

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

January, 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
(July, 2016)

- **TTY Biopharm consolidated sales as of**
2015- NTD 3.20 Billion, USD 97.4 Million
- **Headquarters: Taipei, Taiwan**
Number of employees: 510

TTY BIOPHARM
台灣東洋藥品



- 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\$791mn. As of 12/30/2016
- Currently has three major subsidiaries:
PharmaEngine (listed), Market cap US\$689mn, 19.30% ;
TSH Biopharm (listed), Market cap US\$85mn, 56.48%;
CY Biotech, 29.27%
- Shareholder value creation-
 - TTY's ROE 19.2% in 2011-2015, ROE 24.1% in 2015 (above industry average 7.35%).
 - TTY targets for 28%-35% ROE in 2016-2020.
 - 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
China
Taiwan
South-East Asia

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 (29.27%)

- Probiotics & Obesity Diseases

榮港生技
WORLDCO (100%)

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

ABT泰/ABT菲/越辦事處
40%/87%/100%

- New Drug Development & Marketing

TTY Core Competences



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Product Strategy

Trends for Pharmaceutical Industry







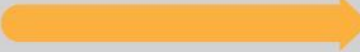


Market Scope
(Risk)



Entry Barrier
(Profit)



TTY Super Generics Pipeline

Programs	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, MM \\ Ovarian cancer		Approved
Caelyx II			
Lipo-Amphotericin B	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		
Col103	Multidrug-resistant Gram-negative Bacteria Serious Infection		

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
Caelyx/Doxil (Lipo-Dox)	Metastatic breast cancer BC、 AIDS-related Kaposi's sarcoma、 Multiple myeloma, MM、 Ovarian cancer	600	Pegylated Liposome Technology	Worldwide manufacturing patent
Lipo- Amphotericin B	Systemic Fungal Infection	440	Liposome Technology	Worldwide manufacturing patent
Leuprolide Acetate Injection	Prostate Cancer、 Management of Endometriosis、 Uterine Fibroids、 Central Precocious Puberty	1,240	Lupron Depot Microsphere Formulation	Worldwide manufacturing patent
Risperidone Injection	Schizophrenia	960	Microsphere Formulation	Worldwide manufacturing patent
SPL206	Functional gastric, intestinal, pancreatic endocrine tumors	1,500	Microsphere Formulation	PLGA used for particular star polymers synthesized by TTY.
LGIA10	Type II Diabetes Mellitus	910	Microsphere Formulation	Worldwide manufacturing patent Microsphere Depot Platform
Col103	Multidrug-resistant Gram-negative Bacteria Serious Infection	150	Formulation	First Choice Irreplaceable Option, TWNH

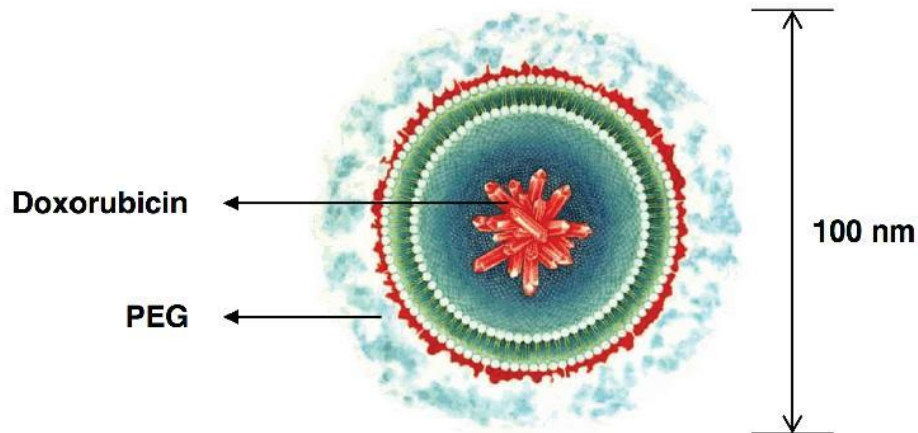
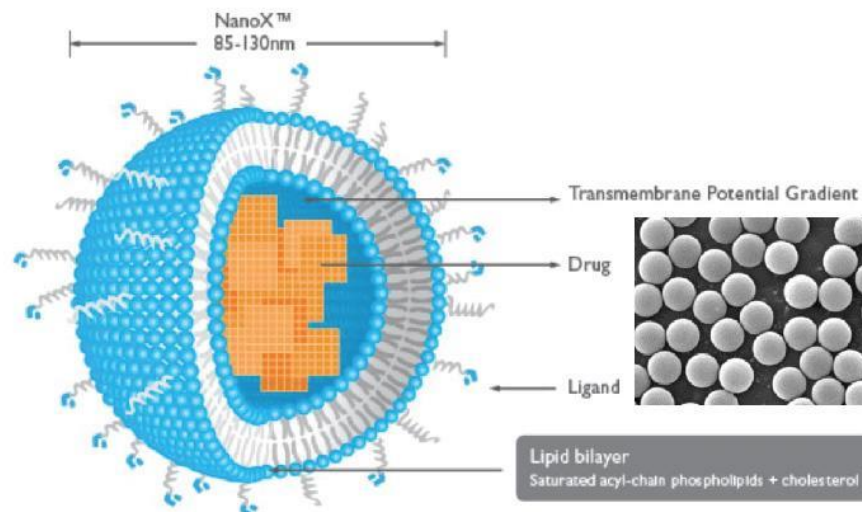
台灣東洋藥品

Specialties- Caelyx®/Doxil®

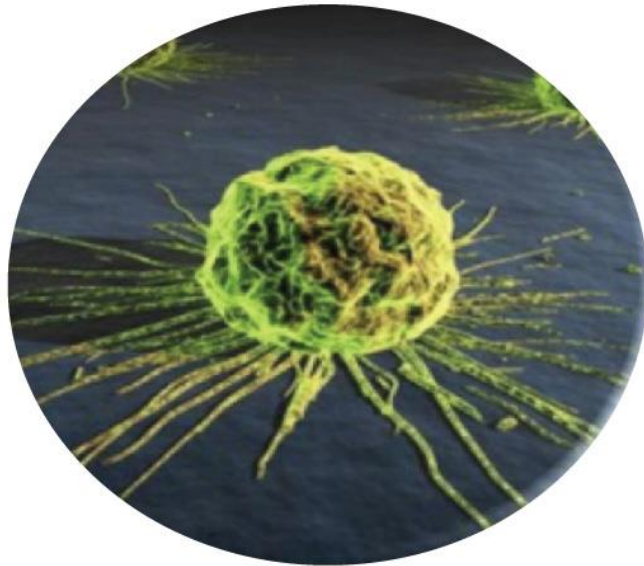
Caelyx®/Doxil® (Doxorubicin HCl Injection)

Liposome: A tiny bubble that can be filled with drugs and carry drugs into tissues.

How does liposome treat cancer? Healthy human blood vessels are encapsulated by endothelial cells which are bounded by tight junctions (BBB->Blood Brain Barrier). Tight junctions will stop large particles like liposome leaking out of the vessel. Tumor vessels do not have tight junctions. Therefore, liposomes can penetrate tumor cells from the blood but blocked out by endothelial wall of healthy cells. In another word, liposome can "target" tumors by nature.

