

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

**TTV** BIOPHARM®

台灣東洋藥品

**WELCOME TO JOIN US**

September, 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

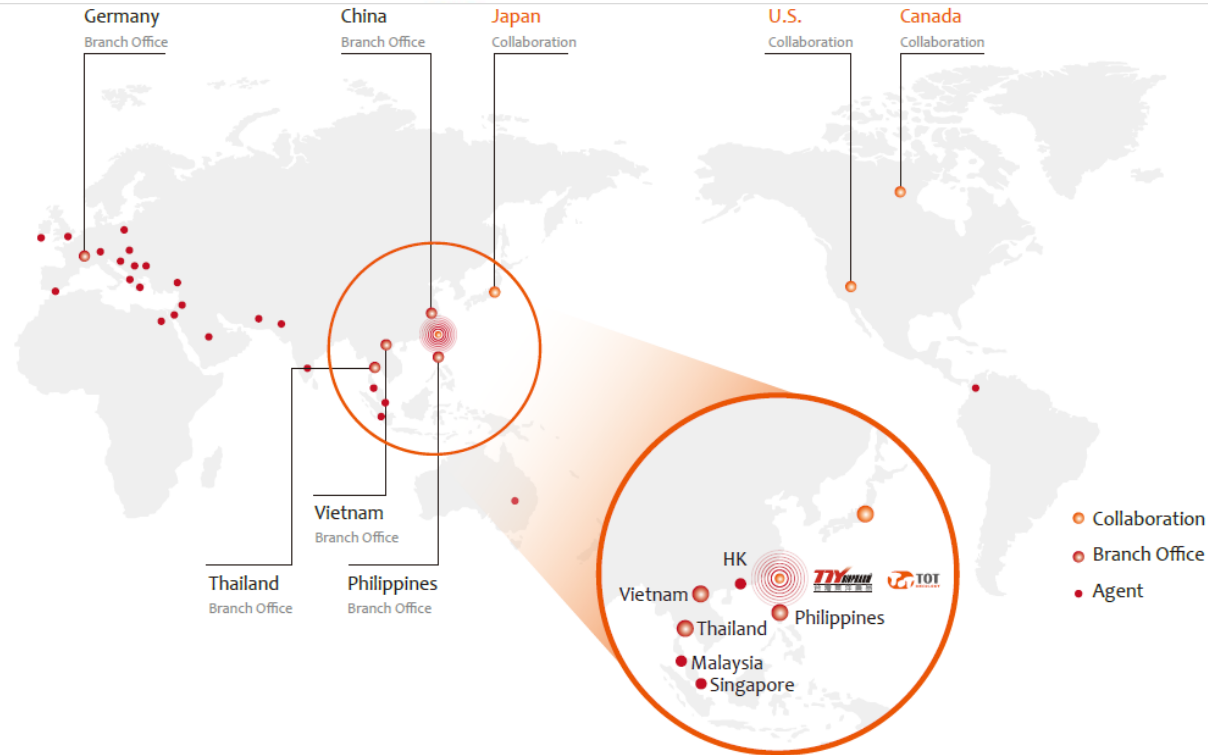
Manufacture Facilities

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 specialty/ 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\$825mn. As of 6/30/2017
- Currently has three major subsidiaries (base on 6/30/2017): PharmaEngine (listed), Market cap US\$804mn, 19.30% ; TSH Biopharm (listed), Market cap US\$103mn, 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

殷漢

EnhanX (67%)

- R&D / New Drug Development
- Clinical Trials & 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%

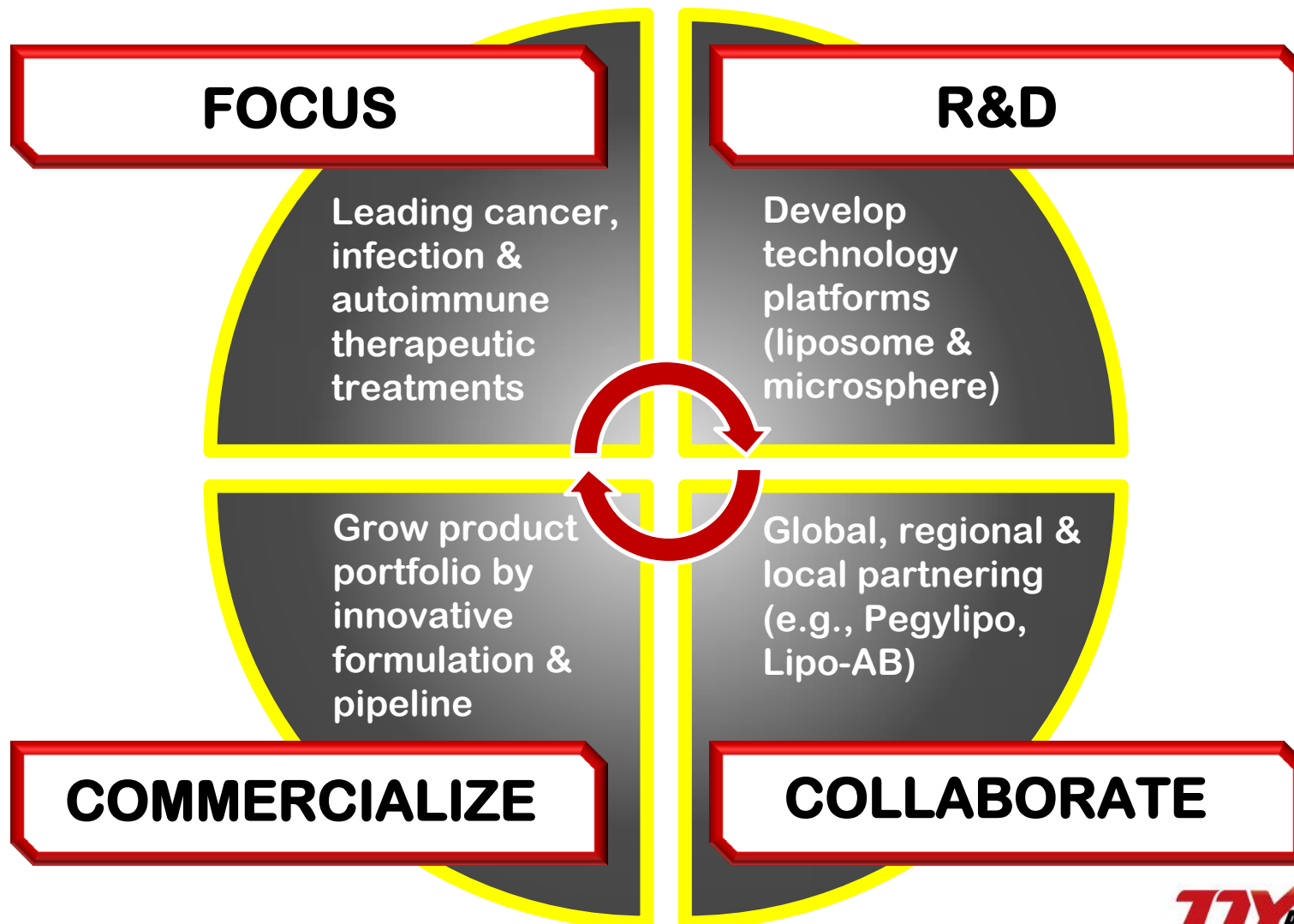
- New Drug Development & Marketing

# TTY Core Competences





# Corporate Strategy



# Agenda

Company Overview

**Product Strategy**

Product Pipeline

Manufacture Facilities

Successful Product Categories

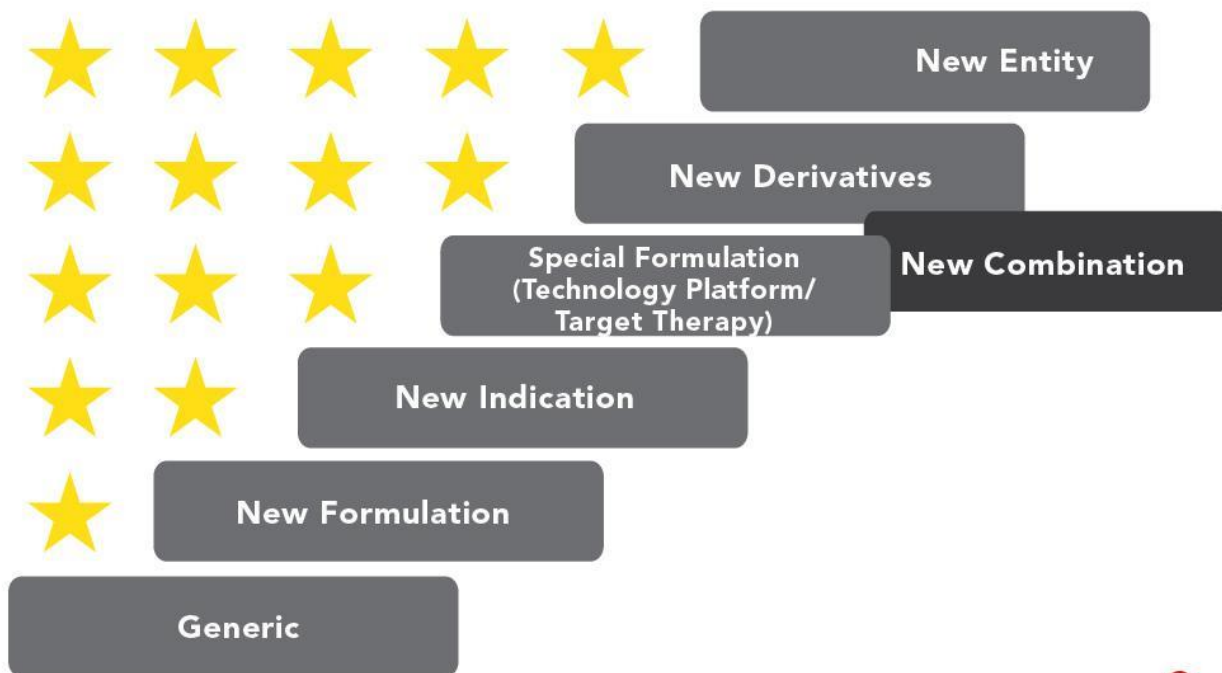
In Progress Status

Biotech Success

# Product Strategy

## Trends for Pharmaceutical Industry

Market Scope  
(Risk)







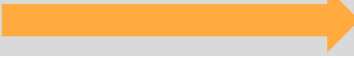





Entry Barrier  
(Profit)



# TTY Super Generics Pipeline

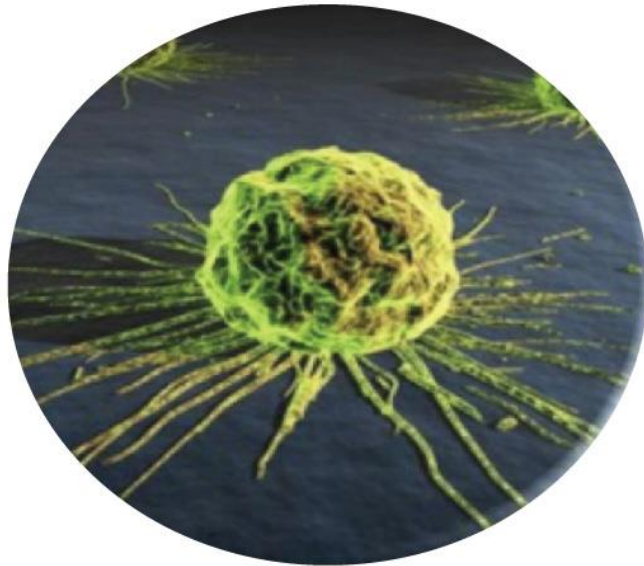
\* Current CDMO price for partner equals to 2016.

