escalation results Pharmacokinetics

- Long circulation half-life of 2B3-201 (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

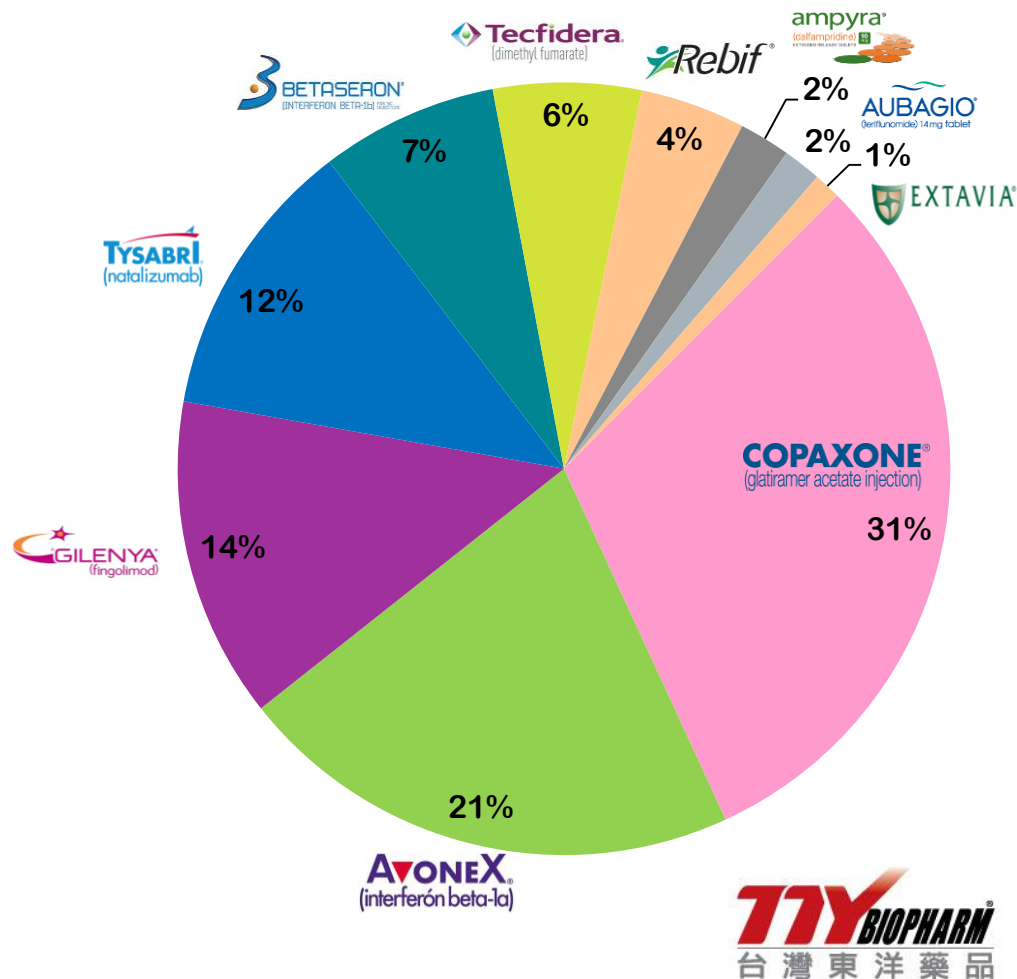
## Major existing choices for MS treatments (2014 Sales & Market Share in Value)