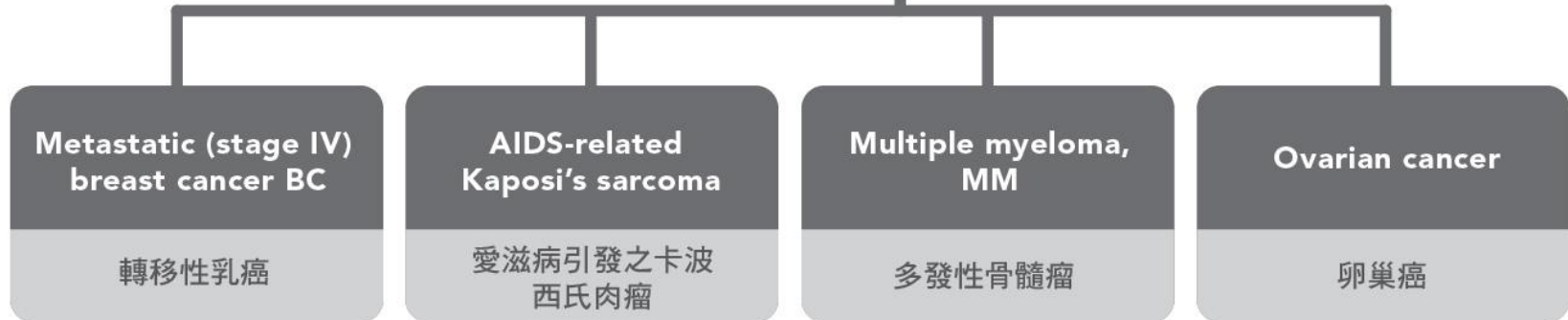


Source: Asia Pacific Equity Research,
March 4th, 2011, JP Morgan

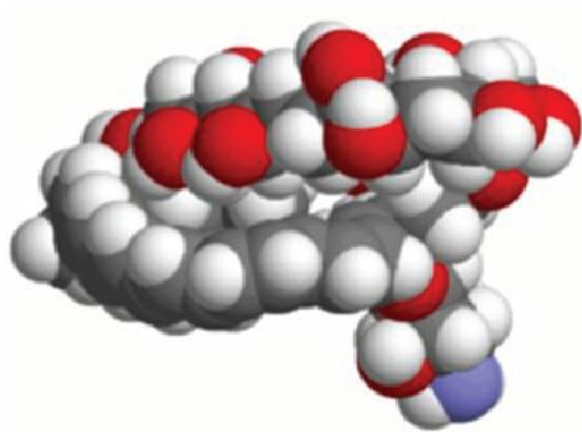


Caelyx®/Doxil®/Caelyx II®

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



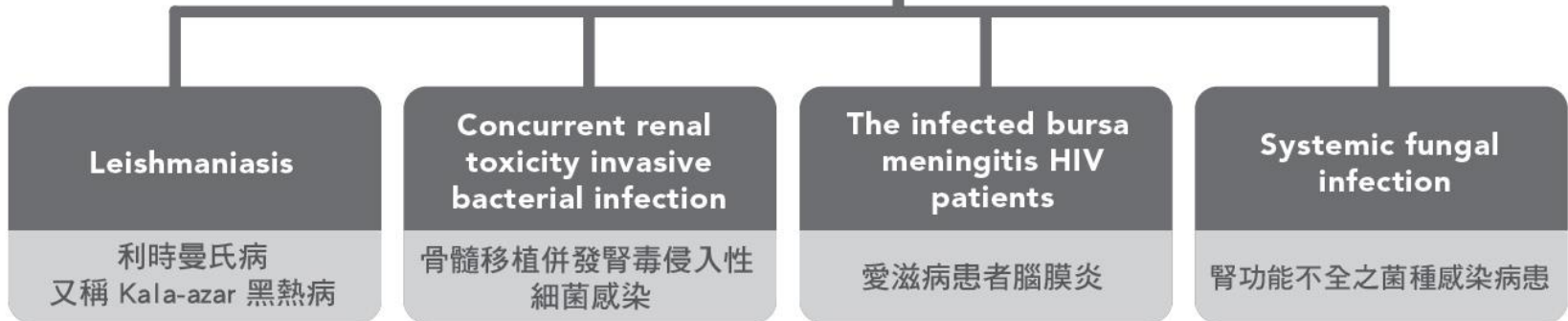
Source: 2011 Evaluate Pharma report; +2008 WHO report

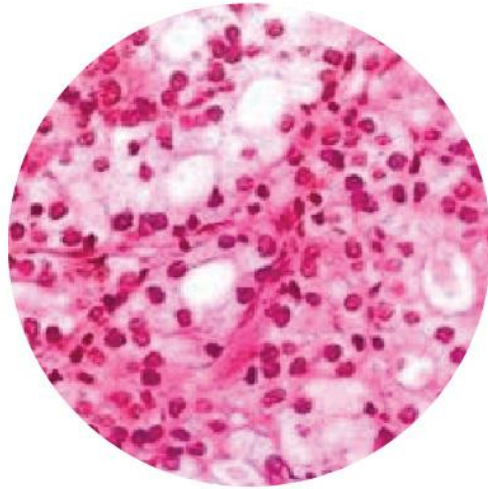


Specialty- Lipo-Amphotericin B

Global Market: USD\$440 Million

Target:Worldwide 35~50%

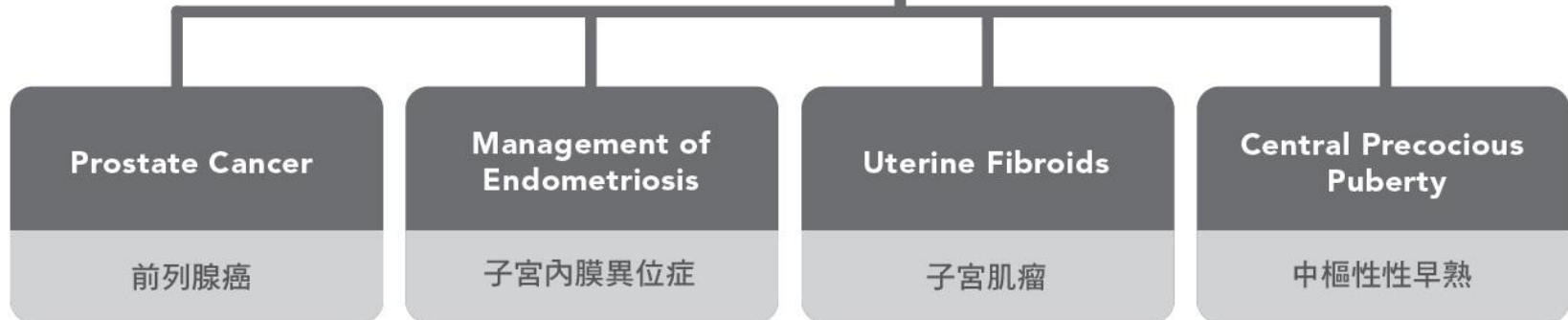




Specialty- Leuprolide Acetate Injection

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

Target: Worldwide 20~35%



Specialty- Leuprolide Acetate Injection

Schedule for launch:

- EU- 2016 est.
- USA- 2018



11.25mg
3-Month

3.75mg
1-Month

Diluent

Table 4-5

World Hormone Therapy Market

Estimated Products Sales by Cancer Type, 2008

(in million of dollars at the manufacturers level)

Cancer Type	Revenues Estimates	% of Market	Number of top Active Ingredients*
Breast	\$5,073	55.6	7
Prostate	4,032	44.2	4
Others	20	0.2	0
Prostate	\$9,125	100	10

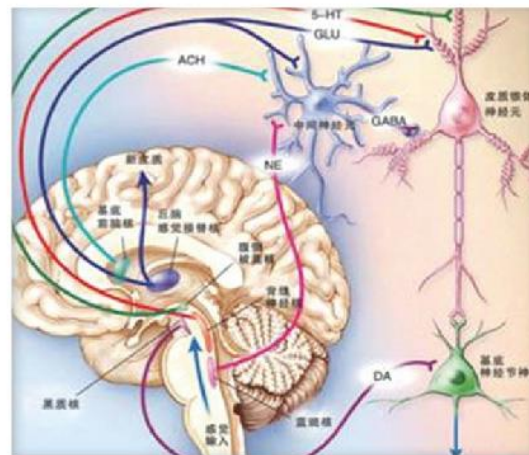
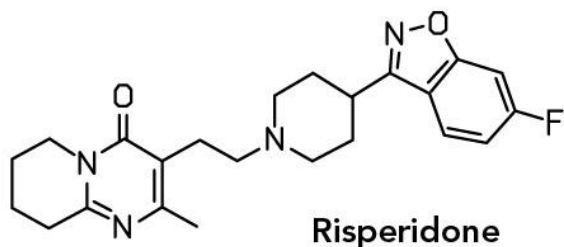
active ingredients with combined sales exceeding \$100 million annually.