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

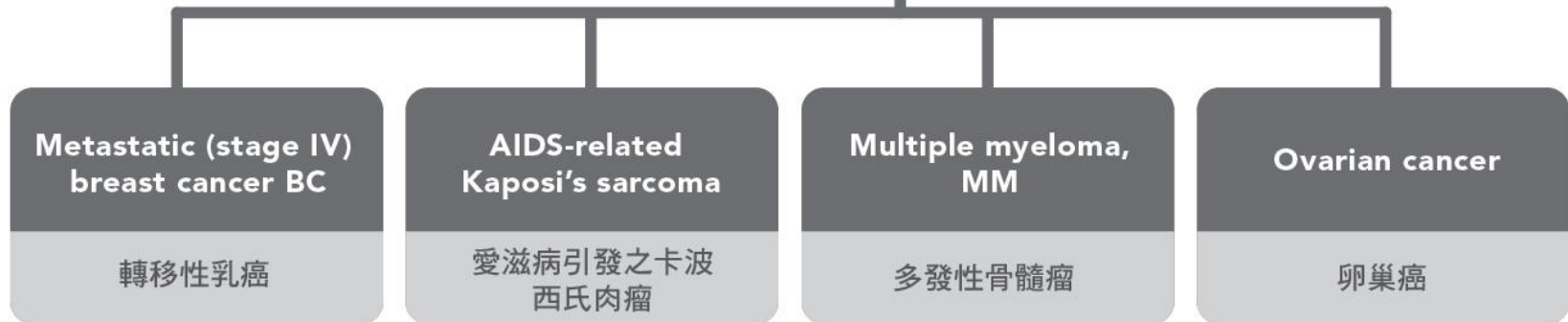
Programs 產品組合	Indication(s) 適應症	World Market (USD/M est.)	Core Technology 核心技術	Advantages 產品優勢
<b>Caelyx/Doxil (Lipo-Dox)</b>	Metastatic breast cancer BC、 AIDS-related Kaposi's sarcoma、 Multiple myeloma, MM、 Ovarian cancer	600	Pegylated Liposome Technology	Worldwide manufacturing patent
<b>Lipo-AB</b>	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

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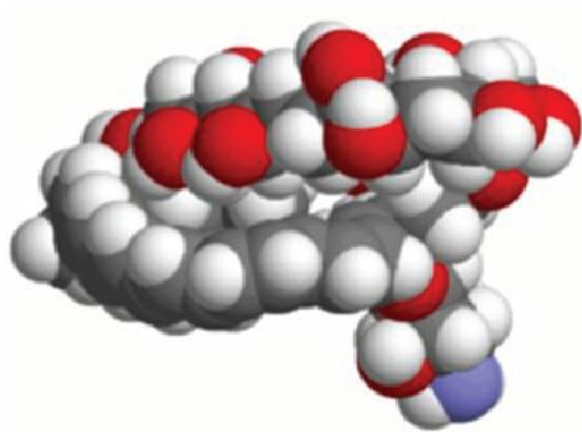


## Caelyx®/Doxil®/Pegylipo®

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



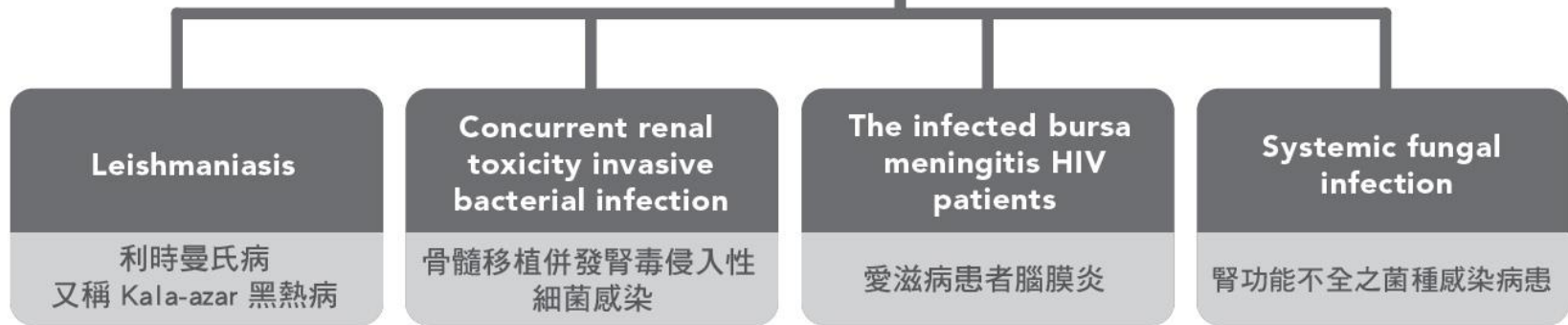
Source : Thomson Reuters Mar./2017

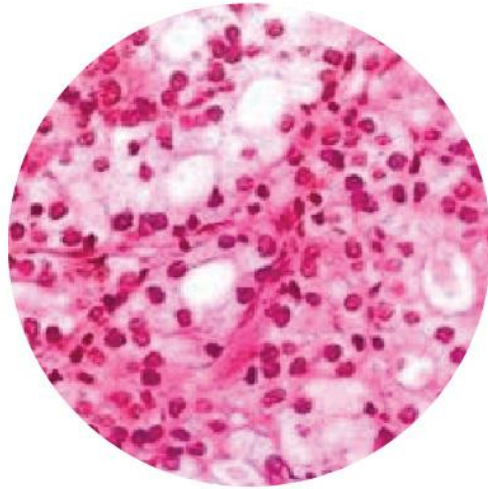


## Lipo-AB

Global Market: USD\$440 Million

Target: Worldwide 35~50%

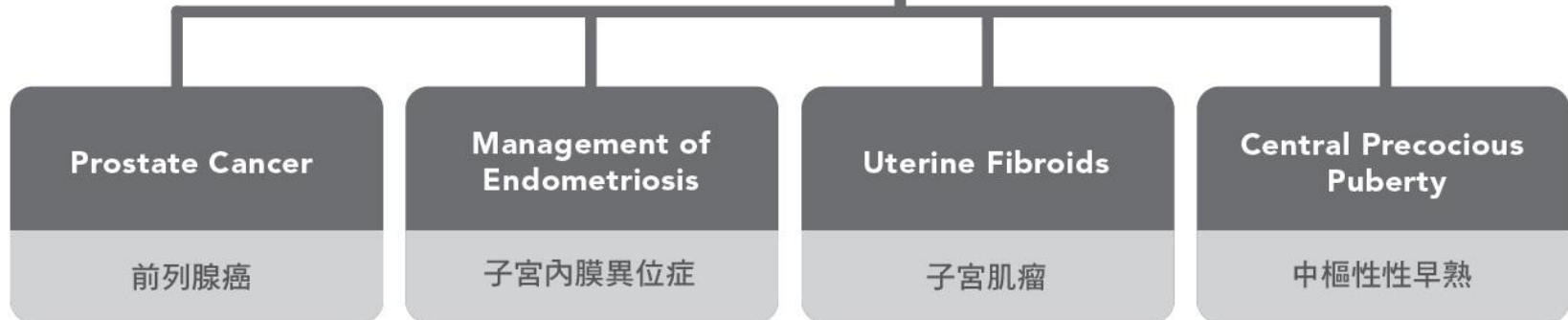




## Specialty- Leuprolide Acetate Injection

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

Target: Worldwide 20~35%

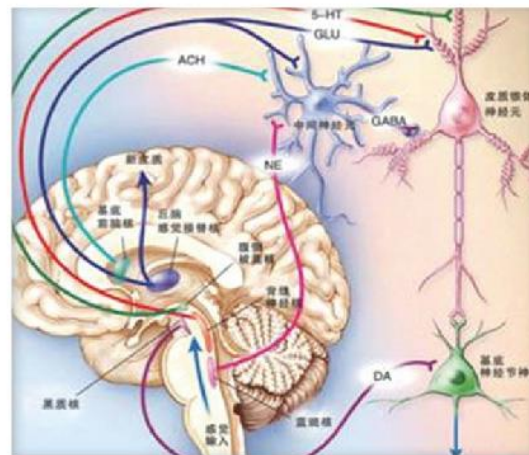
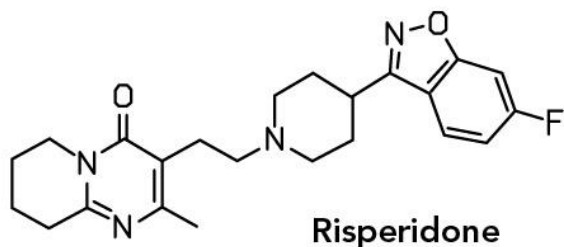




# Specialty- Risperidone Injection

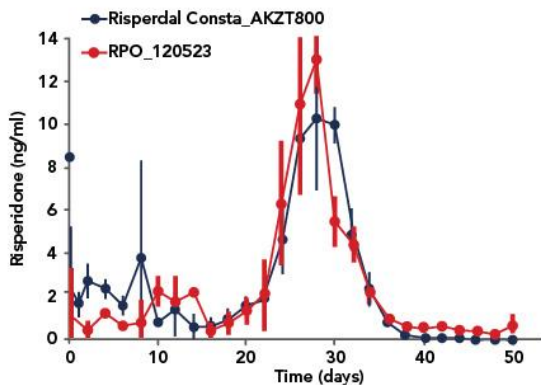
Indication: Schizophrenia

Global market: USD\$960 Million

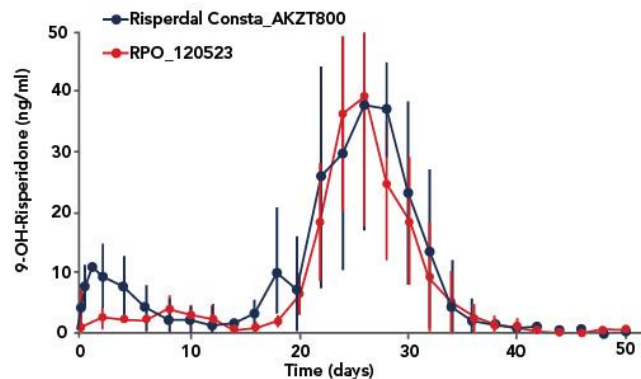


Beagle in vivo release

Risperidone



9-OH-Risperidone



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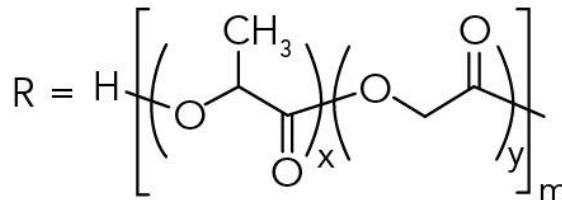
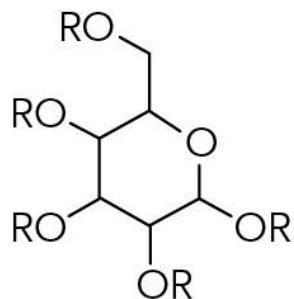


## Indications:

- 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!!**

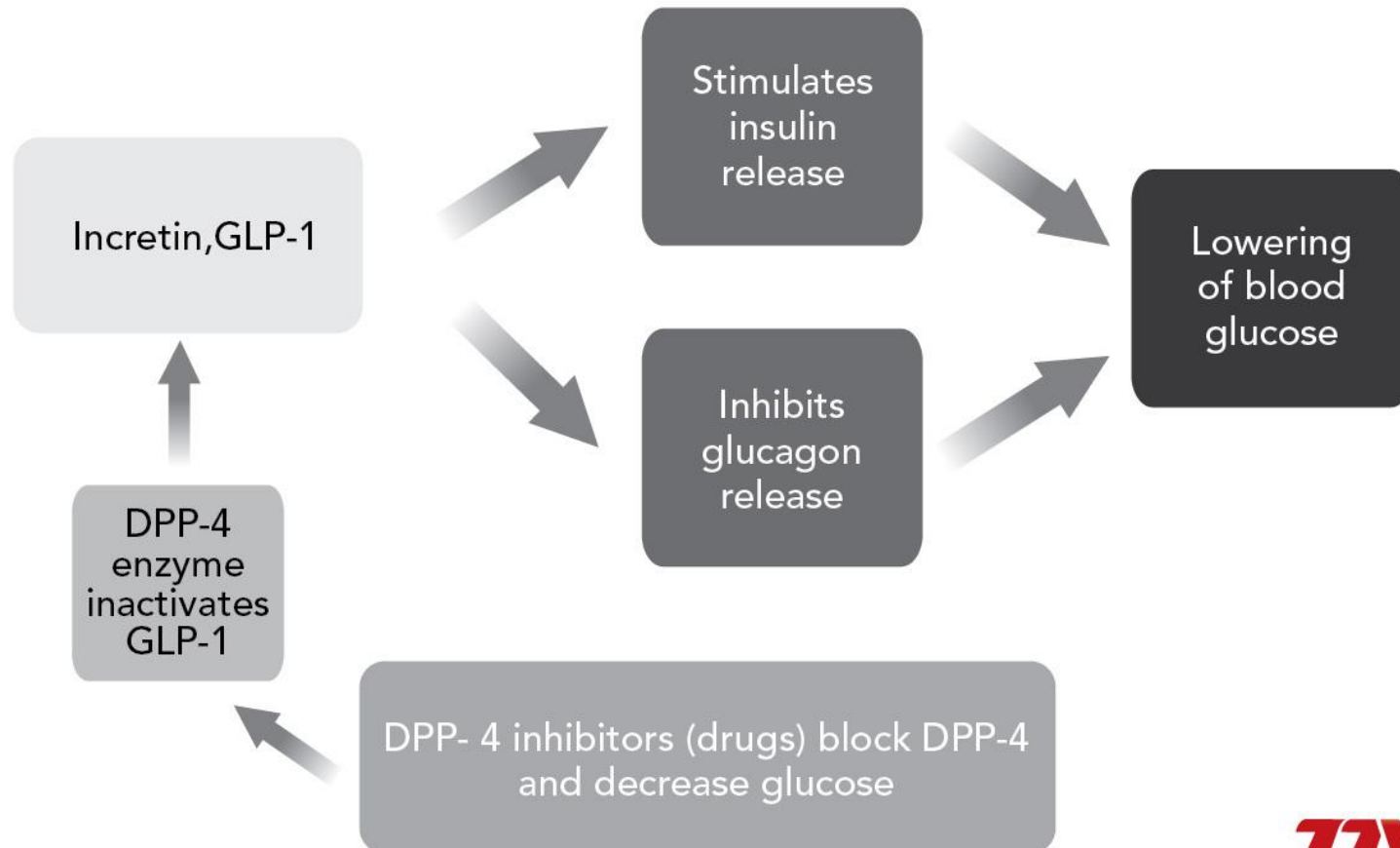


Polymer	Lot	MW(K Da)	PI
Poly(lactide-co-glycolide) star, glucose core LA:GA=1:1	TTY#783053	53	1.67