### MS Therapies

- “ABCRE” 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

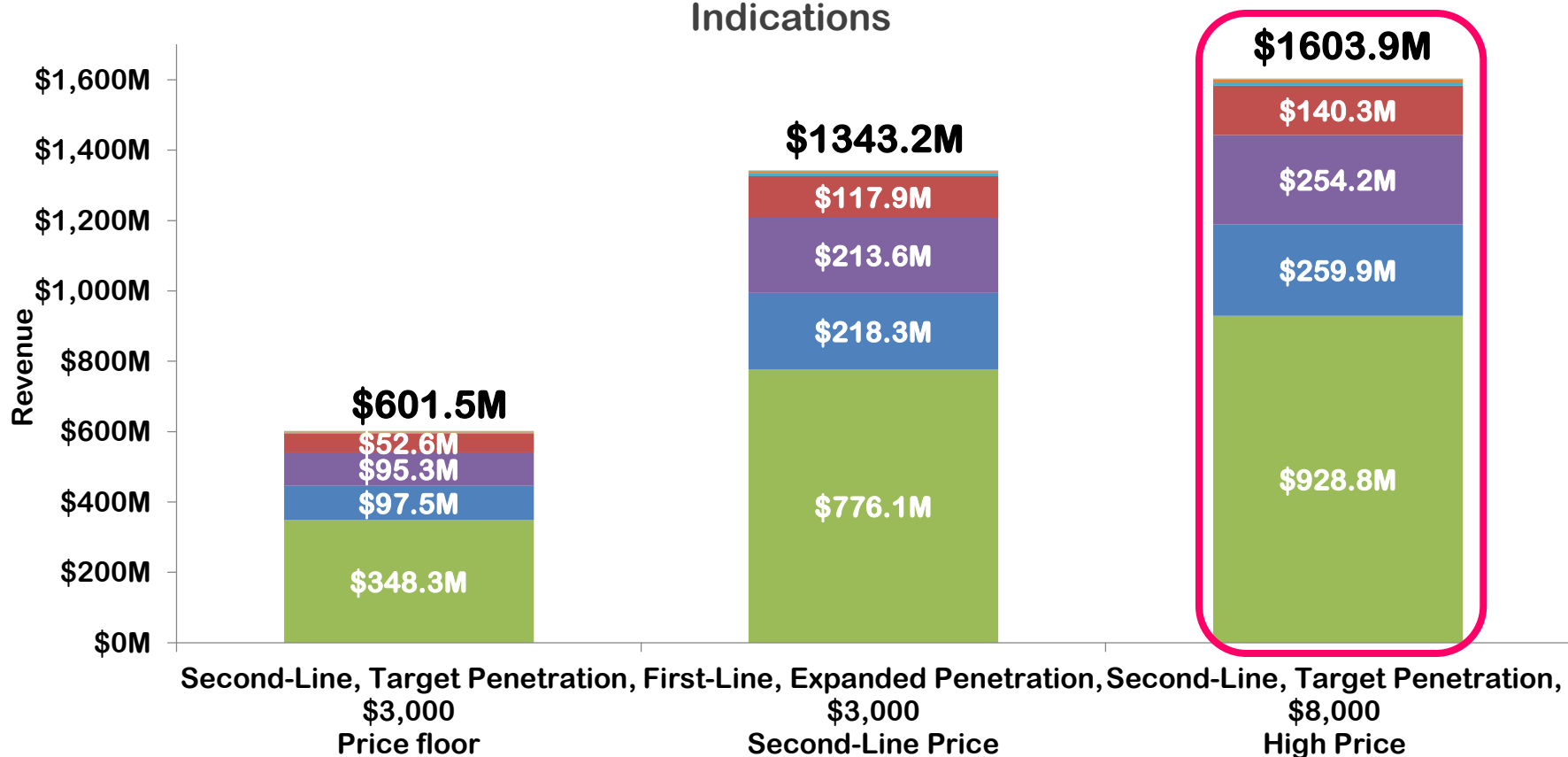
Unit: USD

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

## 2B3-201 US Peak Year Revenue – MS & Other Inflammatory Indications



■ MS relapse 
 ■ Uveitis 
 ■ CNS Lupus 
 ■ Neurosarcoidosis 
 ■ NMO 
 ■ Behcet 
 ■ ADEM



# Potential Market Size Globally

## 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 (USD,000)

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

# Development Strategies

## ■ 2B3-201's strengths

- *2B3-201 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, 2B3-201 is an **one-shot** intravenous injection which brings **home-care convenience** and **better tolerance** to patients suffering acute multiple sclerosis relapses.*

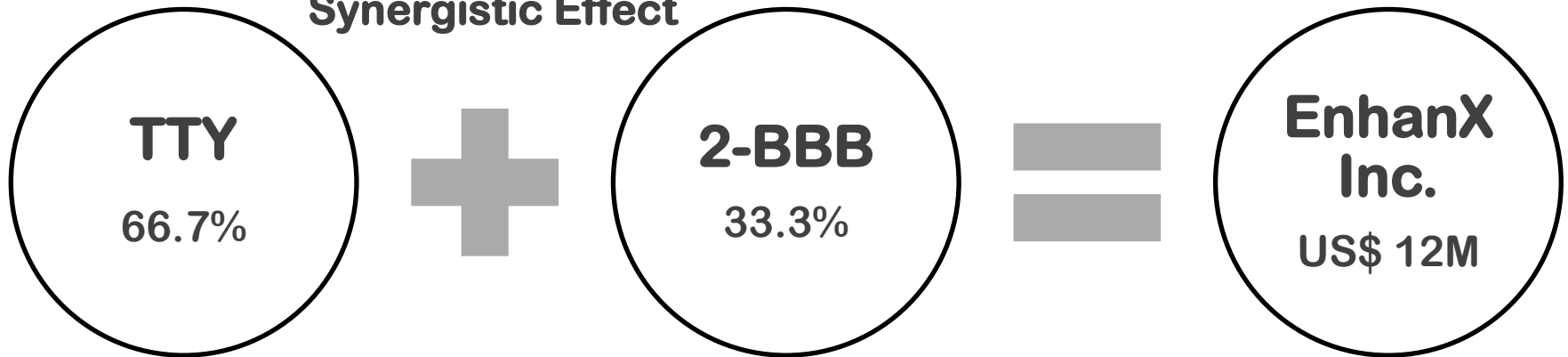
# Multiple Indications (Pipeline)

	Indications to Develop	Market Potential Size	Competitors
1	<b>Multiple Sclerosis</b> (多發性硬化症)	>21.5B	Teva (2014) Biogen EMDSerono Novartis
2	<b>Uveitis</b> (葡萄膜炎) (眼睛發炎)	>0.531B	Humira (2016)
3	<b>Neuropathic Pain</b> (神經性疼痛)	>5.7B	Pfizer (2011)
4	<b>Osteoarthritis</b> (骨關節炎)	>5.335B	Anika (2014)
5	<b>ALS</b> (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	<b>Mucopolysaccharidoses (MPS, 黏多醣症)</b>	>300M	Vimizim
7	<b>Metachromatic leukodystrophy (MLD, 異染性蛋白質失養症)</b>	1B	Shire Plc Nuo Therapeutics GlaxoSmithKline Plc Zymenex A/S RegenxBio Inc. Novartis AG

Unit: USD/Billion

# Multiple Indications

## Synergistic Effect



- **Formulation development and commercial manufacture**

R&D formulation center of TTY has been studying liposomal formulation for more than 10 years and has succeeded in collaborating with J&J to produce a famous drug, Doxil/Caelyx. During cooperating with to-BBB, the initial prototype of 2B3-201 had been reformulated and produced by TTY's lab for Phase I clinical trials.

- **Development of clinical trials**

MS is a critical disease especially for whites. 2-BBB, an European company, has been devoting brain studies for more than 10 years to find a better option. Their deep and dedicated efforts made them more than qualified to design and execute the development of 2B3-201.

- **Marketing globally**

Partner global pharma for marketing

# Management Team



Yu-Fang Hu



Pieter J. Gaillard

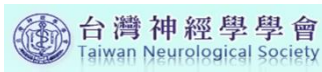


Yuan-Yi Chou

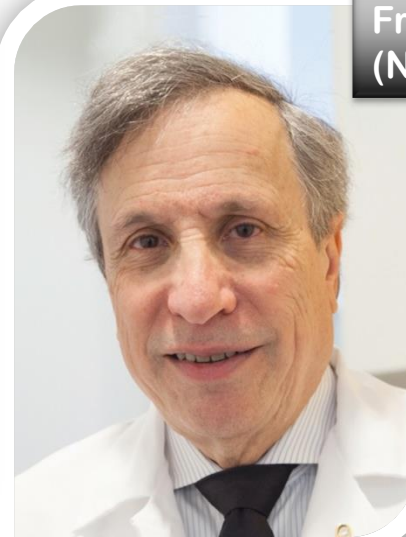


# Scientific Advisory Board

蔡清標  
Taipei, Taiwan



Fred Lublin  
(New York, USA)



HOME OF SIDNEY KIMMEL MEDICAL COLLEGE



Ralf Linker  
(Erlangen, Germany)



UNI  
FREIBURG

UKRUB UNIVERSITÄTSKLINIKUM DER  
RUHR-UNIVERSITÄT BOCHUM

Frederik Barkhof  
(Amsterdam, Netherlands)