Source: Kalorama Information: (Cancer Therapeutics and Biotherapeutics 2009)

Specialty- Risperidone Injection

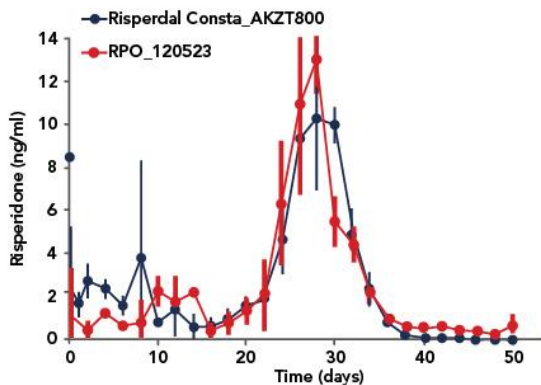
Indication: Schizophrenia

Global market: USD\$960 Million

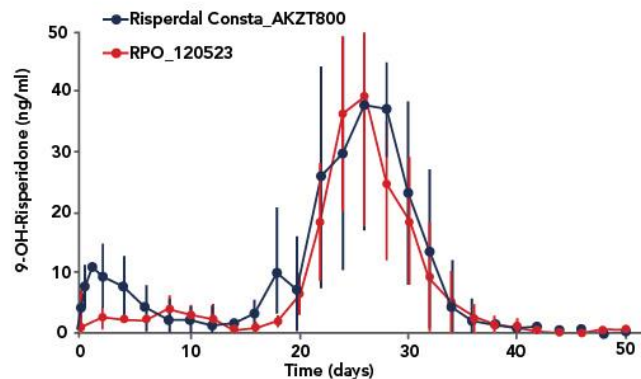


Beagle in vivo release

Risperidone



9-OH-Risperidone



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Specialty- SPL206

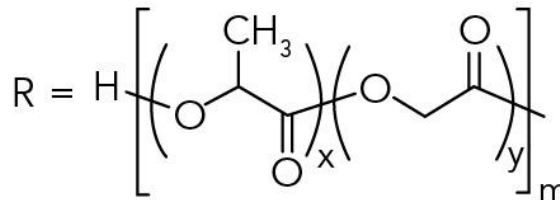
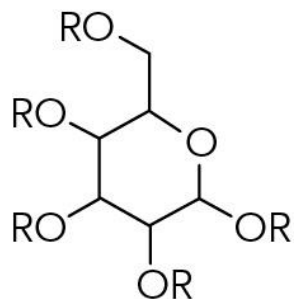


Indications:

- 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!!

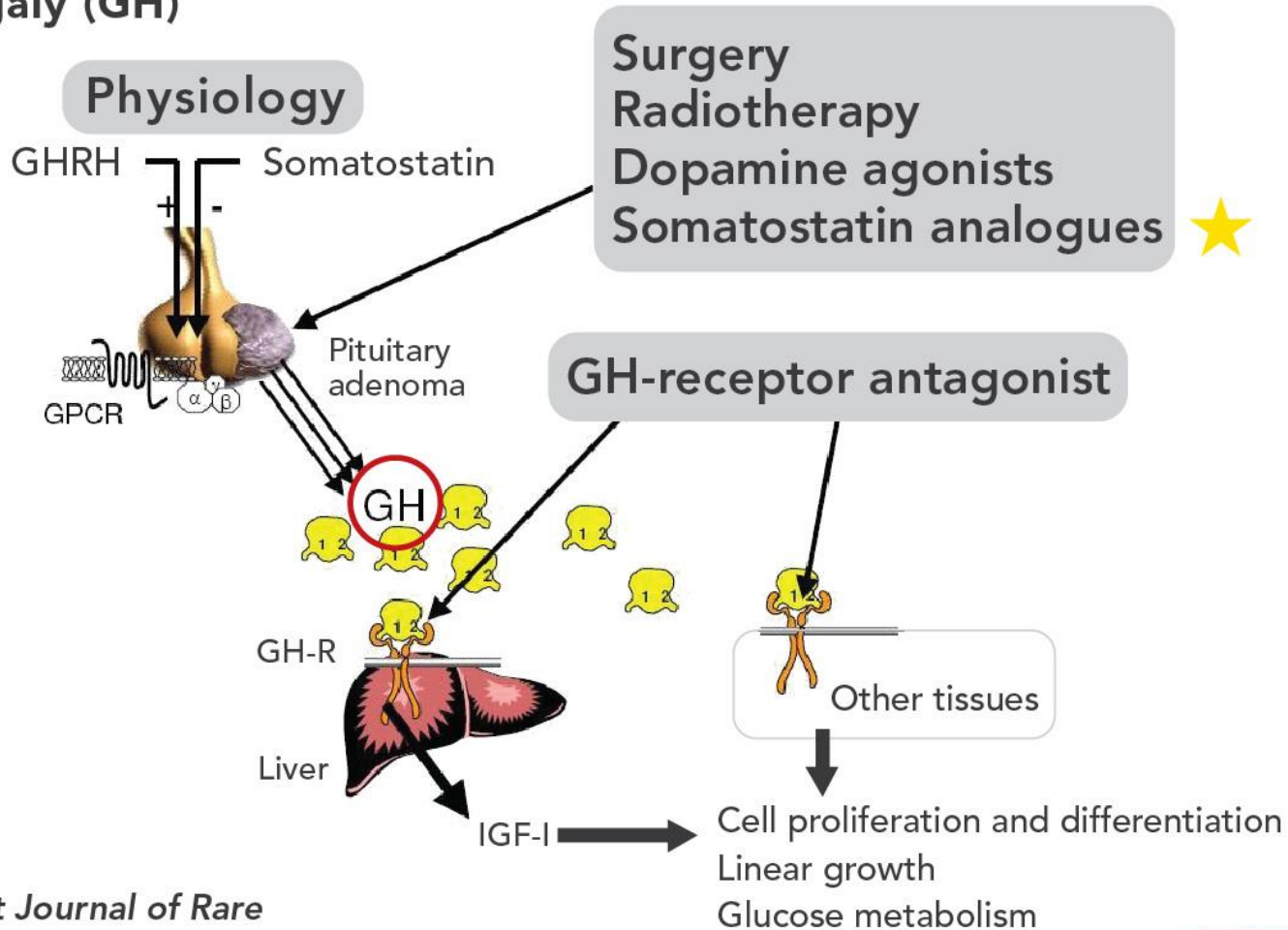


Polymer	Lot	MW(K Da)	PI
Poly(lactide-co-glycolide) star, glucose core LA:GA=1:1	TTY#783053	53	1.67

Mechanism of SPL206



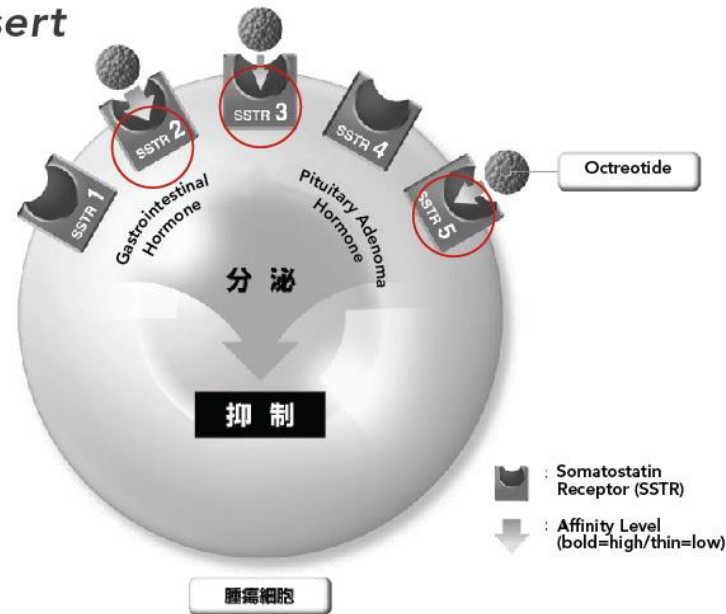
Acromegaly (GH)



Orphanet Journal of Rare Diseases 2008,3:17.