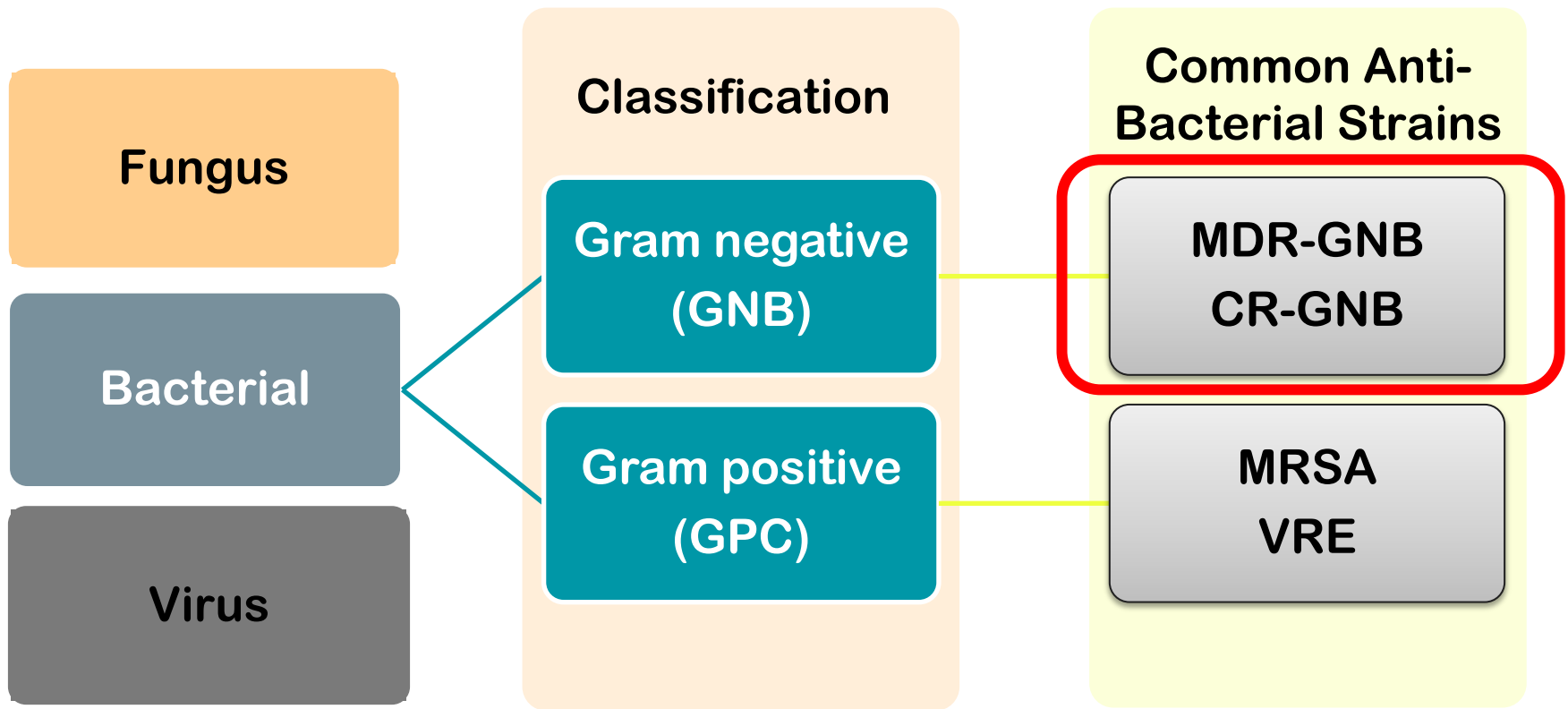
# Mechanism of LGIA10

## GLP-1 and Diabetes

Indication: Type II Diabetes Mellitus



# Specialty – Col103

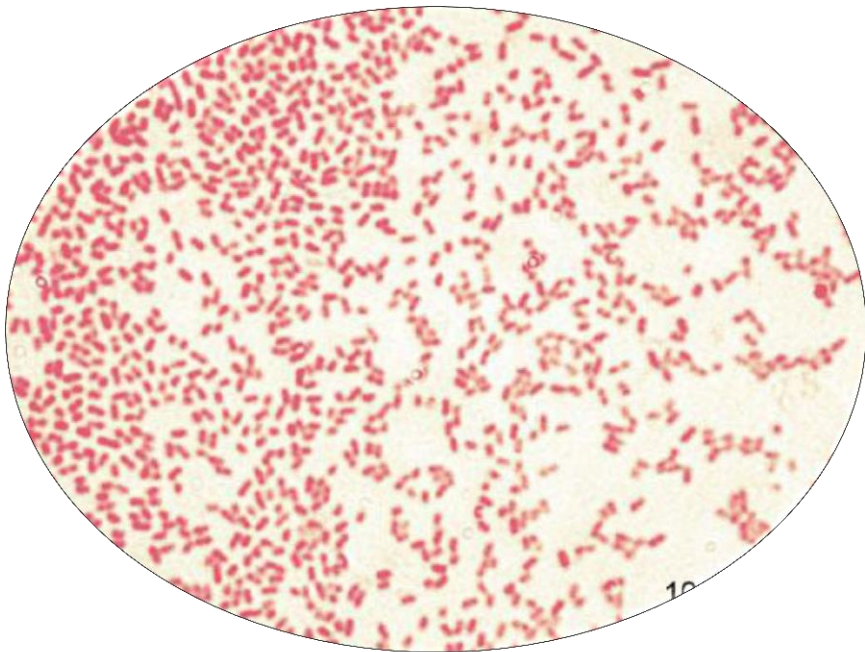


MDR-: multi-drug resistant  
CR-: carbapenem resistant

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

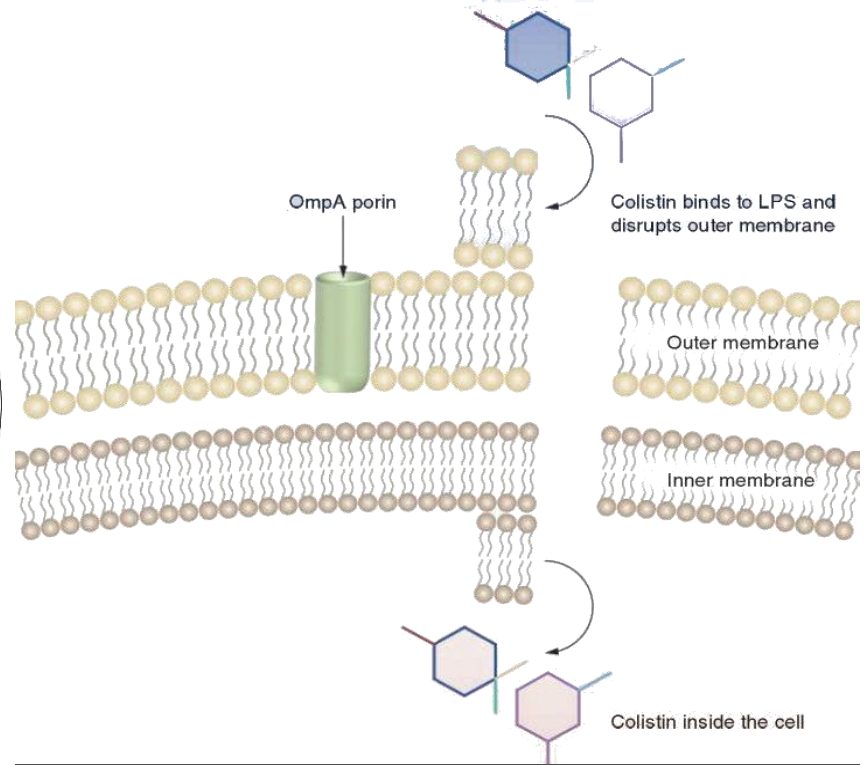
# Col103

Global Market: 150M



Multidrug-resistant  
Gram-negative Bacteria  
Serious Infection

Medscape



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**

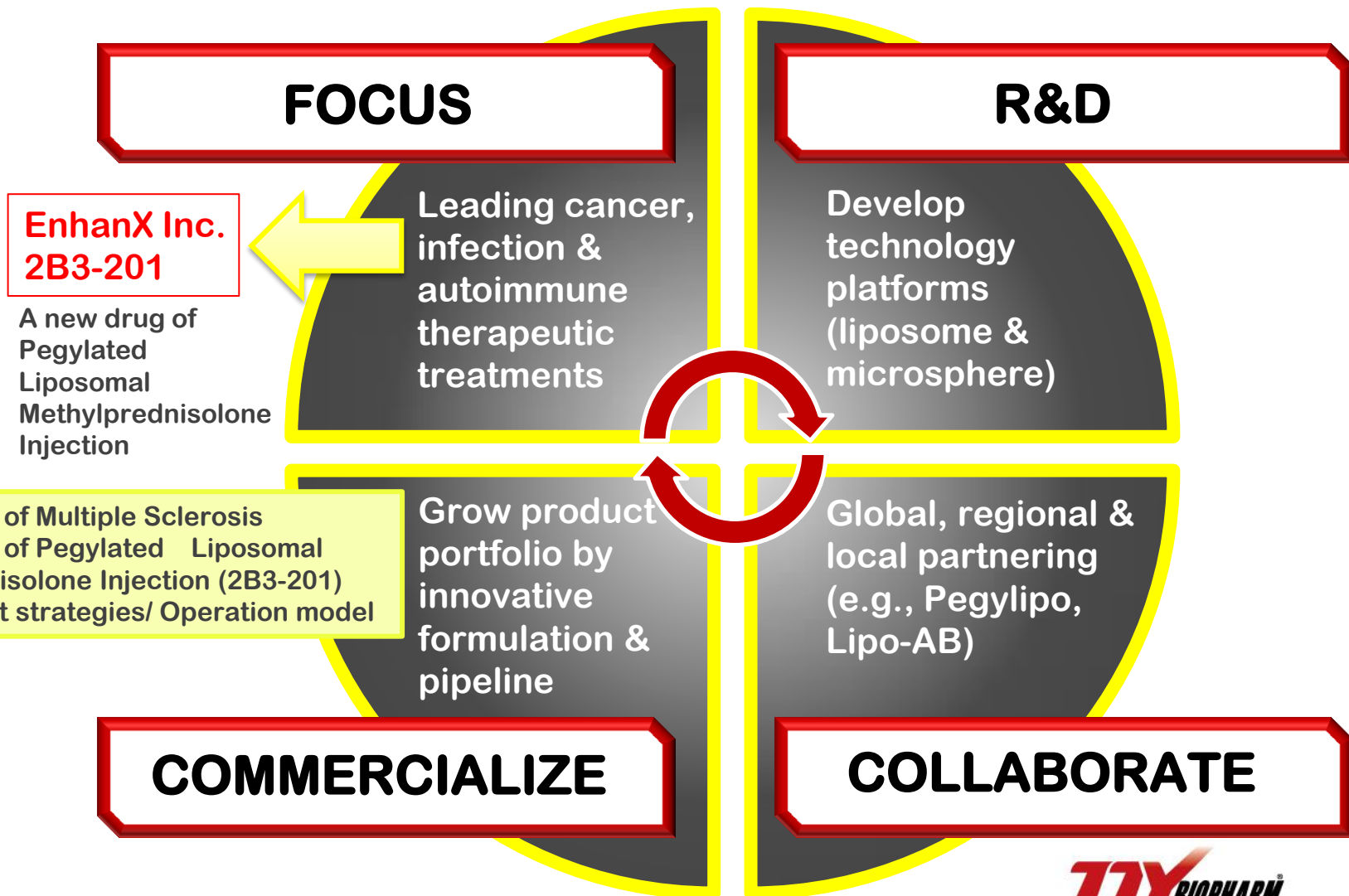
Manufacture Facilities

Successful Product Categories

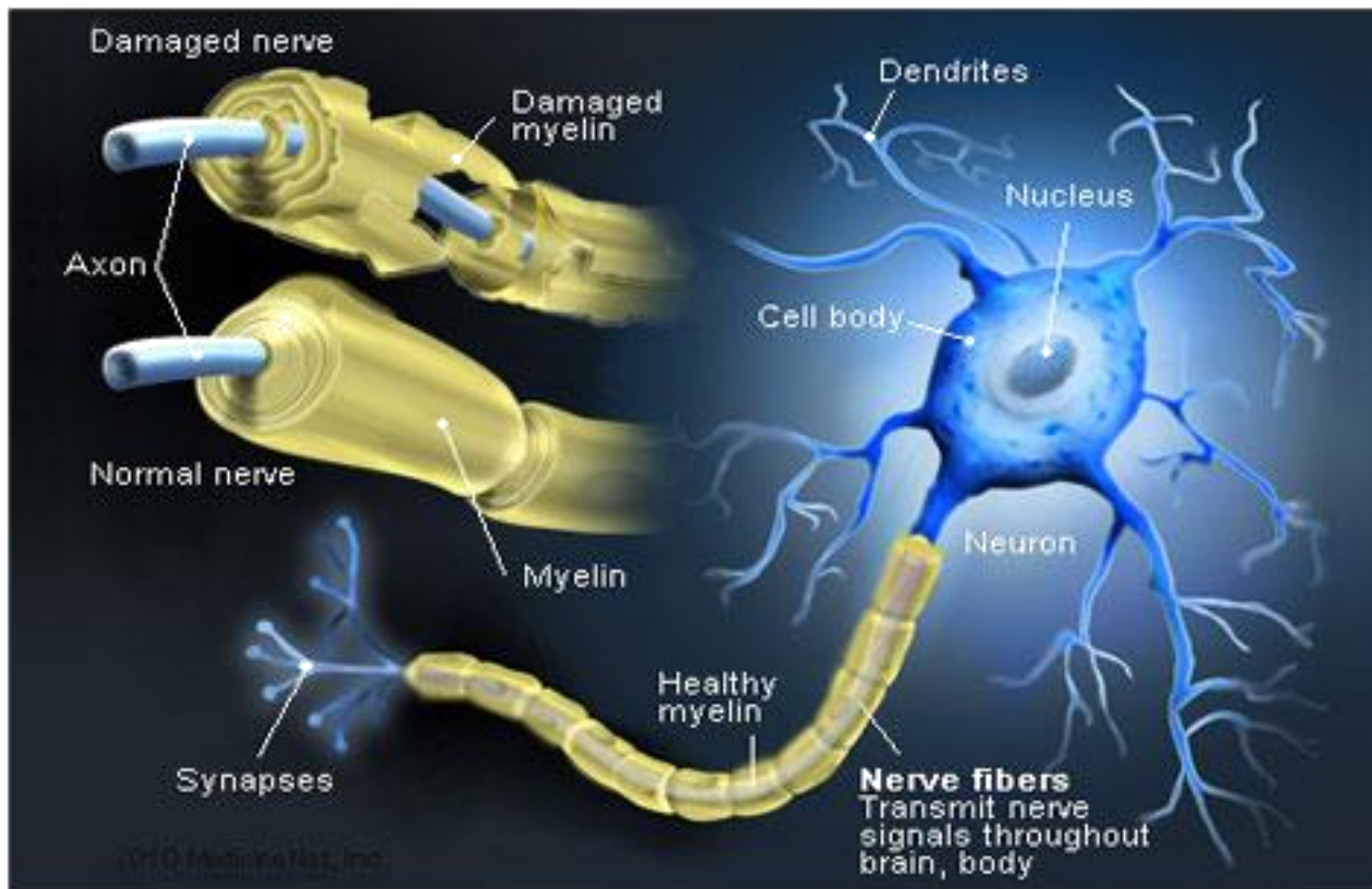