# Agenda

Company Overview

Product Strategy

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



# Chungli Factory



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



# Lioudu Factory



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



**TTY** BIOPHARM<sup>®</sup>  
台灣東洋藥品

# Inspection Certificates

## PMDA (Japan)

承認番号 NDA088603B  
Number of NDA 088603B

品名 特許 特許 特許 特許 特許  
Name of drug 特許 特許 特許 特許 特許  
Trade Name of drug 特許 特許 特許 特許 特許  
Manufacturer 特許 特許 特許 特許 特許

製造元の名称  
Name of drug  
製造元の名称  
Name of drug  
製造元の名称  
Name of drug  
製造元の名称  
Name of drug  
製造元の名称  
Name of drug

製造元の所在地  
Location of the manufacturer  
製造元の所在地  
Location of the manufacturer  
製造元の所在地  
Location of the manufacturer  
製造元の所在地  
Location of the manufacturer  
製造元の所在地  
Location of the manufacturer

承認の区分  
Classification  
承認の区分  
Classification  
承認の区分  
Classification  
承認の区分  
Classification  
承認の区分  
Classification

承認後部 1-5 条の3の1の1に該当する。 特許 特許 特許 特許 特許  
It is certified that the above name is in compliance with the provisions of Article 153 of the Pharmaceutical Affairs Act.  
平成 20 年 8 月 25 日  
2011 Year Month Day  
行政労働大臣 森田 佳子  
Minister of Health, Labour and Welfare

有効期間 平成 23 年 8 月 23 日まで  
Valid period of cert. 2011 Year Month Day  
平成 20 年 8 月 23 日まで  
Valid period of cert. 2011 Year Month Day

承認番号 NDA088603B

## FDA

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
Silver Spring, MD 20904

NDA 20145-016

Supplemental Approval

Janssen Products, L.P.  
Attention: Medical Services  
Associate Director, Global Regulatory Affairs  
920 Route 201 South  
P.O. Box 109  
Raritan, NJ 08869

Dear Mr. Soriano:

Please refer to your Supplemental New Drug Application (sNDA) dated July 12, 2013, received July 17, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Janssen's combination of 6L and drug product, 6L (mg/ml) and 6L (mg/ml) and 6L (mg/ml).

We acknowledge receipt of your amendments to this supplement dated August 16, 2013, August 28, 2013, September 22, 2014, October 1, 2014, January 9, 2015, January 16, 2015, January 20, 2015, and January 22, 2015.

The September 22, 2014, submission constituted a complete response to our November 12, 2013, Complete Response action letter.

This Prior Approval supplemental new drug application provides for:

- a new manufacturing site at TTY Biopharm Company Limited (TTY Biopharm) located in Changlu, Taoyuan, Taiwan, R.O.C. for the manufacturing of the drug product;
- a change in back site of the drug product to 6L and drug product from Incubating process chamber;
- a new pre-sterilized, pre-positioned stopper for the drug product container/closure system;
- addition of a secondary packaging site at Anderson/Intertec, Inc.;
- revisions of the package insert to conform with the requirements of content and format of labeling as described in 21 CFR 201.35 and 201.57, and the Pregnancy and Lactation Labeling Rule (PLLR) and;
- revisions of content and immediate container labeling to mitigate the risk of medication error.

## EMA

13 APR 2015

EMA  
European Medicines Agency

Federal Agency for Medicines and Health Products  
CERTIFICATE NUMBER: 2015/0000000000  
CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1  
Date: Following an inspection on 12 November 2014, at the premises of Janssen Pharmaceutica NV, Division of Janssen Pharmaceutica NV, Belgium, the following information was obtained:  
The compliance of Janssen Pharmaceutica NV with the following conditions:  
The manufacturer Janssen Pharmaceutica NV (Janssen Pharmaceutica NV) is located at: Janssen Pharmaceutica NV, Division of Janssen Pharmaceutica NV, Belgium, 2300 Rixensart, Belgium.  
This has been inspected in accordance with the conditions of the manufacturing licence issued under the European Medicines Directive in accordance with Article 16(1) of Directive 2003/2003/EC concerning the following official certificate:  
Article 16(1) of the scope of the 14 December 2006 related to medicinal products for human and veterinary use.

For the knowledge and entry in the register of this manufacturer, the date of which was conducted on 12 November 2014, it is concluded that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/2003/EC.

This certificate reflects the state of the manufacturing site at the time of the inspection and does not constitute a guarantee of the compliance status of sites that have not been inspected since the date of this inspection. However, this period of validity may be renewed or extended using statutory provisions in force at the date of the certificate or otherwise notified. The certificate is valid only when recorded with all pages and their serial number. The authenticity of this certificate may be verified by contacting EMA. If it does not appear, please contact the issuing authority.

EMA  
European Medicines Agency

## ANVISA (Brazil)

MINISTÉRIO DA SAÚDE  
ANVISA - Agência Nacional de Vigilância Sanitária  
MANTENIMENTO DE REGISTRO DE FABRICAÇÃO  
CERTIFICADO DE BOAS PRÁTICAS DE FABRICAÇÃO

3 - A empresa possui um sistema de controle de qualidade que garante a qualidade dos produtos e a segurança dos pacientes. O sistema de controle de qualidade é baseado em normas internacionais de qualidade, como a ISO 9001:2008 e a ISO 13485:2003, e é certificado por uma autoridade reconhecida internacionalmente.

3 - The company has a quality control system that guarantees the quality of the products and the safety of the patients. The quality control system is based on international quality standards, such as ISO 9001:2008 and ISO 13485:2003, and is certified by an internationally recognized authority.

3 - The company has a quality control system that guarantees the quality of the products and the safety of the patients. The quality control system is based on international quality standards, such as ISO 9001:2008 and ISO 13485:2003, and is certified by an internationally recognized authority.

3 - The company has a quality control system that guarantees the quality of the products and the safety of the patients. The quality control system is based on international quality standards, such as ISO 9001:2008 and ISO 13485:2003, and is certified by an internationally recognized authority.

3 - The company has a quality control system that guarantees the quality of the products and the safety of the patients. The quality control system is based on international quality standards, such as ISO 9001:2008 and ISO 13485:2003, and is certified by an internationally recognized authority.