Mechanism of Action (SPL206)

Sandostatin LAR, JP insert

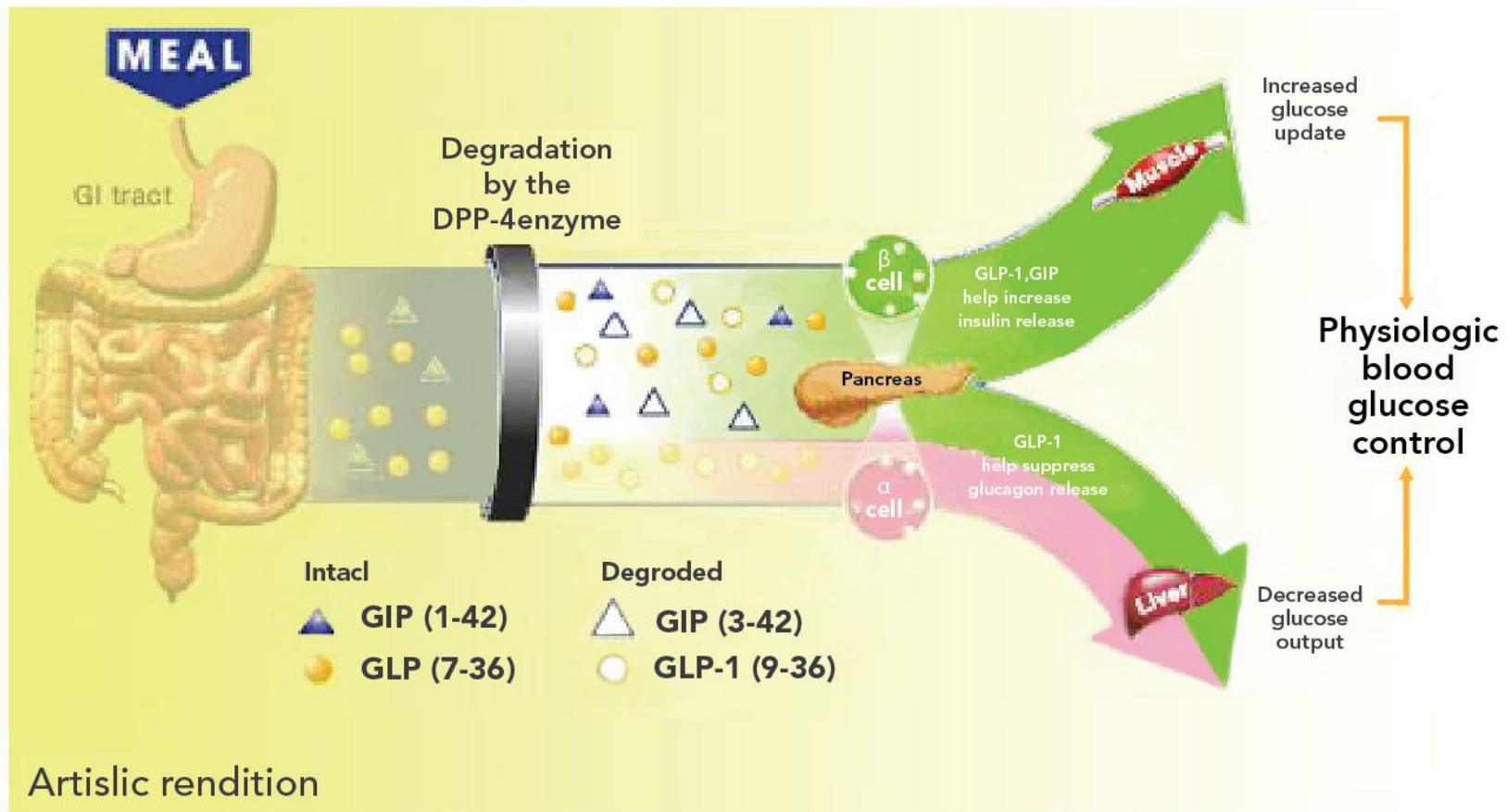


Somatostatin binds to somatostatin receptors (SSTR), exert a variety of physiological effects on various tissues, organs. SSTR has five subtypes (SSTR1 ~ 5), the binding affinity of octreotide varies depending on the sub-type, high in the order of SSTR2> SSTR5> SSTR3

Octreotide is presumed to bind to SSTR present on the cells of the pituitary adenoma and gastrointestinal hormone-producing tumor, VIP, it suppresses the secretion of gastrointestinal hormones and GH of gastrin.