In Progress Status

Biotech Success

# Corporate Strategy



# Introduction of MS's MoA



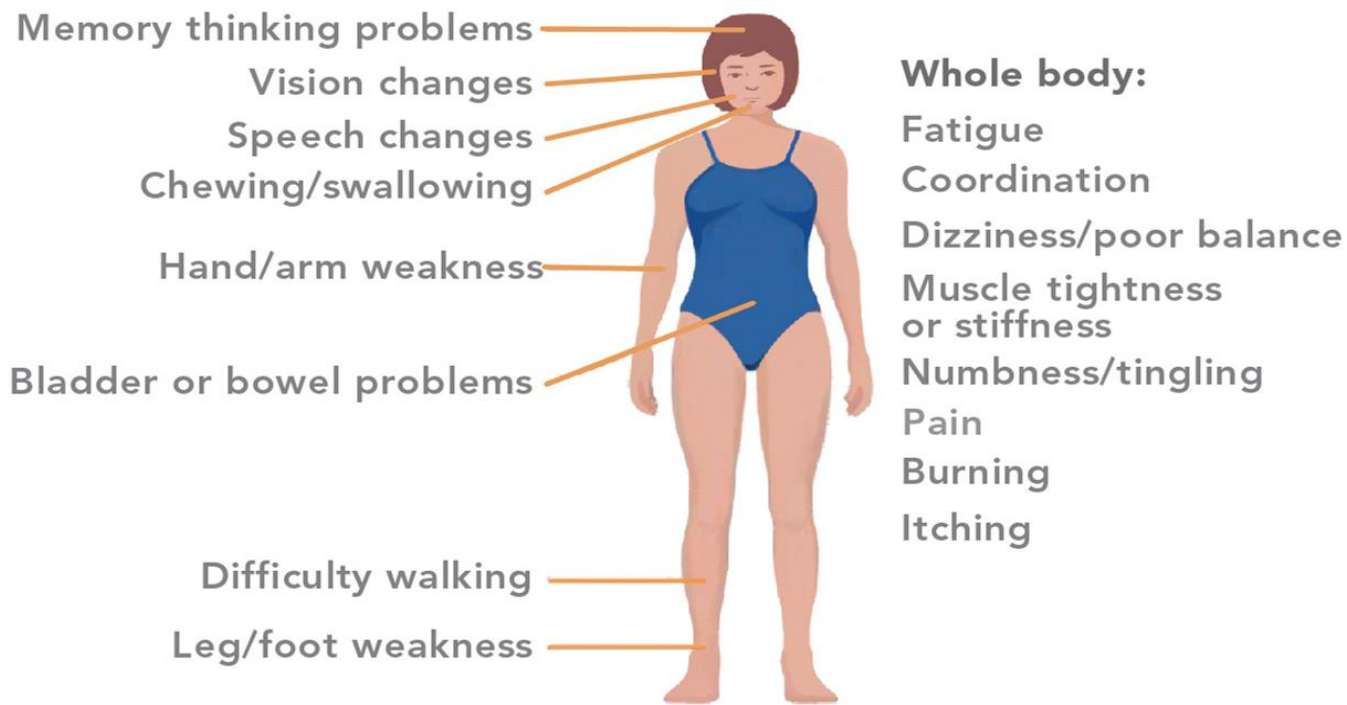


# Introduction of MS

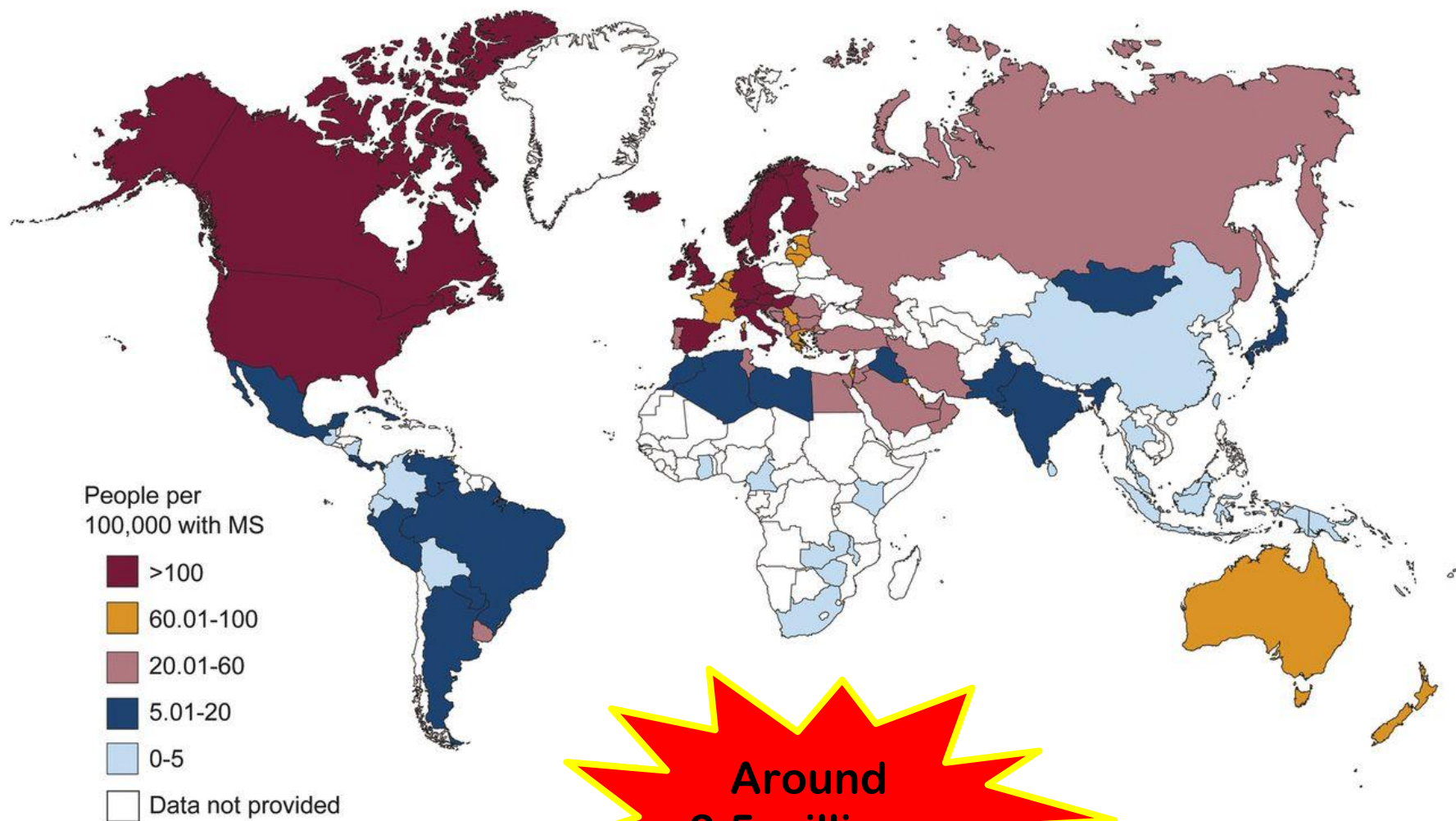
## MS: a chronic, autoimmune & neurodegenerative disorder

### 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



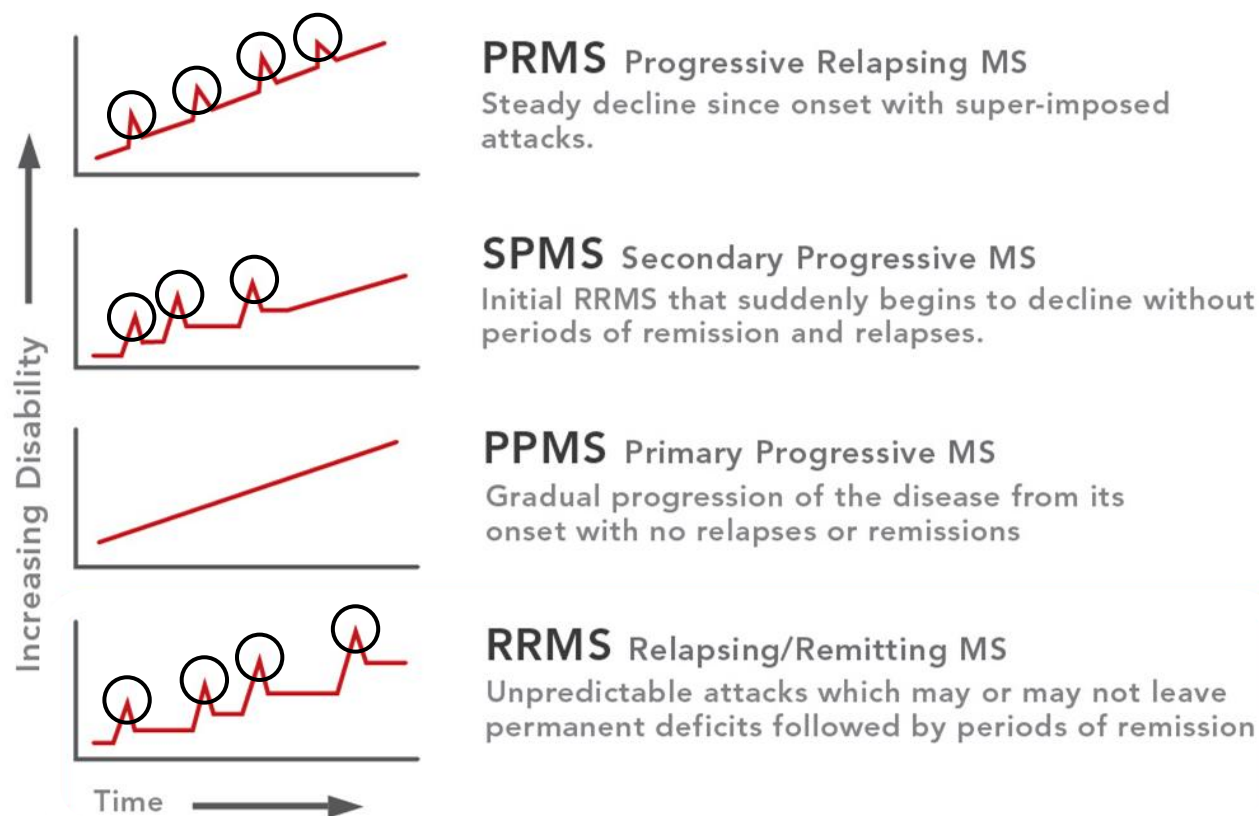
# Introduction of MS



**Around  
2.5 millions**

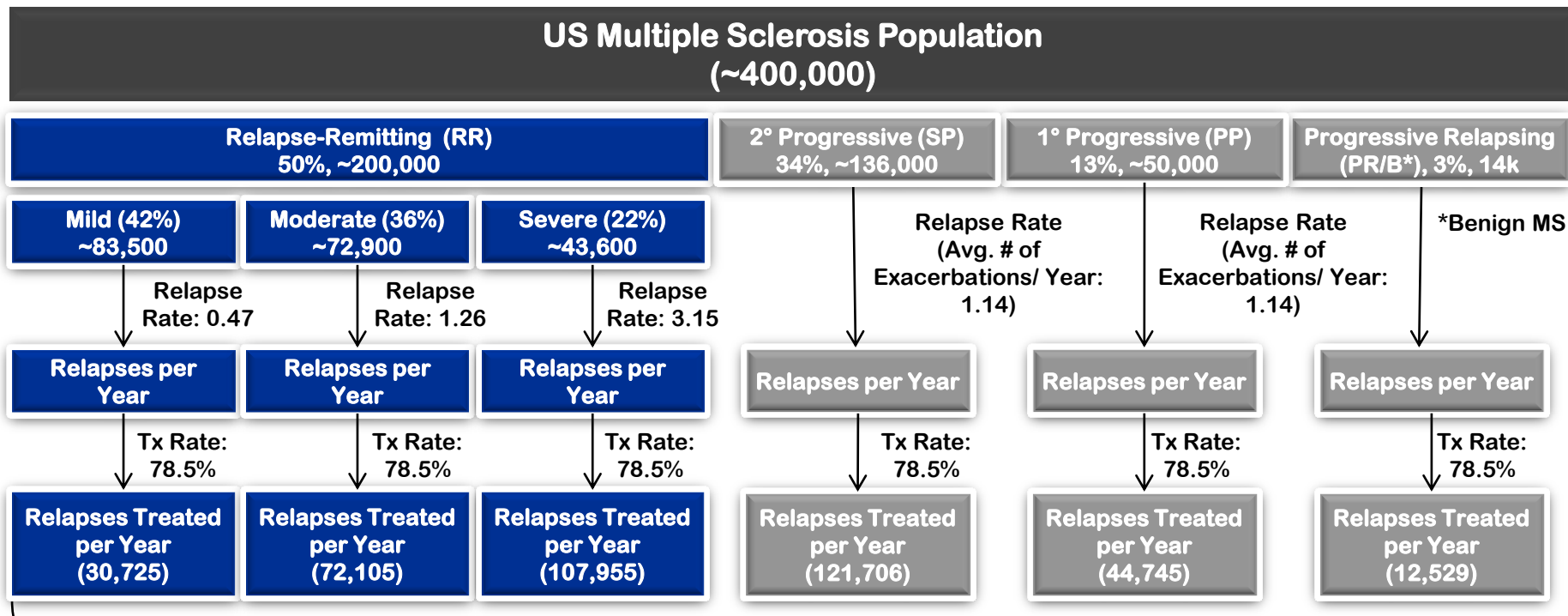
# Introduction of MS

## Four Classifications of MS



Either one of the four classifications occurs in acute is the target patient pool 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