## TFDA

行政院衛生署藥品優良製造證明書  
中華民國衛生署公告 中華民國九十四年四月二十七日  
製藥廠名稱：台灣東洋藥廠有限公司中國廠  
製藥廠地址：新加坡中區禧街中區第一號  
製藥廠之相關資訊及內容：

一、藥品名稱：注射用α-葡聚糖  
二、藥品劑型：注射劑  
三、藥品規格：0.5g/瓶  
四、藥品用途：用於治療各種炎症反應  
五、藥品生產日期：中華民國九十四年四月二十七日  
六、藥品批發日期：中華民國九十四年四月二十七日  
七、藥品批發地點：新加坡中區禧街中區第一號  
八、藥品批發人員：林文建

行政院衛生署  
署長 邱文達

中華民國九十四年四月二十七日  
中華民國九十四年四月二十七日  
中華民國九十四年四月二十七日



# Agenda

**Company Overview**

**Product Strategy**

**Product Pipeline**




**Manufacture Facilities**

**Successful Product Categories**





**In Progress Status**

**Biotech Success**

# Successful Products (Oncology, Taiwan & Segment Market)







Products 產品名稱	Indications 適應症	Market(s) 行銷地區
Asadin (伸定注射液) 	Acute promyelocytic leukemia, APL (急性前骨髓細胞白血病)	Taiwan、Thailand、 Malaysia、Singapore Vietnam
Gemmis (健仕注射液) 	inoperable, locally-advanced (stage IIIa or IIIb) or Metastatic (stage IV) Non-small cell lung cancer (非小細胞肺癌) Inoperable (stage II or III) or metastatic (stage IV) Pancreatic cancer, PC (胰臟癌) Metastatic (stage IV) Urinary bladder cancer, UBC (膀胱癌) Metastatic (stage IV) Breast cancer, BC (轉移性乳癌) Recurrent (stage IV) Ovarian cancer, OC (卵巢癌)	Taiwan、Hong Kong
Lipo-Dox (力得微脂體注射液) 	AIDS-related Kaposi's sarcoma in patients with low CD4 counts and extensive mucocutaneous or visceral disease. (愛滋病引發之卡波西氏肉瘤) Metastasis carcinoma of the ovary with recurrent to both first line platinum- and paclitaxel-based chemotherapy regimens (復發性卵巢癌) Metastatic (stage IV) Breast cancer, BC (轉移性乳癌) Combination with bortezomib in 2nd line multiple myeloma, MM (多發性骨髓瘤)	Taiwan、Thailand、 Philippines
TS-1 (愛斯萬膠囊) 	Gastric cancer, GC (胃癌): Stage II & III gastric cancer adjuvant treatment; Advanced gastric cancer (stage IV); Pancreatic cancer, PC (胰臟癌)	Taiwan
Zobonic (抑骨凍晶靜脈注射液)	Multiple myeloma, MM (多發性骨髓瘤) Hypercalcemia of malignancy (惡性腫瘤之高血鈣併發症)	Taiwan
Painkyl Fentanyl(平舒疼口 類溶片) 	Breakthrough Pain (癌症突發性疼痛)	Taiwan <b>Restricted Drug</b>
Epicin 益彼欣 注射液 	Breast Cancer 乳腺癌、Lymphoma 惡性淋巴瘤、Soft tissue Sarcoma 軟組織肉瘤、Gastric cancer, GC 胃癌、Lung cancer LC 肺癌、Ovarian Cancer, OC 卵巢癌	Taiwan
Ivic® (癌微可) 	CML (慢性骨髓性白血病)	Taiwan

# Successful Products (Oncology, Taiwan & Segment Market)

Products 產品名稱	Indications 適應症	Market(s) 行銷地區
<p>Oxalip (歐力普注射劑)</p> 	<p>Colorectal cancer, CRC (結腸直腸癌): stage III colon cancer adjuvant treatment; Metastatic colorectal cancer (stage IV) Gastric cancer, GC (胃癌): Advanced gastric cancer (stage IV)</p>	Taiwan、Thailand、
<p>Tynen (汰能注射劑)</p> 	<p>Adjuvant &amp; metastatic (lymph node positive) (stage II~IV) Breast cancer, BC (乳癌) Metastatic (stage IV) Non-small cell lung cancer (非小細胞肺癌) Hormone refractory metastatic prostate cancer, PC (前列腺癌) Locally advanced(stage III~stage IVB) squamous cell carcinoma of the head and neck (局部晚期頭頸部癌) Metastatic (stage IV) Gastric gland cancer (胃腺癌)</p>	Taiwan
<p>UFUR (友復膠囊)</p> 	<p>Gastric cancer, GC (胃癌)– Adjuvant Treatment for stage IB, II, III patients after curative surgery; advanced gastric cancer (Stage IV) Colorectal cancer, CRC (大腸結腸直腸癌)– Stage II &amp; III colorectal cancer; metastatic colorectal cancer (stage IV) Breast cancer, BC (乳癌), stage II breast cancer; Metastatic breast cancer (stage IV) Lung cancer, LC (肺癌) stage IB; Metastatic lung cancer (stage IV) Head &amp; Neck cancer (頭頸癌), stage I to IV</p>	Taiwan、Thailand、 Vietnam、Malaysia、 India、Pakistan Nigeria
<p>Thado (賽得膠囊)</p> 	<p>Newly diagnosed multiple myeloma, MM (多發性骨髓瘤) Erythema Nodosum Leprosus, ENL (癩瘋性結節性紅斑)</p>	Taiwan、Philippines、 Malaysia、Vietnam、 Singapore



# Successful Products (Oncology, Taiwan & Segment Market)





Products 產品名稱	Indications 適應症	Market(s) 行銷地區
<b>Anazo</b> (安納柔膜衣錠) 	Treatment of advanced breast cancer in postmenopausal women. (治療停經後婦女晚期乳癌) Adjuvant treatment of early breast cancer in hormone receptor positive post-menopausal women who have received 2 to 3 years of adjuvant tamoxifen. (輔助治療停經後婦女且荷爾蒙接受器為陽性的早期乳癌)	Taiwan、Philippines
<b>Pexeda Inj.</b> (派癌休注射劑) 	Nonsquamous Non-Small Cell Lung Cancer (治療局部晚期或轉移性非小細胞癌); Mesothelioma (治療惡性肋膜間質細胞瘤)	Taiwan
<b>Irino</b> (派癌休注射劑) 	Treatment of patients with advanced colorectal cancer (轉移性大腸直腸癌患者的第一線治療藥物)	Taiwan、Thailand、Japan
<b>Megest</b> (麥格斯口服懸液劑) 	Significant weight loss caused by cachexia in patients with a diagnosis of acquired immunodeficiency syndrome (AIDS) or cancer, and also the treatment of anorexia in patients. 後天免疫缺乏症候群患者及癌症患者之惡病體質引起的體重明顯減輕及厭食症。	Taiwan
<b>Otril</b> (嘔速停靜脈注射劑) 	Prevention and treatment of nausea and/or vomiting associated with cancer chemotherapy. 預防及治療抗腫瘤化學療法、和治療手術後引起的噁心、嘔吐。	Taiwan
<b>Lonsurf</b> 	Treatment of patients who have failed standard treatment of metastatic colorectal cancer. 治療晚期大腸直腸癌已接受標準治療失敗的病人。	Taiwan

# Oncology/Successful Products for Global

TTY has successfully registered **47** oncology product licenses in **12** countries.