Specialty- LGIA10

The Role of Incretins (GLP-1 and GIP) in Glucose Control

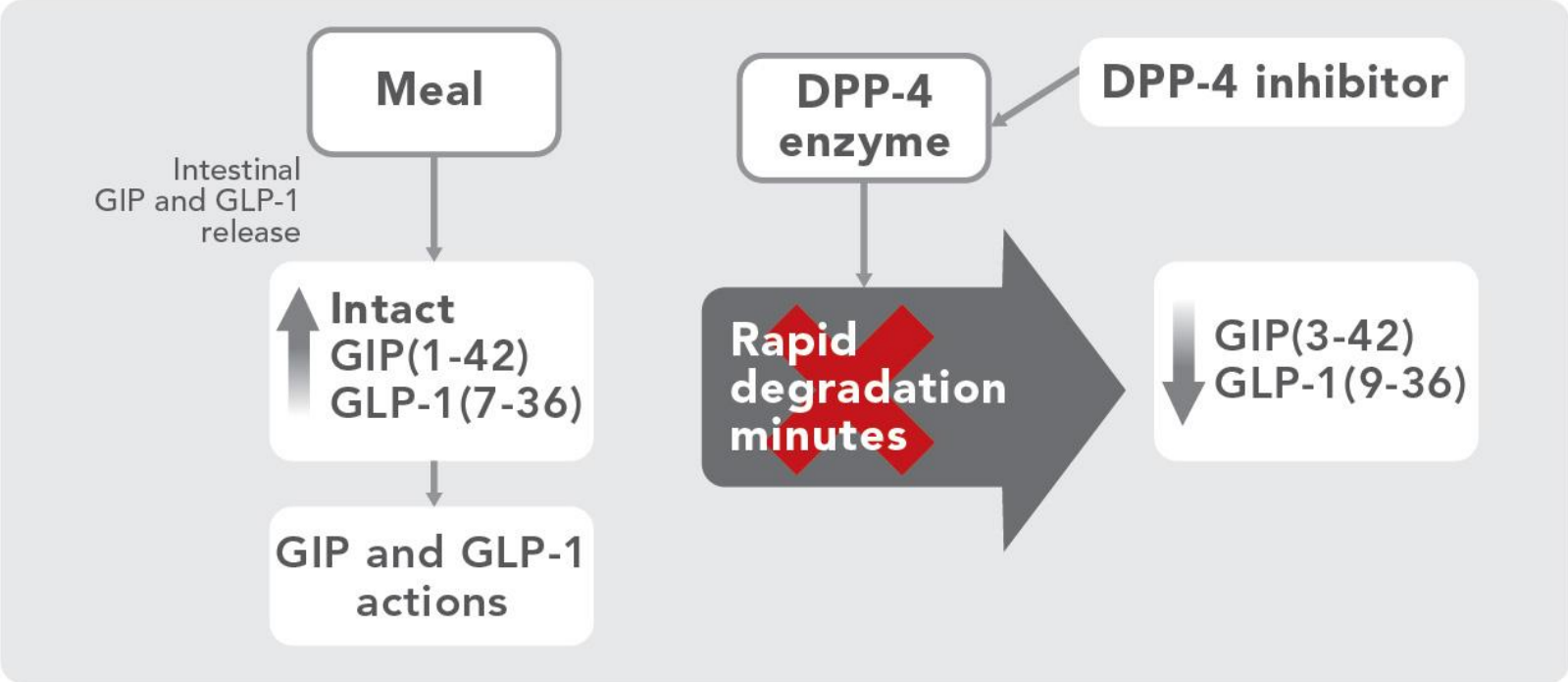


Mechanism of LGIA10



DPP-4 Inhibition: A Means to Achieve Enhancement of Intact Incretins

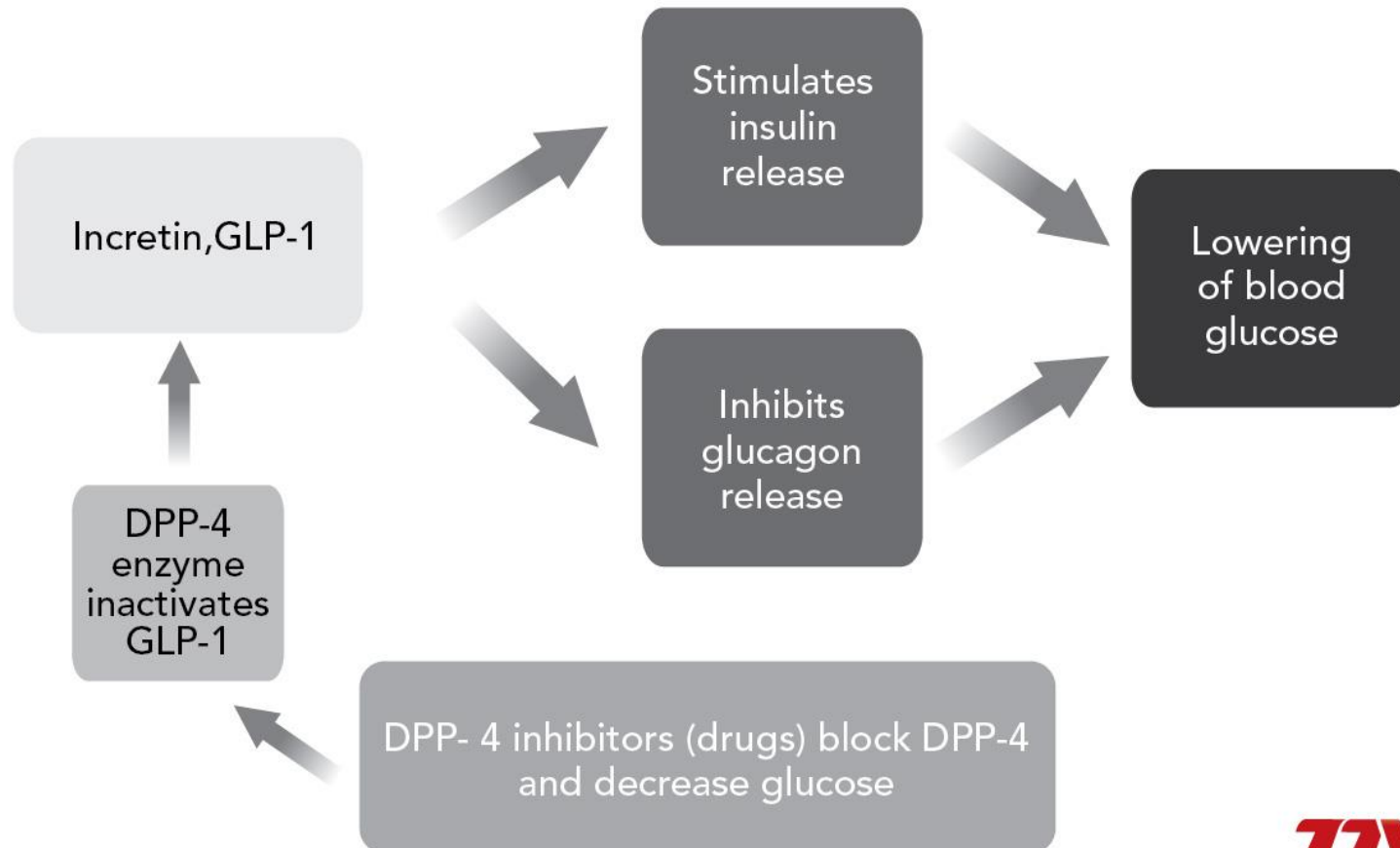
In vitro and in vivo DPP-4 inhibition increases levels of intact incretins (GLP-1 and GIP). ^{1-3,5,15}



Mechanism of LGIA10

GLP-1 and Diabetes

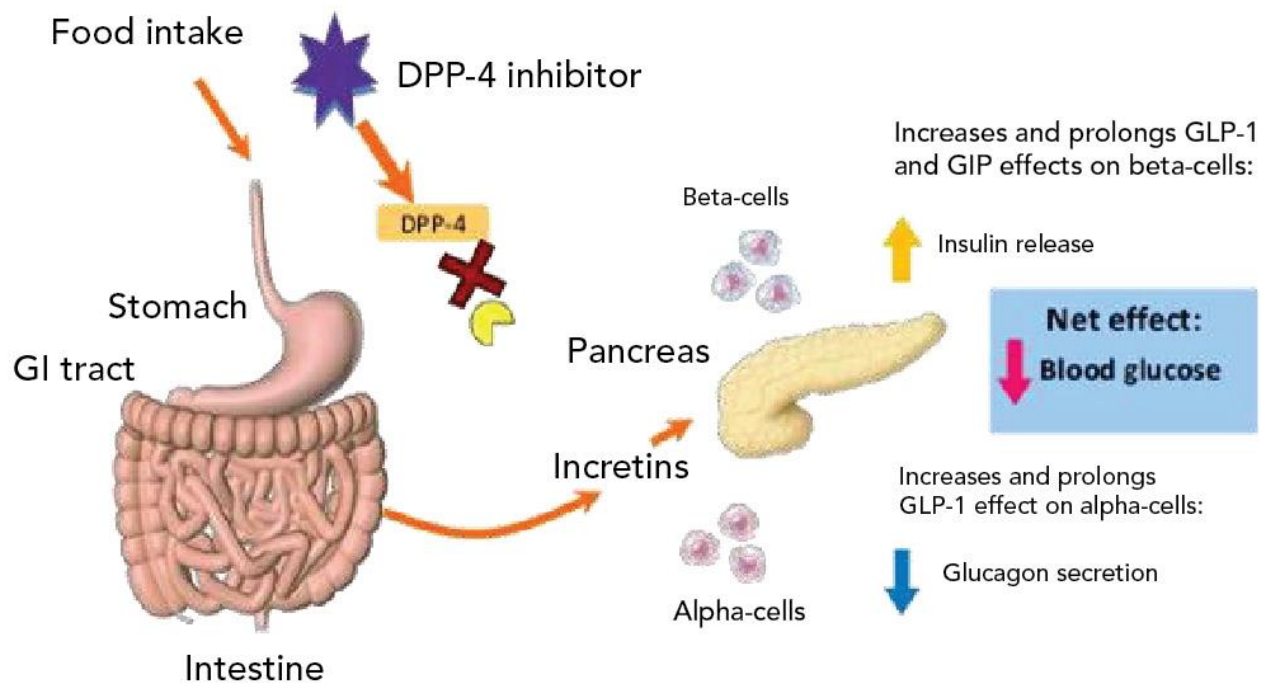
Indication: Type II Diabetes Mellitus



Mechanism of LGIA10

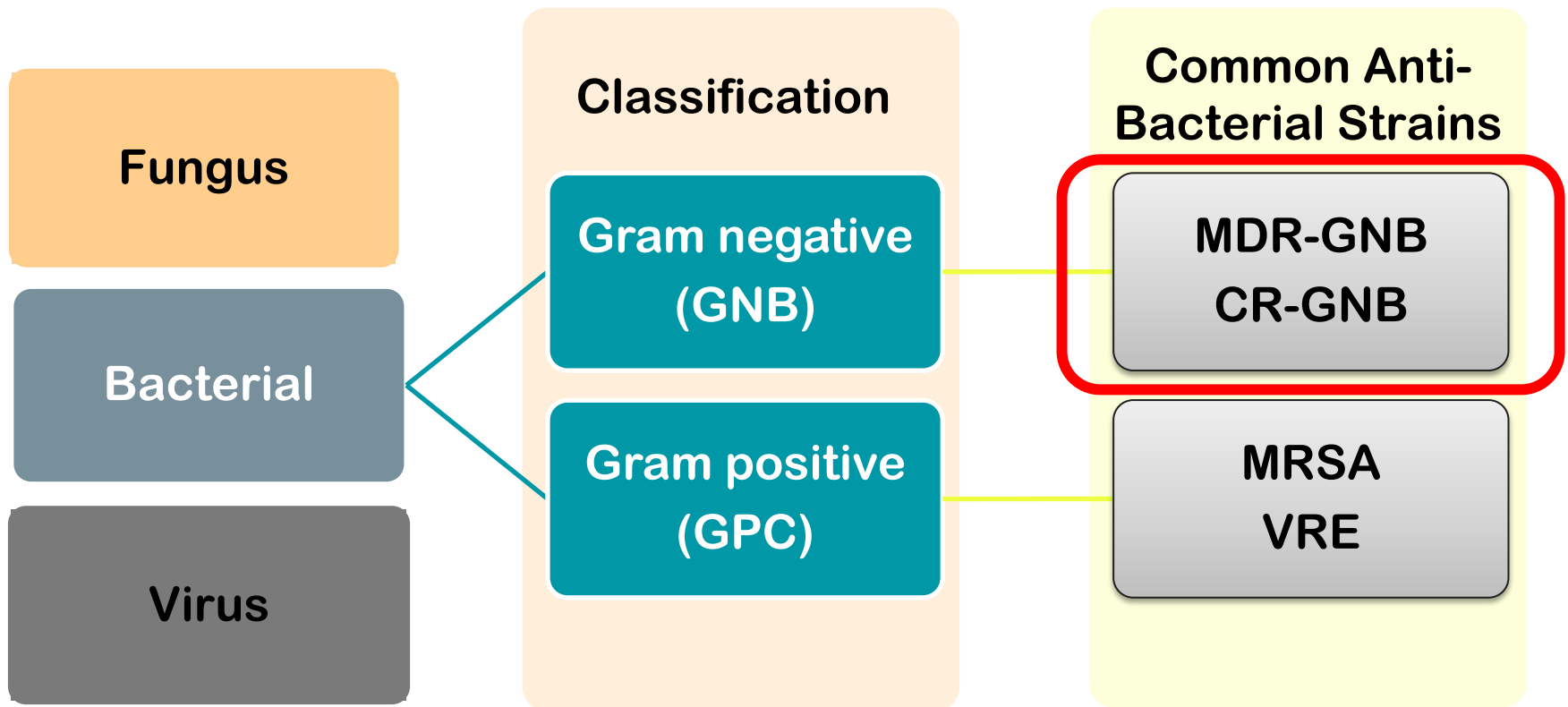


DPP-4 Inhibitors Enhance Incretin and Insulin Secretion



Adapted from: Barnett A. Int J Clin Pract 2006;60:1454-70
Drucker DJ, Nauck MA. Nature 2006;368:1696-705
Idris I, Donnelly R. Diabetes Obes Metab 2007;9:153-65