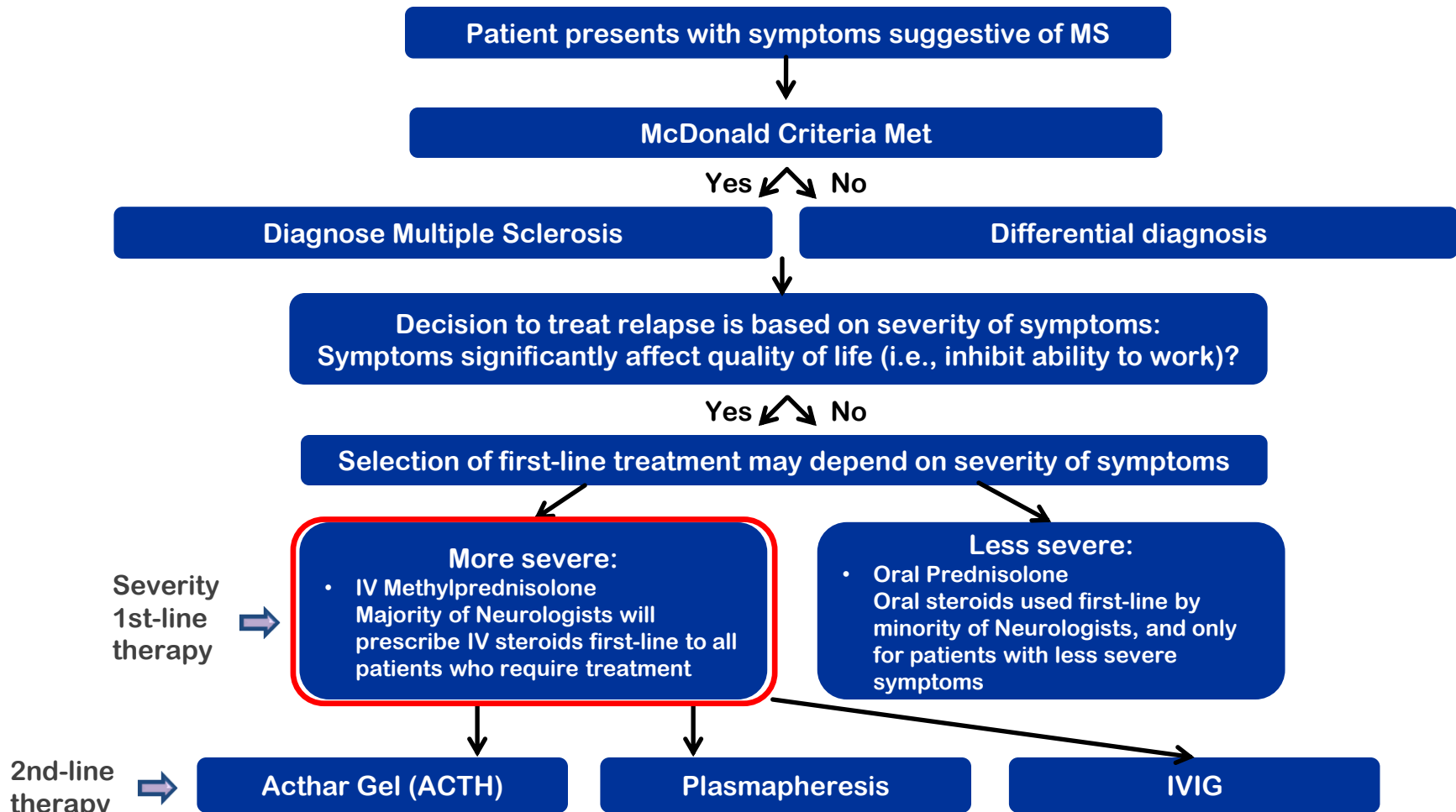


**Minimum, Target, and Ideal Penetration Rates based on Use as First-Line or Second-Line Treatment from Physician Survey**



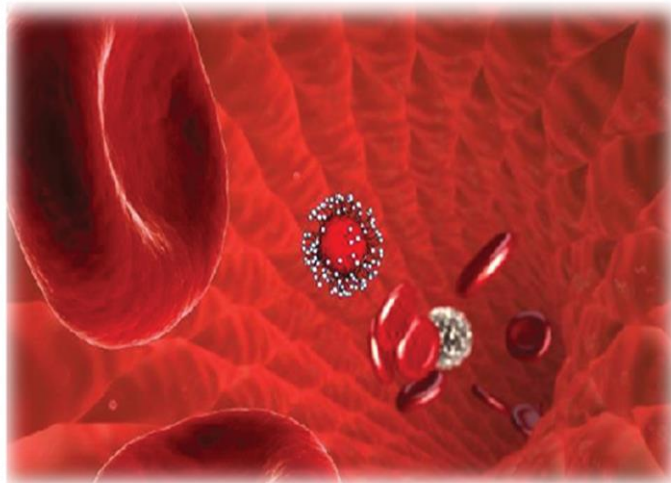
**Relapses Treated with 2B3-201 at Peak Under Minimum, Target, and Ideal 1st-Line/ 2nd-Line Penetration Scenarios**

# Introduction of MS

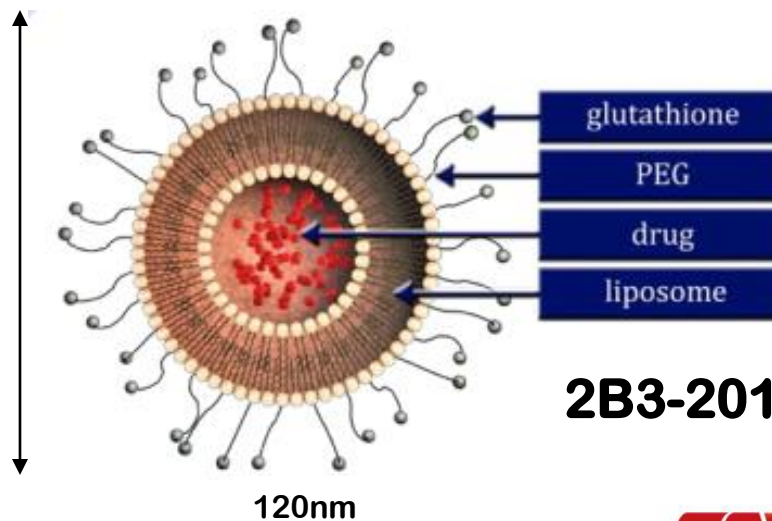


DH Primary Research, Ann Indian Acad Neurol. 2011 Jul.;14(Supp1 1):S65-9

# 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.

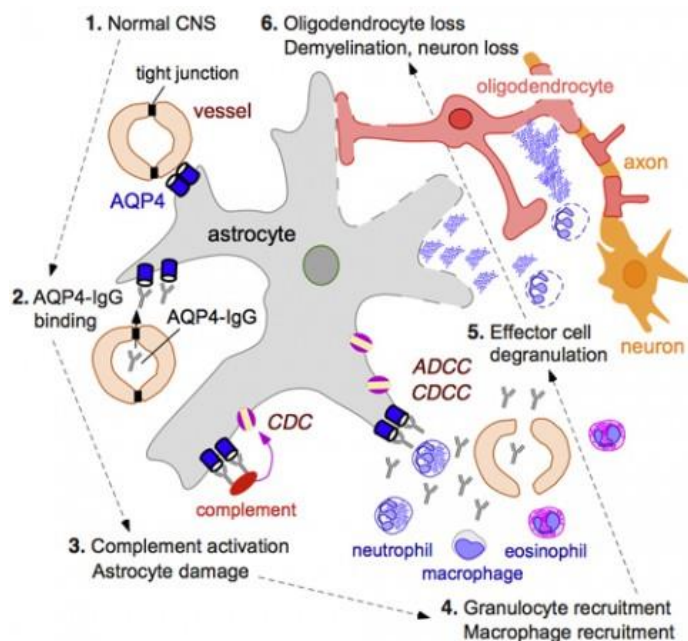


**2B3-201**

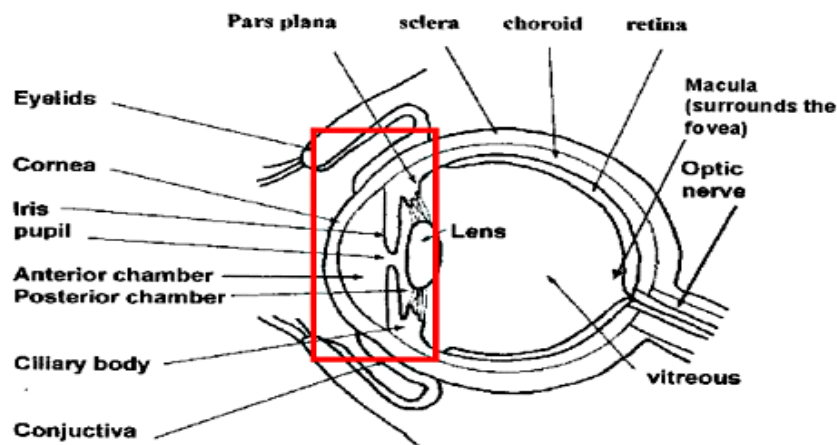
# Introduction of the Product

## 2B3-201's potential indications

### Neuromyelitis Optica



### Uveitis



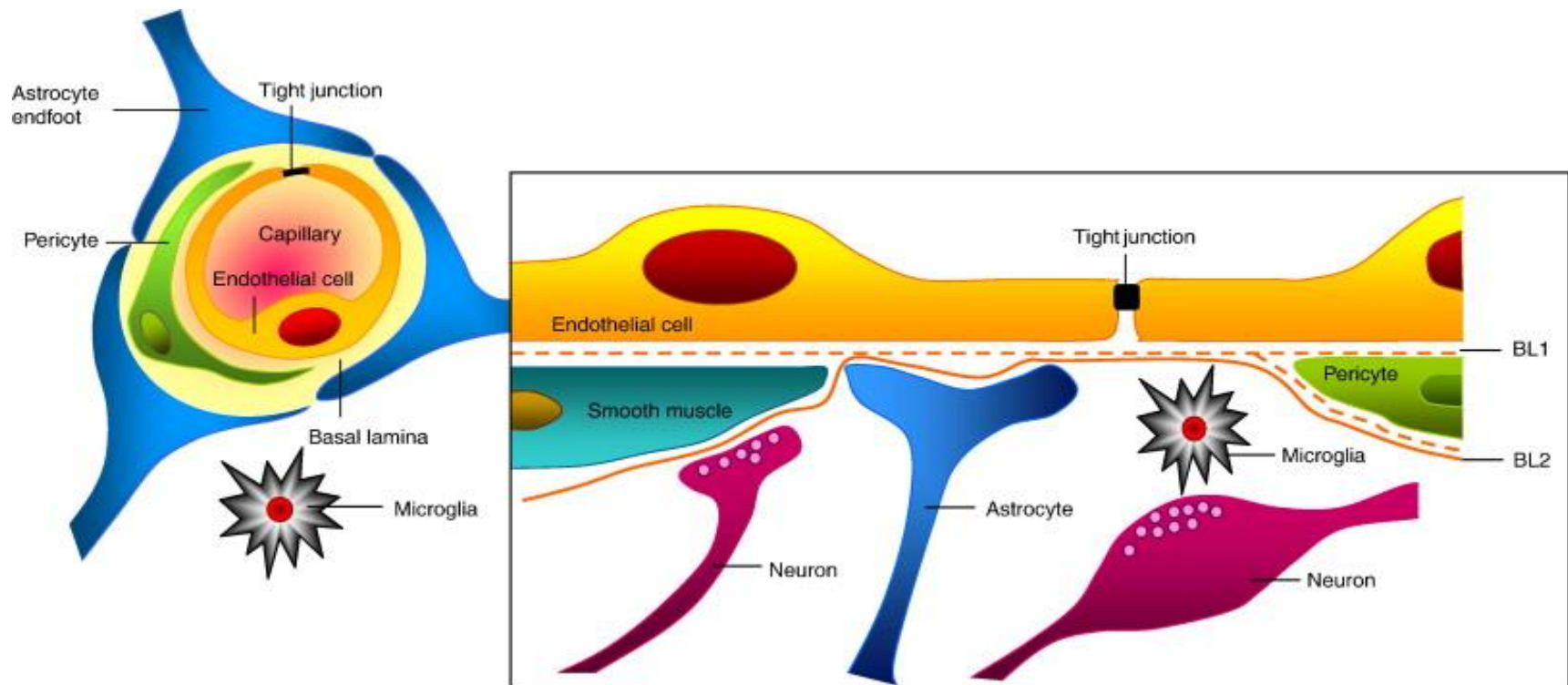
Neuro-inflammation is associated with a wide range of CNS diseases, including multiple sclerosis (MS), optic neuritis, non-infectious uveitis, acute disseminated encephalomyelitis (ADEM), neuromyelitis optica (NMO), as well as neuropathic pain, amyotrophic lateral sclerosis (ALS) and Parkinson's disease.