	Country	UFur	Oxalip	Lipo-Dox	Irino	Asadin	Gemmis	Tynen	Epicin	Thado	Anazo	Folina	Sulfin	Total
EU	Austria							2						2
Asia	Thailand	1	1	1	1	1						1	1	7
	Philippines			1							1		1	3
	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		1					1		4
	Pakistan	1												1
	Jordan				1									1
US	Costa Rica						1		1					2
	Total	6	4	4	7	3	4	7	4	2	2	2	2	47

# Successful Products (Anti-Infectives, Taiwan & Segment Market)

Products 產品名稱	Indications 適應症	Market(s) 行銷地區
<b>Brosym C+S</b> (博益欣) 	適用於治療由感受性細菌所引起的下列感染：上、下呼吸道感染、上、下泌尿道感染、腹膜炎、膽囊炎、膽管炎及其他腹腔內感染、骨盆發炎、子宮內膜炎及其他生殖道感染、以及創傷燙傷、手術後之二次感染。 唯一抗感染新療效付苦心要對鮑氏不動桿菌(AB菌)治療效果佳。	Taiwan
<b>Cubicin</b> (救必辛注射劑) 	1. 治療下列感受性革蘭氏陽性菌引起的複雜皮膚和皮膚組織感染(cSSSI)：Staphylococcus aureus (包括methicillin-resistant isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae subsp. Equisimilis 與 Enterococcus faecalis (vancomycin-susceptible isolates only) 2. Staphylococcus aureus引起之血液感染(菌血症)包括由具methicillin感受性及抗藥性菌株造成之右側感染性心內膜炎。	Taiwan
<b>Colimycin</b> (克痢黴素注射劑) 	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。	Taiwan
<b>Lipo-AB</b> 	1. 骨髓移植後併發腎毒性出現侵入性黴菌感染。 2. 腎功能不全之麴菌屬、念珠菌屬或囊球菌屬類的菌種感染病患。 3. 治療感染囊球菌腦膜炎的HIV患者。 4. 治療麴菌屬、念珠菌屬或是囊球菌屬類的菌種感染，或是無法用 Amphotericin B deoxycholate治療的病患，或是腎功能不全或無法耐受 Amphotericin B deoxycholate所產生的毒性之病患。 5. 治療臟器的利時曼氏病。在免疫不全且患有臟器的利時曼氏病之患者使用 Amphotericin B Liposome for Injection治療，在初期寄生蟲清除後仍有高復發率。 6. 對發燒的重度嗜中性白血球缺乏症患者可能罹患黴菌感染症之經驗療法。	Taiwan

# R&D Investment 研究及臨床

Subject		Year										
		2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	
*D&C Resource  營收為 總公司 + 分公司	Revenue (NTD,000)	1,519,680	1,773,420	2,067,360	1,786,500	2,098,500	2,158,500	2,307,540	2,384,220	2,738,956	3,344,262	
	R&D Expense (NTD,000)	197,550	200,040	238,650	290,040	384,360	366,750	289,530	283,470	236,398	230,192	
	Total Staff	319	339	400	338	374	404	484	494	450	508	
	R&D Manpower	82	92	90	94	97	104	111	105	97	105	
	R&D Expense/ Revenue	13.00%	11.30%	11.50%	16.20%	18.30%	16.90%	12.55%	11.89%	8.63%	6.88%	
	R&D Total Staff	25.70%	27.10%	22.50%	27.80%	25.90%	25.70%	22.93%	21.26%	21.56%	20.67%	

- Continuous investment in development & clinical research:
  - Strong product portfolio
  - Long product life cycle
  - Abundant Asian clinical data

# Agenda

**Company Overview**

**Product Strategy**

**Product Pipeline**

**Manufacture Facilities**

**Successful Product Categories**

**In Progress Status**

**Biotech Success**

# Registration Approval Status

	送件日期 Apply Date	預估領證日期 Approval Date (Est.)	核可類別 Category	NPD Code
1	2016/6/1	<b>2016/12/13</b>	第二等級醫材 Class II Medical Device	ES0013
2	2017/1/1	2018	新成分新藥 NCE	TT7016
3	2016/7/1	2018	新成分新藥 NCE	PT2014

# Agenda

**Company Overview**

**Product Strategy**

**Product Pipeline**

**Manufacture Facilities**

**Successful Product Categories**

**In Progress Status**

**Biotech Success**

# Biotech Success Strategy (2017-2021)

## ● Marketing Development

- TS-1 、Painkyl 、Brosym(C+S) 、Episil 、Lonsurf 、Aplidin into peak sale
- Liposome Doxorubicin into global peak sale
- Liposome Amphotericin B
- Risperidone PLGA
- Leuprolide Depot
- Colimycin
- Regional markets integration
- Thailand ABT IPO

} Complete listing for global  
(Including China market)

## ● R&D

- CMO/CDMO
- PLGA(Microsphere) Development
- 1-2 NCE/NBE Projects
- Dual Chamber-Filling System ready



# Financial Comparison (Individual)

Item NTD ,000	2013 (Actual)		2014 (Actual)		2015 (Actual)		2016 (Actual)	
	Amount	%	Amount	%	Amount	%	Amount	%
Net Sales	2,292,163	100%	2,384,207	100%	2,738,956	100%	3,344,262	100%
Gross Profit	1,404,003	61%	1,411,875	59%	1,777,941	65%	2,217,286	66%
Operating Expenses	-1,121,548	-49%	-1,144,400	-48%	-1,035,412	-38%	-1,063,104	-32%
Operating Profit	282,455	12%	267,475	11%	742,529	27%	1,154,182	34%
Non-Operating Income and Expenses	413,685	18%	596,585	25%	705,211	26%	277,855	9%
Income before Tax	696,140	30%	864,060	36%	1,447,740	53%	1,432,037	43%
Net Income	587,440	26%	779,645	33%	1,211,018	44%	1,193,324	36%
<b>EPS</b>	<b>2.52</b>		<b>3.14</b>		<b>4.87</b>		<b>4.80</b>	