Specialty – Col103

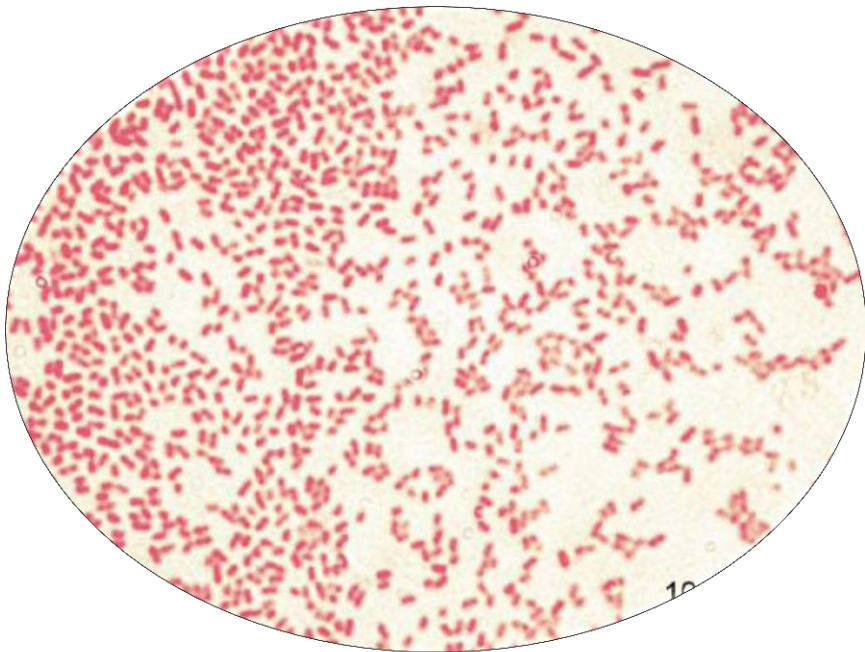


MDR-: multi-drug resistant
CR-: carbapenem resistant

MRSA: methicillin resistant Staphylococcus aureus
VRE: vancomycin resistant Enterococcus

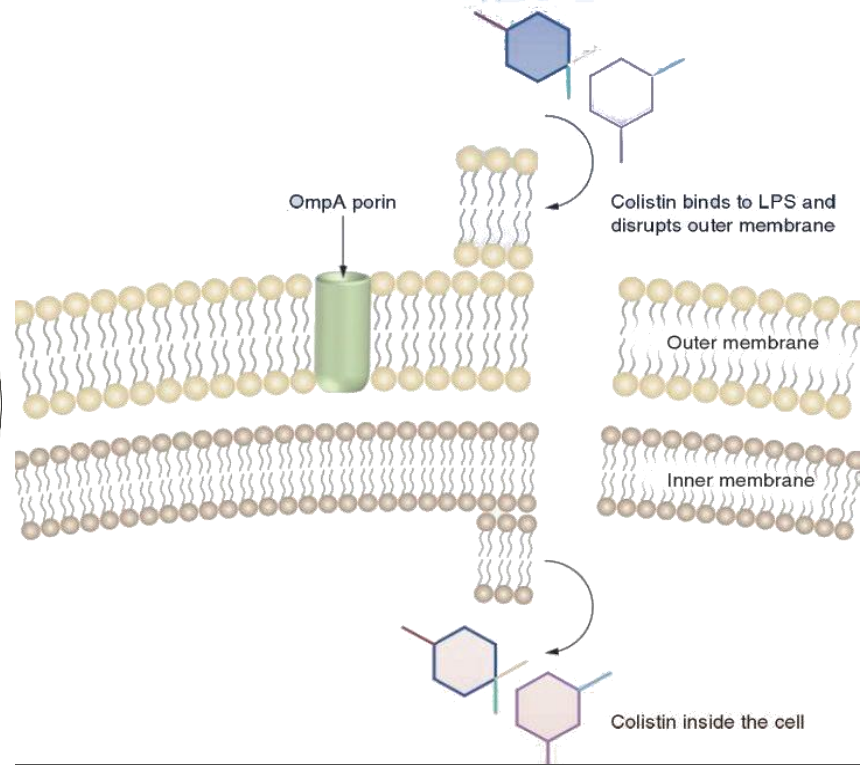
Col103

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>



Susceptibility rates of XDR-AB

MIC and susceptibility rates of extensive drug-resistant *A. baumannii* isolates

Antibiotic	Range	MIC (mg/l-1)		Susceptibility rate (%)		
		MIC50	MIC90	Susceptible	Intermediate	Resistant
Tigecycline	0.38-16	2	4	56	36	8
Rifampin	2-32	32	32	0	0	0
Col103	0.064-1	0.38	0.75	100	-	-

The Journal of Antibiotics (2010) 63, 51 – 53

Susceptibility rates of CR-PA

Table 1

Antimicrobial susceptibility comparison of MBL gene-positive and MBL gene-negative CRPA

Antimicrobial agents	Non MBL-containing CRPA (N = 55)				MBL-containing CRPA (N = 17)			
	MIC (mg/L)			Susceptibility (%)	MIC (mg/L)			Susceptibility (%)
	Range	MIC ₅₀	MIC ₉₀		Range	MIC ₅₀	MIC ₉₀	
AMK	2.0 to >32.0	8.0	32.0	85.5	2.0 to >32.0	32.0	>32.0	17.6
TOB	≤0.5 to >8.0	1.0	>8.0	65.5	8.0 to >8.0	>8.0	>8.0	0.0
GEN	1.0 to >8.0	4.0	>8.0	50.9	8.0 to >8.0	>8.0	>8.0	0.0
ATM	4.0 to >16.0	16.0	>16.0	38.2	≤1.0 to >16.0	16.0	>16.0	35.3
CAZ	≤1.0 to >32.0	8.0	>32.0	67.3	16.0 to >32.0	>32.0	>32.0	0.0
FEP	1.0 to >16.0	8.0	>16.0	60.0	8.0 to >16.0	16.0	>16.0	5.9
IMP	8.0 to >8.0	>8	>8.0	0.0	8.0 to >8.0	>8.0	>8.0	0.0
TIM	16.0 to >128.0	64.0	>128.0	52.7	128.0 to >128.0	>128.0	>128.0	0.0
TZP	4.0 to >64.0	32.0	>64.0	9.1	16.0 to >64.0	64.0	64.0	8.2
CIP	0.1 to >2.0	0.5	>2.0	67.3	0.25 to >2.0	>2.0	>2.0	0.0
COL	0.38 to 1.5	1.0	1.5	100.0	0.25 to 1.0	0.75	1.0	100.00

AMK = amikacin; TOB = tobramycin; GEN = gentamicin; ATM = aztreonam; CAZ = ceftazidime; FEP = cefepime; IMP = imipenem; TIM = ticarcillin/clavulanate; TZP = piperacillin/tazobactam; CIP = ciprofloxacin; COL = colistin.

Diagnostic Microbiology and Infectious Disease (2007) 59, 211–216

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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



TTY BIOPHARM
台灣東洋藥品

Lioudu Factory



Inspection Certificates

PMDA (Japan)

承認番号 NDA180603
Number of Approval
NDA 180603

品名 特製アセピリン錠
Name of the Applicant
TTV Biopharm Co., Ltd.

製薬所の名称
Name of the Manufacturing Establishment
TTV Biopharm Co., Ltd. (Changshu) Biotech

製造所の所在地
Location of the Manufacturing Establishment
No. 588, Sec. 1, Changshu No. 1 (Fuzhou), Suzhou, Jiangsu, P.O.C.