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

8147-neuromyelitis-optica-part-2-pathogenesis

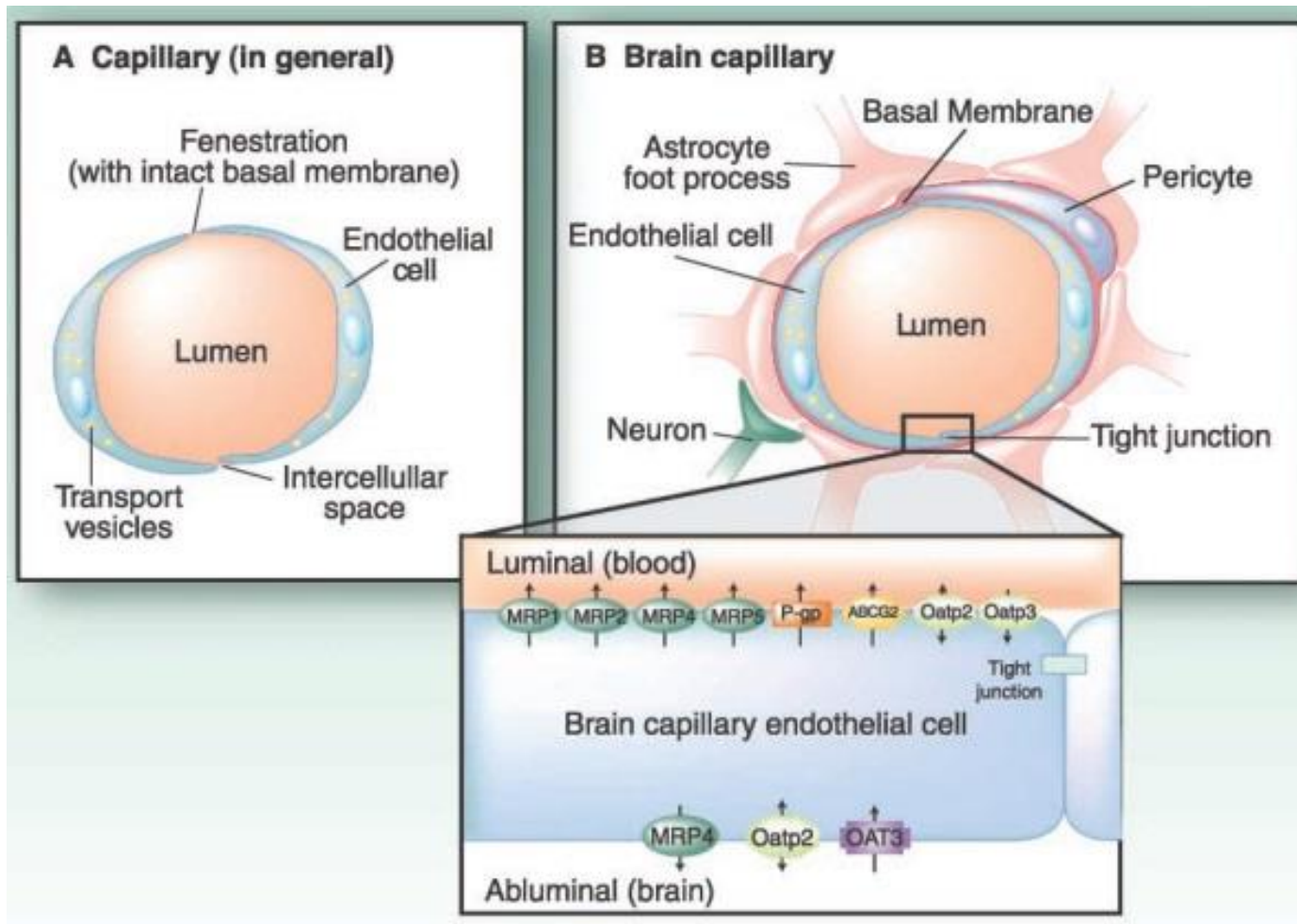
Source: <https://www.uveitis.net/patient/anterior.php>

# Introduction of BBB

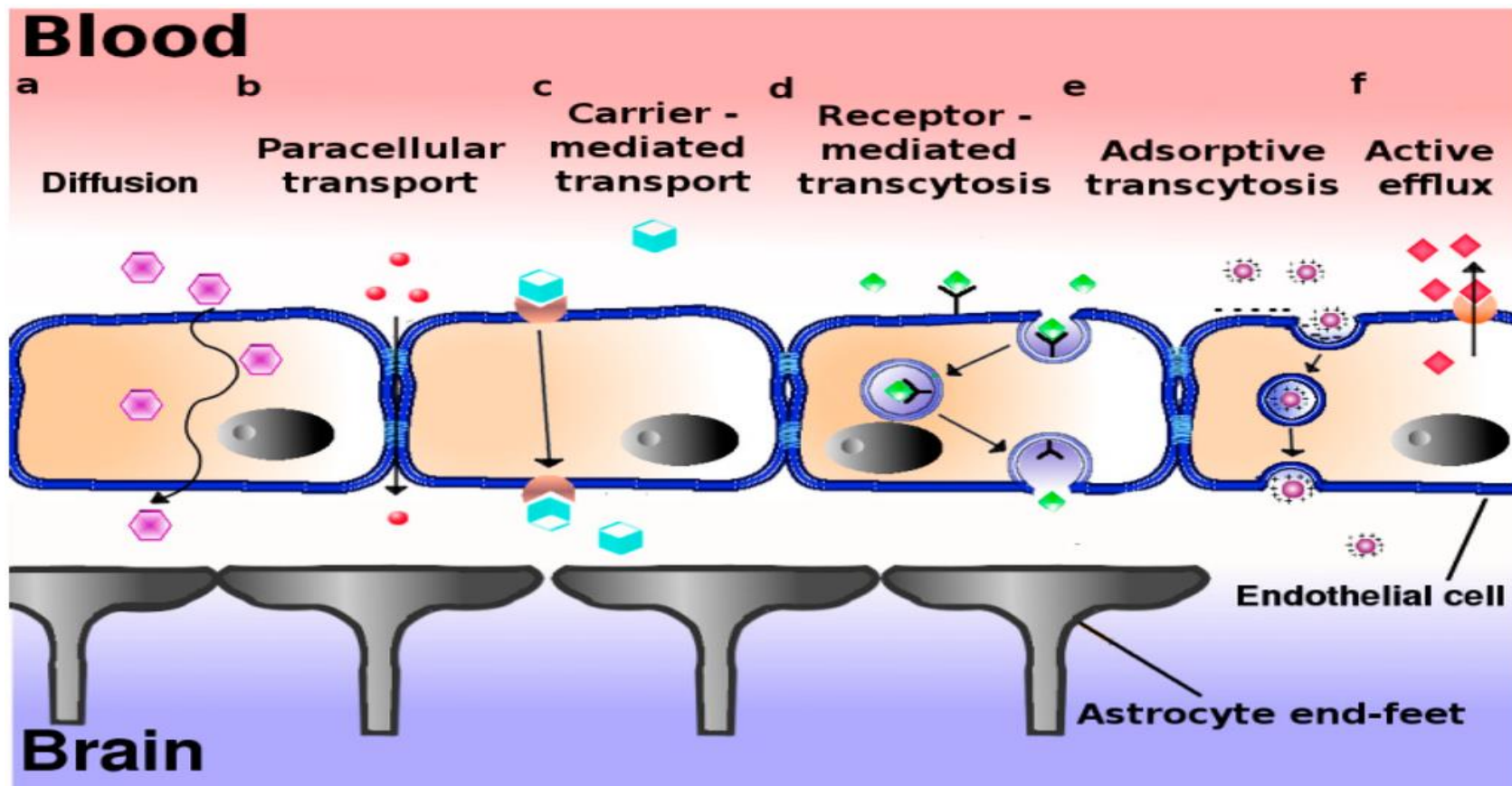




# Introduction of BBB



# Introduction of BBB

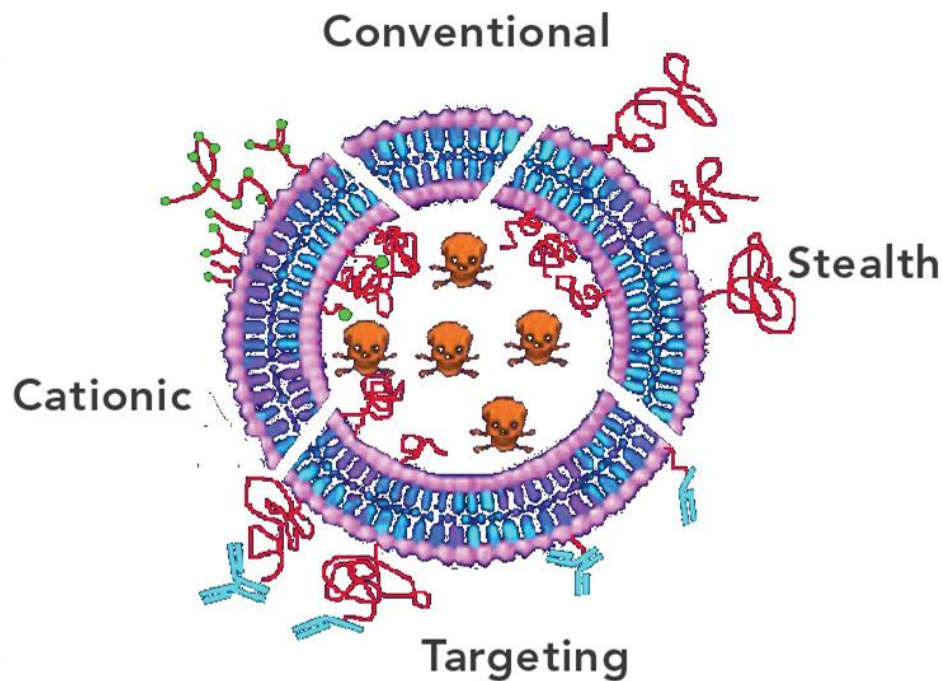
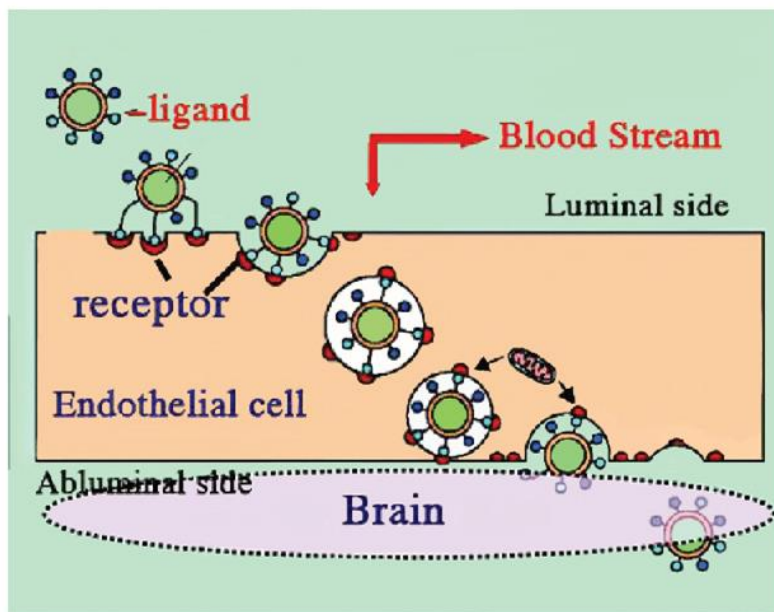