# Financial Comparison (Consolidated)

Item NTD ,000	2013 (Actual)		2014 (Actual)		2015 (Actual)		2016 (Actual)	
	Amount	%	Amount	%	Amount	%	Amount	%
Net Sales	3,110,092	100%	2,979,902	100%	3,195,218	100%	3,760,717	100%
Gross Profit	2,049,211	66%	1,898,936	64%	2,183,144	68%	2,559,220	68%
Operating Expenses	-1,709,349	-55%	-1,560,841	-53%	-1,393,357	-44%	-1,379,533	-36%
Operating Profit	339,862	11%	338,095	11%	789,787	24%	1,179,687	32%
Non-Operating Income and Expenses	496,394	16%	571,745	19%	735,808	23%	332,372	8%
Income before Tax	836,256	27%	909,840	30%	1,525,595	47%	1,512,059	40%
Net Income (Consolidated)	644,530	21%	811,695	27%	1,246,592	38%	1,254,724	33%
Net Income (TTY)	587,440	19%	779,645	26%	1,211,018	37%	1,193,324	31%
<b>EPS</b>	<b>2.52</b>		<b>3.14</b>		<b>4.87</b>		<b>4.80</b>	

# 2014-2015-2016 Net Profit (Individual)

Eliminated the investment traded out

Unit : NTD,000

Year Season	2014		2015		2016	
	Pretax	<i>After Tax</i>	Pretax	<i>After Tax</i>	Pretax	<i>After Tax</i>
Q1+Q2	95,926	<i>76,156</i>	321,740	<i>281,251</i>	735,949	<i>635,684</i>
Q3+Q4	284,325	<i>219,680</i>	552,446	<i>453,717</i>	696,088	<i>557,640</i>
<b>Total</b>	<b>380,251</b>	<b><i>295,836</i></b>	<b>874,186</b>	<b><i>734,968</i></b>	<b>1,432,037</b>	<b><i>1,193,324</i></b>

# 2014-2015-2016 Net Profit (Individual)

Eliminated the investment traded out

Unit : NTD,000

Year Season	2014		2015		2016	
	Pretax	After Tax	Pretax	After Tax	Pretax	After Tax
Q1+Q2	95,926	76,156	321,740	281,251	735,949	635,684
Q3+Q4	284,325	219,680	552,446	453,717	696,088	557,640
<b>Total</b>	<b>380,251</b>	<b>295,836</b>	<b>874,186</b>	<b>734,968</b>	<b>1,432,037</b>	<b>1,193,324</b>

Growing comparison

2015 Growth		2016 Growth	
Pretax	After Tax	Pretax	After Tax
225,814	205,095	414,209	354,433
268,121	234,037	143,642	103,923
<b>493,935</b>	<b>439,132</b>	<b>557,851</b>	<b>458,356</b>

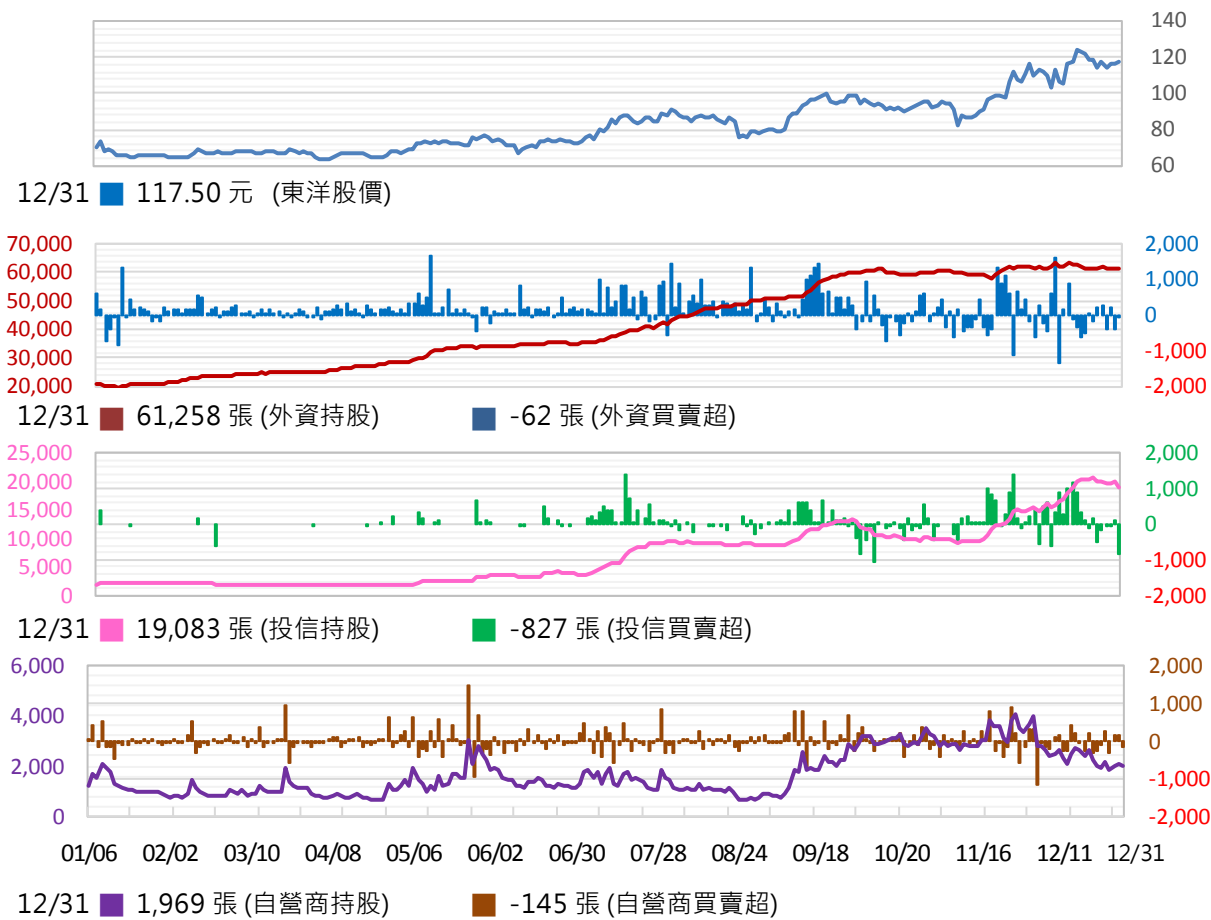
# Earning Distribution

<b>Year</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>
<b>Item</b>						
Yield Rate (%)	0.22	1.25	1.91	2.39	3.86	3.71
P/E	45.00	44.24	41.65	33.23	18.61	21.35
Cash Dividend	0.30	1.40	2.00	2.50	3.50	3.80*
Stock Dividend	2.40	0.89	0.67	-	-	-
Total	2.70	2.29	2.67	2.50	3.50	3.80

\* Awaiting for shareholder meeting decision.