認可の区分
Approval Category
新薬品 経口薬品 (New Drug)

製造所 1. 品名, 2. 品名, 3. 品名
1. It is certified that the above name is in compliance with the provisions of Article 163 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 佳江
Minister of Health, Labour and Welfare

有効期間 平成 23 年 8 月 23 日まで
Valid period from 2011 Year Month Day
平成 28 年 8 月 23 日まで
with 2016 Year Month Day

ANVISA (Brazil)

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 Science
Associate Director, Global Regulatory Affairs
920 Route 201 South
P.O. Box 100
Raritan, NJ 08869

Dear Mr. Soriano:

Please refer to your Supplemental New Drug Application (sNDA) dated July 12, 2015, received July 17, 2015, submitted under control number 10103 of the Padded Label, Drug, and Cosmetic Act (FDCA), for Dexamethasone and Dexamethasone Injection, 20 mg/10 mL and 50 mg/10 mL.

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

The September 22, 2015, submission constituted a complete response to our November 12, 2015, Complete Response action letter.

This Prior Approval supplemental new drug application provides for:

- a new manufacturing site at TTV Biopharm Company Limited (TTV Biopharm) located in Changshu, Suzhou, Jiangsu, P.O.C. for the manufacturing of the drug product;
- a change in back site of the drug product to 60 L and drug product manufacturing process changes;
- a new prescription, pre-positioned stopper for the drug product container/closure system;
- addition of a secondary packaging site at Anderson/Tennessee, Inc.;
- revision of the package insert to conform with the requirements of content and format of labeling as described in 21 CFR 201.25 and 201.27, and the Pregnancy and Lactation Labeling Rule (PLLR), and;
- revision of content and immediate container labeling to mitigate the risk of medication error.

TFDA

EMA

13 APR 2016

EMA - European Medicines Agency
MEDICINES UNIT
Marketing Authorisation Unit
London, EC2A 2DP, United Kingdom
Tel: +44 (0)20 7418 5000
www.ema.europa.eu

Federal Agency for Medicines and Health Products
CERTIFICATE NUMBER: 200363908/0010

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1
Date: Following an inspection at production site
Site: 11151 of December 2006 (FFP) on Annex 1
The compliance certificate of Belgium can be found in the following link:
This is for the company TTV Biopharm Company Limited of (Changshu) Biotech
Site address: 588, Sec. 1, Changshu No. 1 (Fuzhou), Suzhou, Jiangsu, P.O.C.
This has been prepared in accordance with marketing authorisation (MA) (date manufacturing started) under the European Economic Area in accordance with Article 11(1) of Directive 2003/2003/EC regarding the following official conditions:
Article 13 of the scope of Annex 1 of December 2006 related to medicinal products for human use (category one)

For the knowledge and control activities of this manufacturer, the latest of which was conducted on 2016/04/13, it is considered that it complies with:
• The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/2003/EC.
This certificate reflects the status of the manufacturing site at the time of the inspection noted above and a valid indication as to whether the compliance status of the site that has been here stipulated under the scope of this inspection. However, this cannot be validly used or extended using statutory provisions. This manufacturing process for use only as the certificate in the labeling of the product. This certificate is valid only when received with all pages and this Part 1 and 2. The compliance of this certificate may be verified by the following:
1. The official registration number of 11151 of December 2006 (FFP) of Belgium (EMA) in the required file:
2. The official registration number of Belgium Part 1
3. The official registration number of Belgium Part 2
4. The official registration number of Belgium Part 2

EMA

MUNICIPIO DE SÃO PAULO
ANVISA SÃO PAULO DE VIGILANÇAS
MUNICIPAL DE SAÚDE
CERTIFICADO DE BOAS PRÁTICAS DE FABRICAÇÃO

2. O estabelecimento inscrito em nome de TTV Biopharm Company Limited, inscrita no CNPJ nº 06.944.475/0001-00, localizada na Rua 11151, nº 11151, Fuzhou, Suzhou, Jiangsu, P.O.C. (China), foi inspecionado em 2016/04/13 e constatou-se que o mesmo cumpre os requisitos exigidos para a fabricação de medicamentos sujeitos a controle especial, em conformidade com o Regulamento (CE) nº 2003/2003/CE, da Comissão Europeia, de 28 de fevereiro de 2006, relativo à boa prática de fabricação de medicamentos sujeitos a controle especial.

3. O estabelecimento inscrito em nome de TTV Biopharm Company Limited, inscrita no CNPJ nº 06.944.475/0001-00, localizada na Rua 11151, nº 11151, Fuzhou, Suzhou, Jiangsu, P.O.C. (China), foi inspecionado em 2016/04/13 e constatou-se que o mesmo cumpre os requisitos exigidos para a fabricação de medicamentos sujeitos a controle especial, em conformidade com o Regulamento (CE) nº 2003/2003/CE, da Comissão Europeia, de 28 de fevereiro de 2006, relativo à boa prática de fabricação de medicamentos sujeitos a controle especial.

BRASIL 09/04/2016
ANVISA SÃO PAULO DE VIGILANÇAS
MUNICIPAL DE SAÚDE

ANVISA (Brazil)

行政院衛生署藥品優良製造證明書
中華民國 105 年 04 月 13 日

製藥商名稱：台灣東洋藥行 藥品商標名稱：特製阿司匹靈錠
製藥廠名稱：新瑞藥中港南中華路一號製藥廠
藥品製造日期與內容：
● 藥名：
● 劑型與包裝：
● 藥效成份：
● 主要成份：阿司匹靈錠，每片 0.1 克。
● 藥效成份：阿司匹靈錠，每片 0.1 克。
● 藥效成份：阿司匹靈錠，每片 0.1 克。
● 藥效成份：阿司匹靈錠，每片 0.1 克。

衛生署
局長 邱文達

中華民國 105 年 04 月 13 日
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TFDA



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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、Philippine、 Vietnam
Gemis (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、Vietnam、 Malaysia、Sri Lanka、 Nigeria
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、 Vietnam、Sri Lanka
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 Restricted Drug
Epicin 	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>	<p>Taiwan、Thailand、Vietnam、Singapore、Nigeria、Sri Lanka</p>
<p>Tynen (汰能注射劑)</p> 	<p>Adjuvant & 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>	<p>Taiwan、Austria、Germany、Sweden、Other EU members、</p>
<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 & 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 & Neck cancer (頭頸癌), stage I to IV</p>	<p>Taiwan、Thailand、Vietnam、Malaysia、India、Pakistan</p>
<p>Thado (賽得膠囊)</p> 	<p>Newly diagnosed multiple myeloma, MM (多發性骨髓瘤) Erythema Nodosum Leprosum, ENL (癩瘋性結節性紅斑)</p>	<p>Taiwan、Philippines、Malaysia</p>

Successful Products (Oncology, Taiwan & Segment Market)





Products 產品名稱	Indications 適應症	Market(s) 行銷地區
Anazo (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、Vietnam、Sri Lanka
Pexeda Inj. (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
Irino (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、Vietnam、Hong Kong、Singapore、Jordan、Sri Lanka
Megest (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
Otril (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
Lonsurf 	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 **62** oncology product licenses in **17** countries.

	Country	UFUR	Oxalip	Lipo-Dox	Irino	Asadin	Gemmis	Tynen	Epicin	Thado	Anazo	Folina	Total
EU	Belgium							3					3
	Czech Republic							4					4
	Portugal						1						1
	Spain				2								2
	Austria							4					4
Asia	Thailand	1	1	1	1	1						1	6
	Philippines			1							1		2
	Vietnam	1	1	1	2	1	2			1	1		10
	Hong Kong	1	1		1		2	2	3				10
	Malaysia	1	1			1	1	1		1		1	7
	Singapore				1								1
	India	1											1
	Sri Lanka			1	1		1				1		4
	Pakistan	1											1
	Jordan				1								1
America	Costa Rica				1		1		1				3
Africa	Nigeria				1		1						2
	Total	6	4	4	11	3	9	14	4	2	3	2	62