# Introduction of BBB

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	

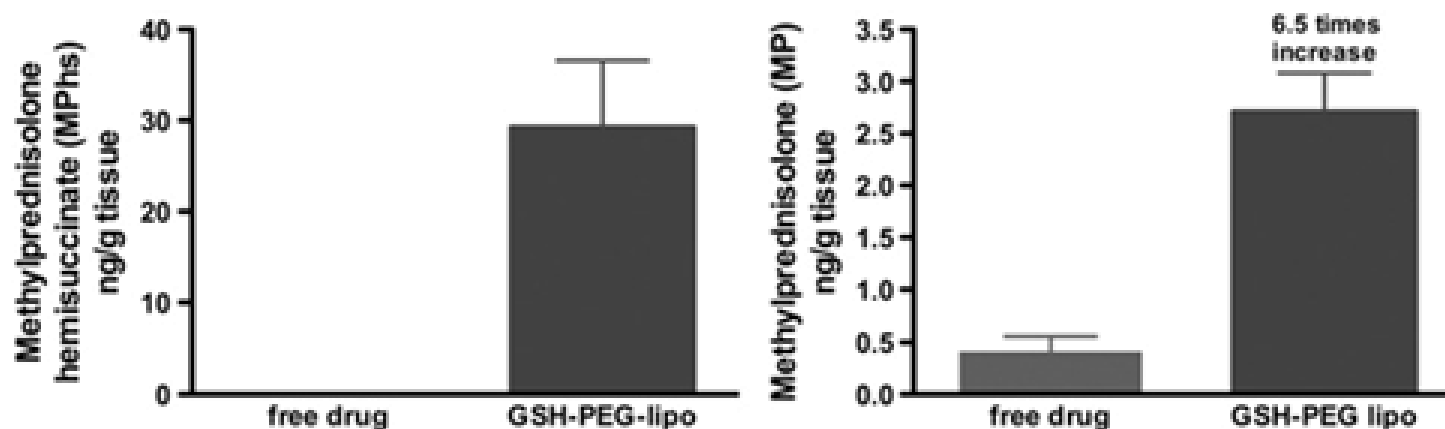
# Introduction of 2B3-201

## 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。

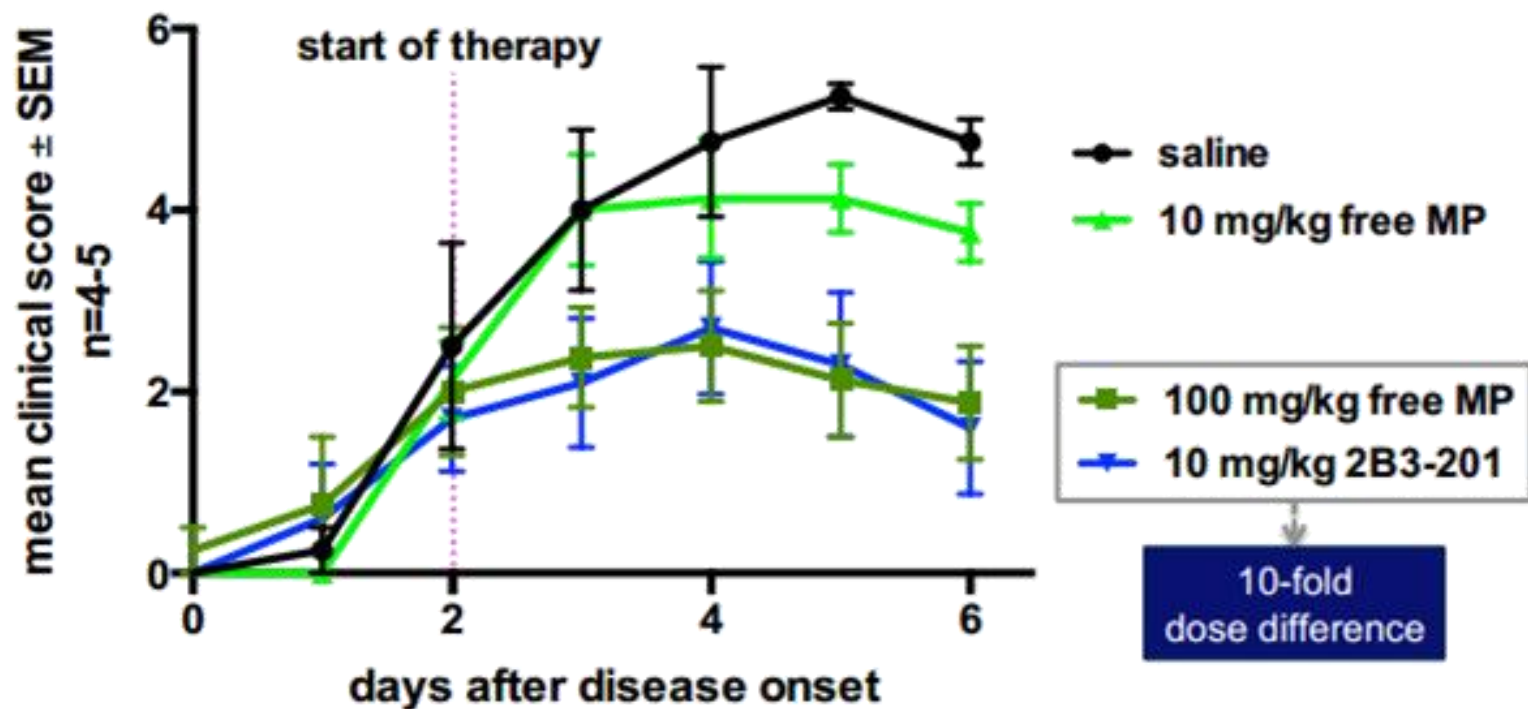


**Fig. 3.** Brain uptake of methylprednisolone hemisuccinate (left) and methylprednisolone (right). Rats ( $n=4$ /group) received 1 bolus i.v. administration of 10mg/kg glutathione pegylated liposomal methylprednisolone (GSH-PEG lipo) or free methylprednisolone (free MPHs, 10mg/kg). Brain uptake was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

# Preclinical Study

2B3-201: 藥效驗證試驗

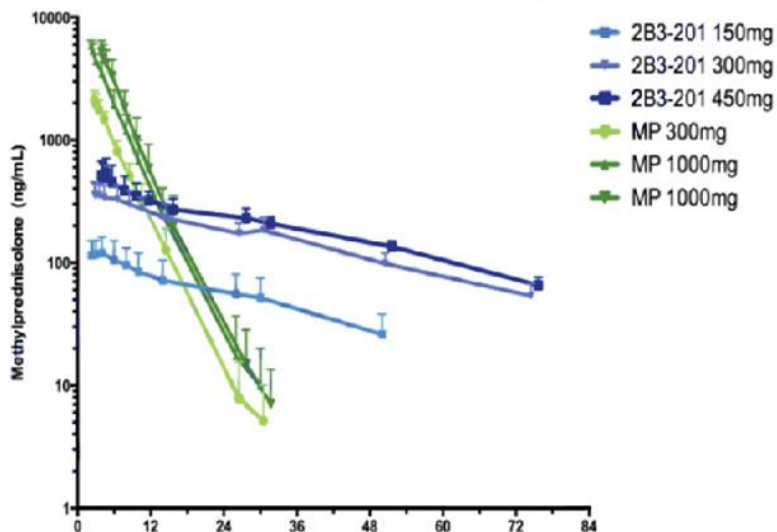
EAE-MOG mouse model of MS



# Phase I Study (Solution)

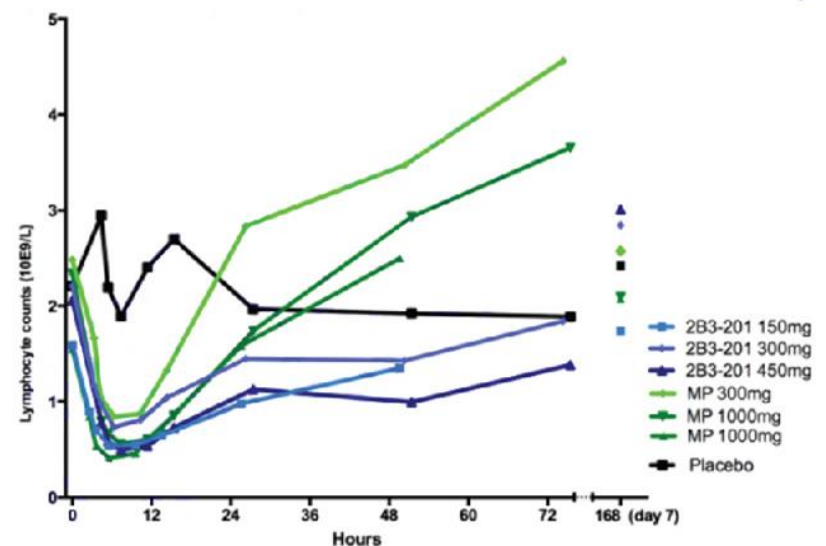
## Phase I dose-escalation results Pharmacokinetics

- 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

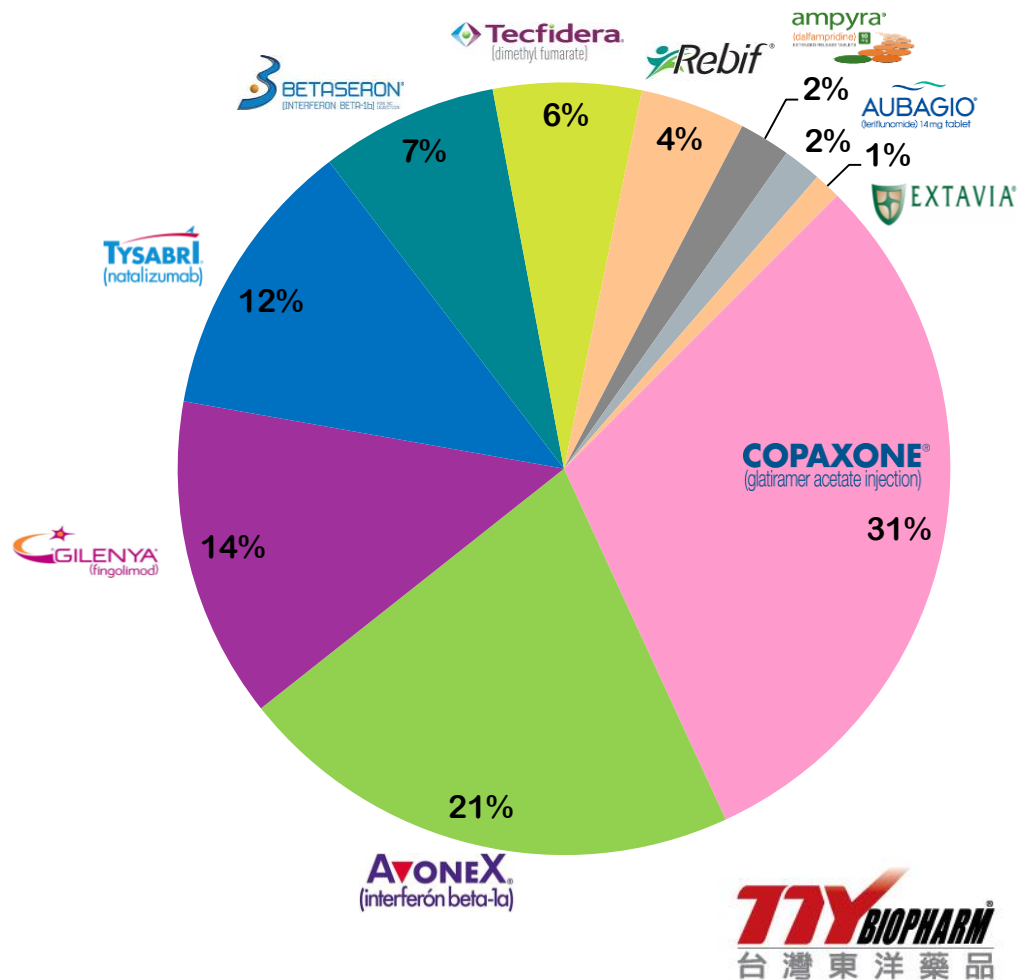
## Major existing choices for MS treatments (2014 Sales & Market Share in Value)

### 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

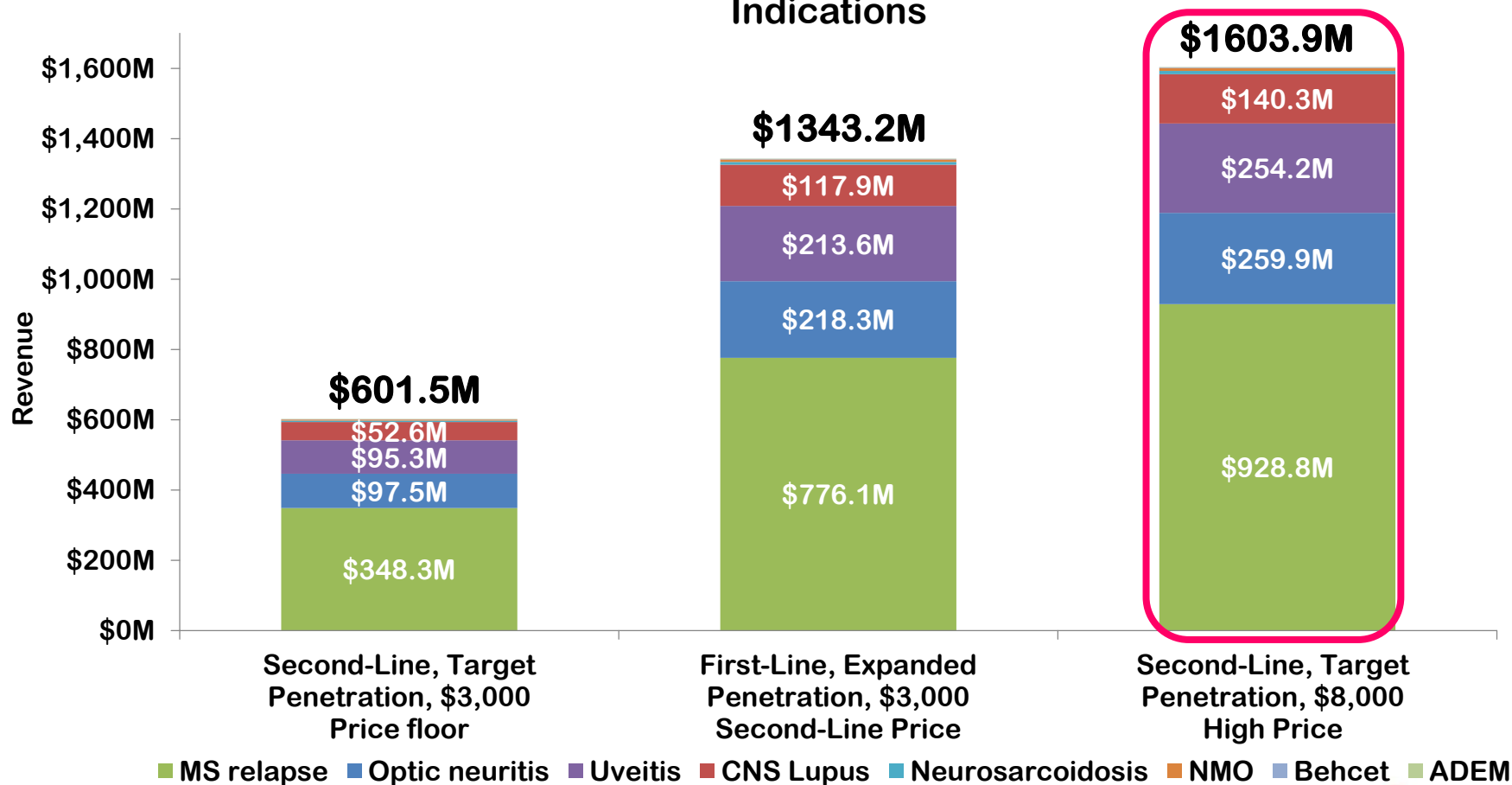
4.328B	■ Copaxone
3.0B	■ Avonex
1.9B	■ Gilenya
1.67B	■ Tysabri
1.05B	■ Betaseron
876M	■ Tecfidera
622M	■ Rebif
302M	■ Ampyra/ Fampyra
266M	■ Aubagio
159M	■ Extavia