# 3 Major Investors Holdings 2015

台灣東洋(4105)法人持股走勢圖



1/6 → 12/31 Shift

## 3 Majors

2.39萬張(9.63%)



8.22萬張(33.09%)

## Foreign Investor

2.09萬張(8.39%)



6.12萬張(24.63%)

## Investment Trust

0.18萬張(0.74%)



1.91萬張(7.67%)

## Dealers

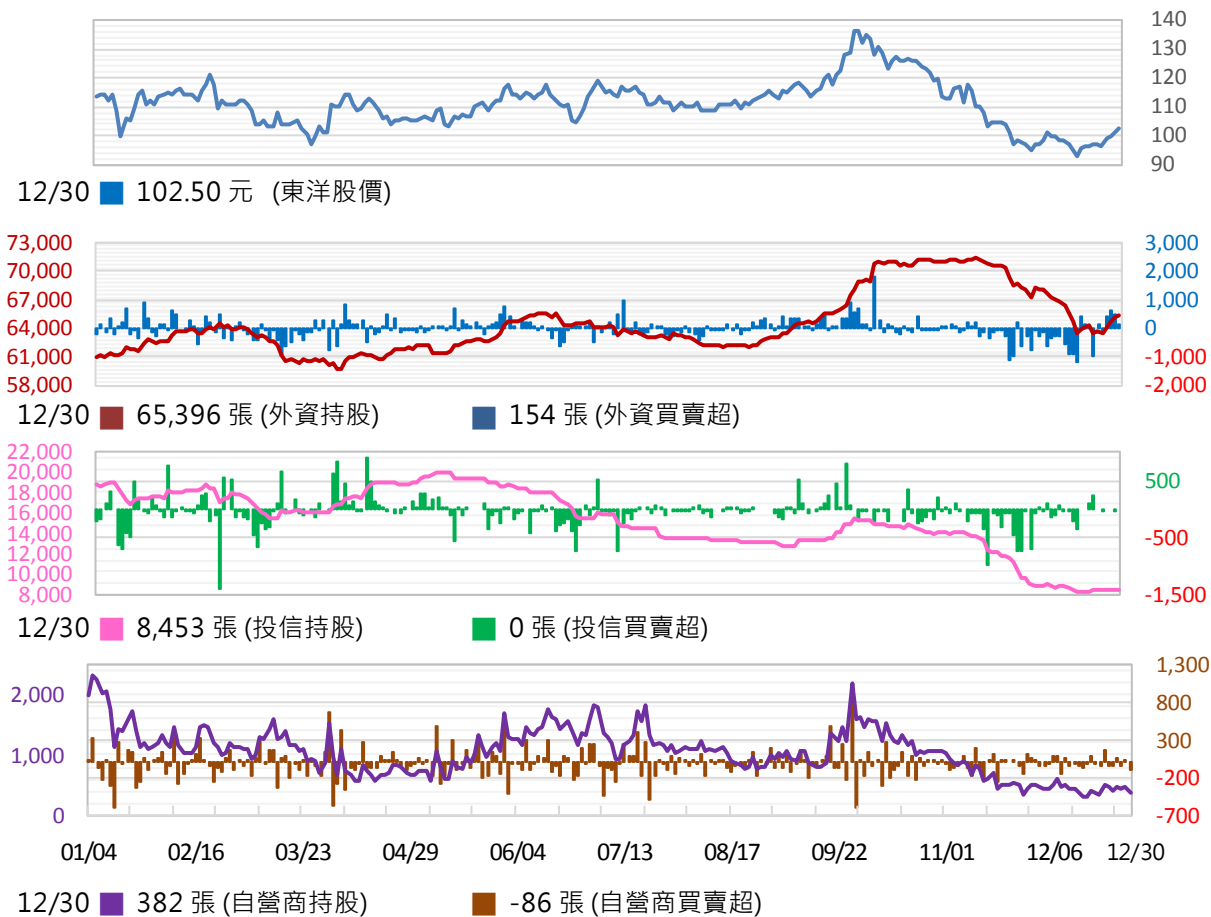
0.12萬張(0.50%)



0.19萬張(0.79%)

# 3 Major Investors Holdings 2016

台灣東洋(4105)法人持股走勢圖



1/4 → 12/30 Shift

## 3 Majors

8.19萬張(32.93%)



7.42萬張(29.85%)

## Foreign Investor

6.10萬張(24.54%)



6.53萬張(26.30%)

## Investment Trust

1.89萬張(7.59%)



0.84萬張(3.40%)

## Dealers

0.20萬張(0.80%)