# Potential Market Size

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



# 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

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

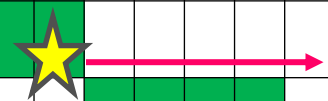
## ■ 2B3-201's strengths

- *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.*

# 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																						



# 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, 異染性腦白質失養症)</b>	1B	Shire Plc Nuo Therapeutics GlaxoSmithKline Plc Zymenex A/S RegenxBio Inc. Novartis AG

Unit: USD/Billion

# Management Team



Yu-Fang Hu



Pieter J. Gaillard



Yuan-Yi Chou

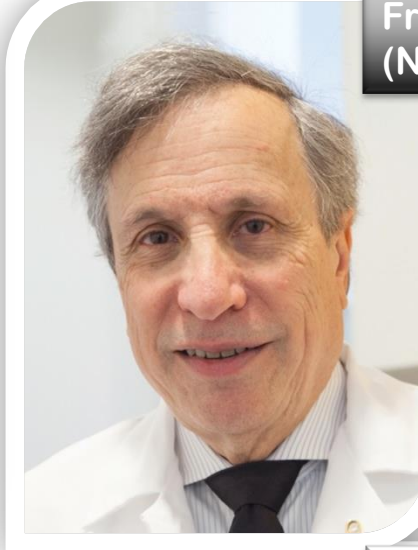


# Scientific Advisory Board

蔡清標  
Taipei, Taiwan



Fred Lublin  
(New York, USA)



HOME OF SIDNEY KIMMEL MEDICAL COLLEGE



Ralf Linker  
(Erlangen, Germany)



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)

認定番号: AF19080036  
Number of AF: 19080036

医薬品名  
Drug Name of application: **TTY Biopharm Co., Ltd.**

製造所の名称  
Name of drug manufacturing establishment: **TTY Biopharm Co., Ltd. (Chang)**

製造所の所在地  
Location of the manufacturing establishment: **No. 108, Sec. 1, Chung-Yue Rd. (Fong), Taichung, Taiwan, R.O.C.**

認可の成分  
Active ingredient: **既製品 錠剤医薬品 (Gen II Drug)**

承認番号  
Approval number: **既製品 錠剤医薬品 (Gen II Drug)**

製造者  
Manufacturer: **TTY Biopharm Co., Ltd.**

It is certified that the above name, name of manufacturing establishment, date of approval and date of expiry are in accordance with Article 183 of the Pharmaceutical Affairs Act.

平成 29 年 8 月 23 日  
2017 Year Month Day

厚生労働大臣 森田 貞二  
Minister of Health, Labour, and Welfare

有效期間 平成 29 年 8 月 23 日から  
Valid period of issue 2017 Year Month Day  
平成 30 年 8 月 23 日まで  
until 2018 Year Month Day

AF19080036

## FDA

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

Supplemental New Drug Application  
SUPPLEMENTAL APPROVAL

Supplemental New Drug Application Number: **NDA 20165-016**

Applicant: **Jason Products, L.P.**  
Attention: Medical Science  
Associate Director, Global Regulatory Affairs  
920 Route 201 South  
P.O. Box 109  
Rutherford, NJ 07070

Date: **March 20, 2018**

Dear Mr. Soriano:

Please refer to your Supplemental New Drug Application (sNDA) dated July 12, 2017, received July 17, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lasta (acetaminophen HCl) (generic name, 325 mg/5 mL oral suspension).

We acknowledge review of your amendments to this supplement dated August 16, 2018, August 28, 2018, September 22, 2018, October 1, 2018, January 9, 2019, January 16, 2019, January 20, 2019, and January 22, 2019.

The September 22, 2018, submission constituted a complete response to our November 12, 2018, Complete Response action letter.

The Prior Approval supplemental new drug applications provide for:

- a new manufacturing site at TTY Biopharm Company Limited (TTY Biopharm) located in Chungli, Taichung, Taiwan, R.O.C. for the manufacturing of the drug product;
- a change in back site of the drug product to 6L L and drug product manufacturing process changes;
- a new pre-positioned, pre-positioned stopper for the drug product container/closure system;
- addition of a secondary packaging site at Anderson-Helmuth, 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 incorporate the risk of medication error.

## EMA

EMA logo

13 APR 2018

REGISTRATION NUMBER: **REGISTRATION**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Date: following inspection on accordance with Art. 11(1) of Directive 2003/85/EC

The compliance certificate of Belgium can have the following text:

The manufacturer **TTY Biopharm Company Limited (Taichung, Taiwan, R.O.C)** has been inspected in accordance with Article 11(1) of Directive 2003/85/EC

This has been inspected in accordance with the manufacturing conditions in the manufacturing conditions in accordance with Art. 11(1) of Directive 2003/85/EC

The certificate is valid only when accompanied with all pages of the certificate. The certificate is valid only when accompanied with all pages of the certificate.

The certificate is valid only when accompanied with all pages of the certificate.

EMA logo

## ANVISA (Brazil)

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

Atividade inspecionada: **Atividade de fabricação de medicamentos**

Nome do estabelecimento: **TTY BIOPHARM CO. LTD.**

Endereço: **Rua dos Remédios, 100 - Vila Industrial - CEP 13240-000 - Taubaté - SP**

Nome do responsável técnico: **Dr. [Signature]**

Atividade inspecionada: **Atividade de fabricação de medicamentos**

Atividade inspecionada: **Atividade de fabricação de medicamentos**

## TFDA

行政院衛生署藥品優良製造證明書

製藥廠名稱：台灣東洋藥品工業股份有限公司中國廠

製藥廠地址：新加坡中環街中環街一號中國廠

製藥廠登記證號碼：TAI924322C

本證書之發給係根據中華民國藥事法及藥事法施行細則之規定，其有效期間為三年。

一、發給日期：中華民國 106 年 05 月 17 日

二、發給地點：臺北

三、發給對象：製藥廠

四、發給事由：優良製造證明書

五、發給範圍：優良製造證明書

六、發給對象：優良製造證明書

七、發給事由：優良製造證明書

八、發給範圍：優良製造證明書

行政院衛生署

署長 邱文達

中華民國 106 年 05 月 17 日

發給地點：臺北

發給對象：製藥廠

發給事由：優良製造證明書

發給範圍：優良製造證明書



# 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 瘤	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(+2)** oncology product licenses in **12** countries.

	Country	UFur	Oxalip	Lipo-Dox	Irino	Asadin	Gemmis	Tynen	Epicin	Thado	Anazo	Folina	Sulfina	Total
EU	Austria			1 (Caelyx in whole EU)				2						2(+1)
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 (Doxil in whole US)			1		1					2(+1)
	Total	6	4	4(+2)	7	3	4	7	4	2	2	2	2	47(+2)

TTY's CMO partner holds the licenses of TTY brand drug- Lipo-Dox/ Doxil in US and Lipo-Dox/Caelyx in EU.

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

# 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芳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**

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**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

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# 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
- } Complete listing for global (Including China market)
- 2B3-201 MS clinical trials Completed & NDA
  - Regional markets integration
  - Thailand ABT IPO

## ● R&D

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

# Financial Performance (Parent Company Only)

NTD in Thousands

Item	2013		2014		2015		2016	
	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 Performance (Consolidated)

NTD in Thousands

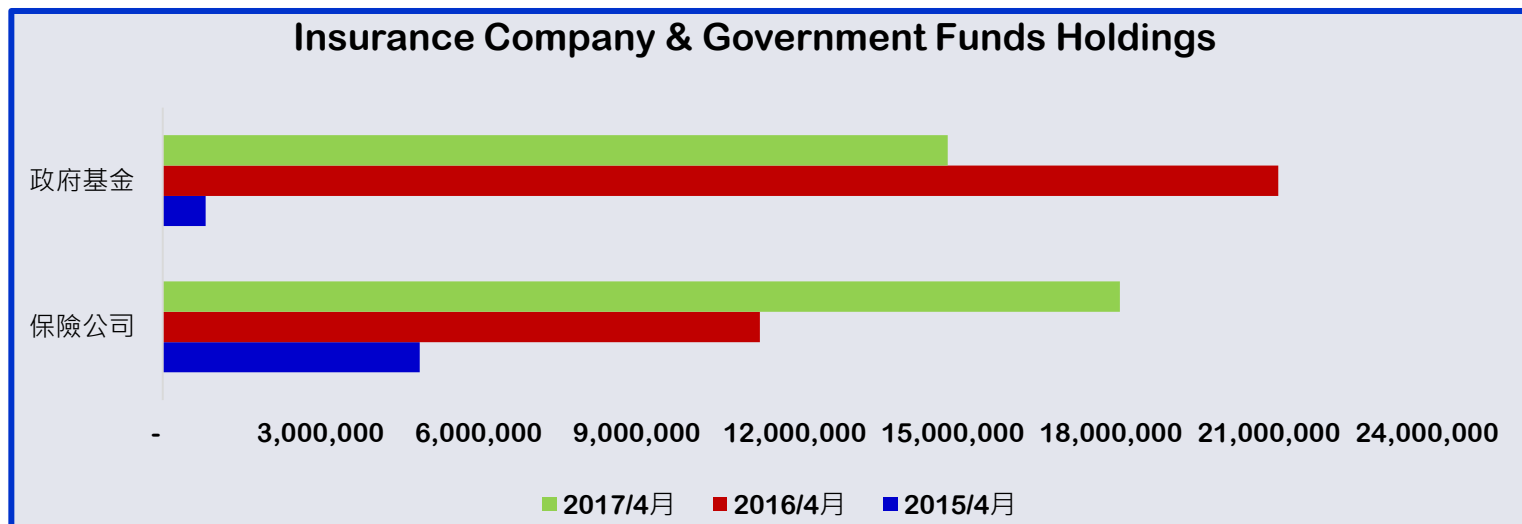
Item	2014		2015		2016		1H/2017	
	Amount	%	Amount	%	Amount	%	Amount	%
Net Sales	2,979,902	100%	3,195,218	100%	3,760,717	100%	1,876,568	100%
Gross Profit	1,898,936	64%	2,183,144	68%	2,559,220	68%	1,267,286	68%
Operating Expenses	-1,560,841	-53%	-1,393,357	-44%	-1,379,533	-36%	-677,768	-36%
Operating Profit	338,095	11%	789,787	24%	1,179,687	32%	589,518	32%
Non-Operating Income and Expenses	571,745	19%	735,808	23%	332,372	8%	-8,532	-1%
Income before Tax	909,840	30%	1,525,595	47%	1,512,059	40%	580,986	31%
Net Income (Consolidated)	811,695	27%	1,246,592	38%	1,254,724	33%	478,274	26%
Net Income (TTY)	779,645	26%	1,211,018	37%	1,193,324	31%	464,887	25%
<b>EPS</b>	<b>3.14</b>		<b>4.87</b>		<b>4.80</b>		<b>1.87</b>	

# Dividend Payout

Item \ Year	Year					
	2011	2012	2013	2014	2015	2016
Yield Rate (%)	0.22	1.25	1.91	2.39	3.86	3.42
P/E	45.00	44.24	41.65	33.23	18.61	23.16
Cash Dividend	0.30	1.40	2.00	2.50	3.50	3.80
Stock Dividend	2.40	0.89	0.67	-	-	-
Total Dividend	2.70	2.29	2.67	2.50	3.50	3.80

# Gov't Funds & Ins. Co.'s Holdings

Institution \ Holdings	April/2015		April/2016		April/2017	
	Shares	Holdings (%)	Shares	Holdings (%)	Shares	Holdings (%)
Insurance Company	4,880,800	1.96%	11,339,000	4.56%	18,169,000	7.31%
Government Funds	817,021	0.33%	21,177,843	8.52%	14,904,000	5.99%
<b>Total</b>	<b>5,697,821</b>	<b>2.29%</b>	<b>32,516,843</b>	<b>13.08%</b>	<b>33,073,000</b>	<b>13.30%</b>





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