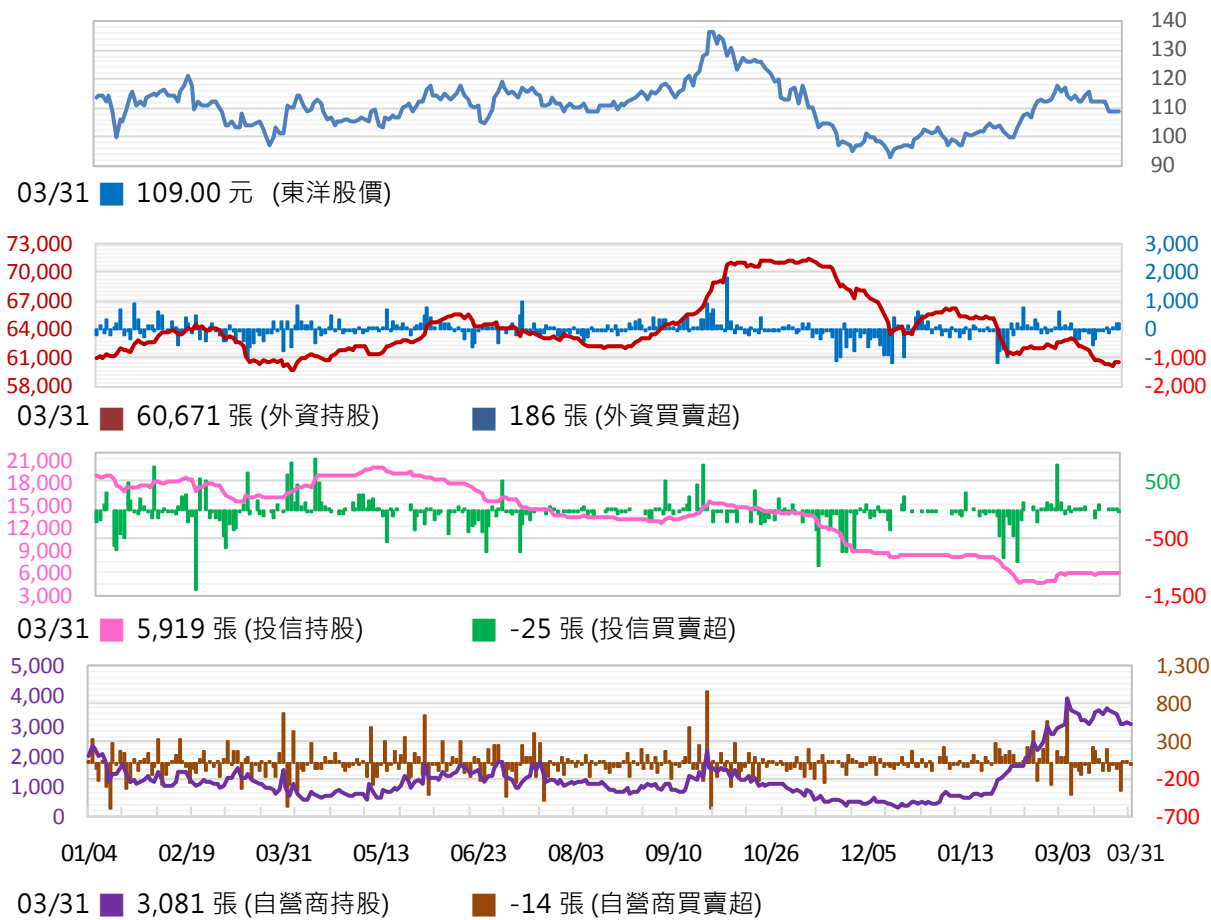


0.03萬張(0.15%)



# 3 Major Investors 20160104~20170331

台灣東洋(4105)法人持股走勢圖



2016/1/4 →  
2017/3/31 Shift

## 3 Majors

8.19 萬張 (32.93%)



6.97 萬張 (28.02%)

## Foreign Investor

6.10 萬張 (24.54%)



6.07 萬張 (24.40%)

## Investment Trust

1.89 萬張 (7.59%)



0.59 萬張 (2.38%)

## Dealers

0.20 萬張 (0.80%)



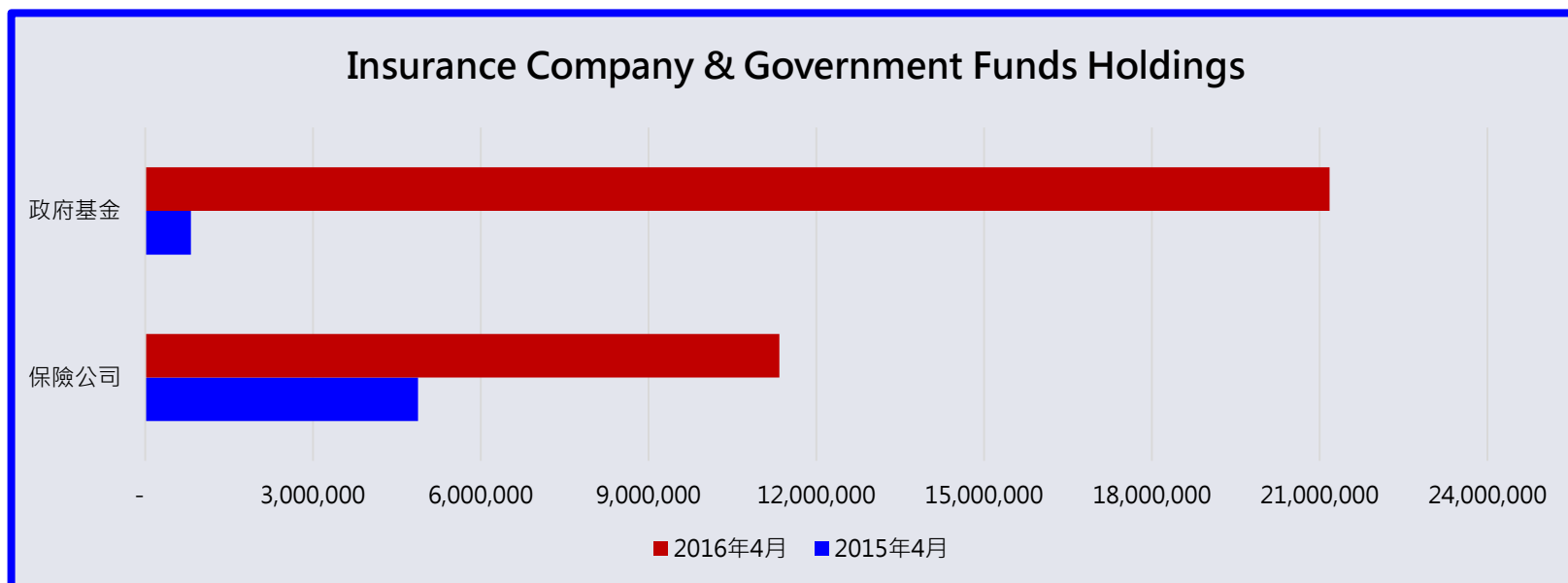
0.31 萬張 (1.24%)





# Government & Insurance Holdings

Institution / Holdings	April/2015		April/2016	
	持有股數Stocks	持股比例%	持有股數Stocks	持股比例%
Insurance Company	4,880,800	1.96%	11,339,000	4.56%
Government Funds	817,021	0.33%	21,177,843	8.52%
<b>Total</b>	<b>5,697,821</b>	<b>2.29%</b>	<b>32,516,843</b>	<b>13.08%</b>





Let's share and grow together  
in this big family

**T1Y BIOPHARM**  
台灣東洋藥品



東生華製藥  
tsh biopharm

**T1Y BIOPHARM**  
榮 港 生 技



PharmaEngine

智擎生技製藥股份有限公司

**CI BIOTECH**  
創 益 生 技