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

Products 產品名稱	Indications 適應症	Market(s) 行銷地區
<p>Cubicin (救必辛注射劑)</p> 	<p>1. Complicated Skin and Skin Structure Infections caused by susceptible isolates of the following Gram-positive bacteria (治療下列感受性革蘭氏陽性菌引起的複雜性皮膚和皮膚組織感染 (cSSSI)如下): Staphylococcus aureus (including methicillin-resistant isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae subsp. equisimilis, and Enterococcus faecalis (vancomycin-susceptible isolates only)</p> <p>2. Staphylococcus aureus Bloodstream Infections (Bacteremia), Including Those with Right-Sided Infective Endocarditis, Caused by Methicillin-Susceptible and Methicillin-Resistant Isolates (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)</p>	Taiwan
<p>LIPO-AB</p> 	<p>1. 利時曼氏病leishmaniasis又稱黑熱病Kala-azar</p> <p>2. 骨髓移植後併發腎毒性侵入性細菌感染Concurrent renal toxicity invasive bacterial infection</p> <p>3. 感染囊球菌腦膜炎的HIV患者The infected bursa meningitis HIV patients</p>	Global(2016/7) Taiwan
<p>C+S (博益欣)</p> 	<p>為一抗感染新療效複方新藥對鮑氏不動桿菌(AB菌)治療效果更佳,目前市場尚無cefoperazone/sulbactam複方製劑,上市後可實際提供臨床用藥選擇性實際藥價低於單方用藥,減低醫療浪費</p>	Taiwan
<p>Colimycin (克痢黴素注射劑)z</p> 	<p>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。</p>	Taiwan

Anti-Infectives Portfolio



	Categories 類別	Products 產品	Indications 適應症	Stages 開發階段
1	抗細菌	Cubicin	G (+)	現有產品
2		CMS	G (-)	現有產品
3		Exacin	G (-)	現有產品
4		Brosym	Broad spectrum	現有產品
5		New formulated colistin	Anti-carbapenem resistant	Formulation
6		New cephalosporin	Broad spectrum	評估授權
7	抗黴菌	Lipo-AB	Broad spectrum	現有產品
8		Flusine	Cryptococcus and Candida	現有產品
9	Anti-HIV	DL7014 and TL7014	HIV	Formulation
10	Niche generic and TNCE	Antibiotics, Antifungals, Anti-virus	TBD	爭取經銷及自行開發

R&D Investment 研究及臨床

Subject		Year								
		2007	2008	2009	2010	2011	2012	2013	2014	2015
*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
	R&D Expense (NTD,000)	197,550	200,040	238,650	290,040	384,360	366,750	289,530	283,470	236,398
	Total Staff	319	339	400	338	374	404	484	494	450
	R&D Manpower	82	92	90	94	97	104	111	105	97
	R&D Expense/ Revenue	13.00%	11.30%	11.50%	16.20%	18.30%	16.90%	12.55%	11.89%	8.63%
	R&D Total Staff	25.70%	27.10%	22.50%	27.80%	25.90%	25.70%	22.93%	21.26%	21.56%

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

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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	2016/12/13	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

Biotech Success Strategy (2016-2020)

• Marketing Development

- Liposome Doxorubicin into global peak sale
 - TS-1 、Painkyl 、Brosym(C+S) 、Aplidin into Peak sale
 - Liposome Amphotericin B
 - Risperidone PLGA
 - Leuprolide Depot
 - 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)	
	Amount	%	Amount	%	Amount	%
Net Sales	2,292,163	100%	2,384,207	100%	2,738,956	100%
Gross Profit	1,404,003	61%	1,411,875	59%	1,777,941	65%
Operating Expenses	-1,121,548	-49%	-1,144,400	-48%	-1,035,412	-38%
Operating Profit	282,455	12%	267,475	11%	742,529	27%
Non-Operating Income and Expenses	413,685	18%	596,585	25%	705,211	26%
Income before Tax	696,140	30%	864,060	36%	1,447,740	53%
Net Income	587,440	26%	779,645	33%	1,211,018	44%
EPS	2.52		3.14		4.87	

Financial Comparison (Consolidated)

Item NTD ,000	2013 (Actual)		2014 (Actual)		2015 (Actual)		2016 Q3 (Actual)		2016 Q1~3 (Actual)	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
Net Sales	3,110,092	100%	2,979,902	100%	3,195,218	100%	935,583	100%	2,808,168	100%
Gross Profit	2,049,211	66%	1,898,936	64%	2,183,144	68%	650,621	69%	1,948,397	70%
Operating Expenses	-1,709,349	-55%	-1,560,841	-53%	-1,393,357	-44%	-346,314	-37%	-1,004,433	-36%
Operating Profit	339,862	11%	338,095	11%	789,787	24%	304,307	32%	943,964	34%
Non-Operating Income and Expenses	496,394	16%	571,745	19%	735,808	23%	-44,567	-5%	123,890	5%
Income before Tax	836,256	27%	909,840	30%	1,525,595	47%	259,740	27%	1,067,854	39%
Net Income (Consolidated)	644,530	21%	811,695	27%	1,246,592	38%	213,720	22%	906,409	33%
Net Income (TTY)	587,440	19%	779,645	26%	1,211,018	37%	212,586	22%	848,271	31%
EPS	2.52		3.14		4.87		0.85		3.41	

2014-2015 Net Profit (Individual)

Eliminated the investment traded out

Unit : NTD,000

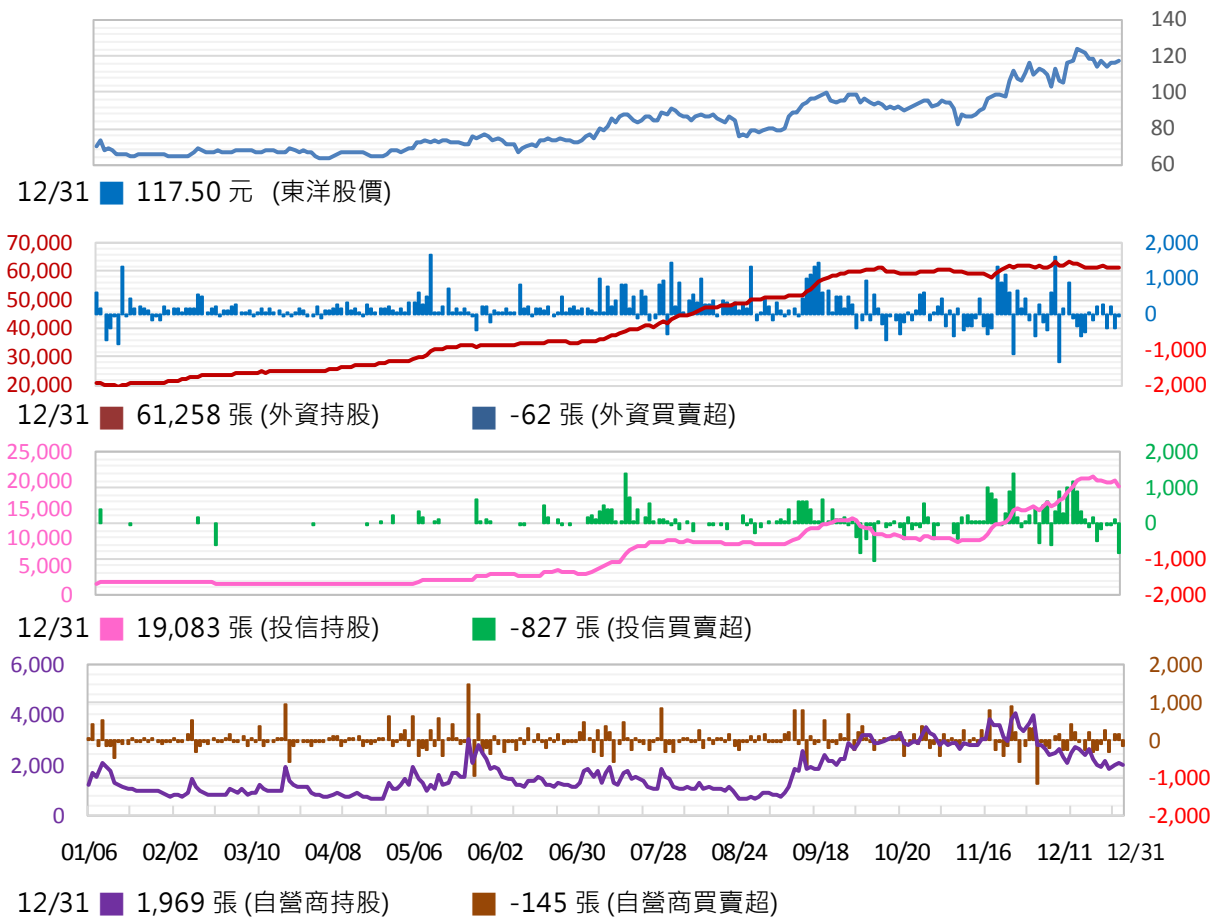
Year Season	2014		2015		2015 Growth	
	Pretax	<i>After Tax</i>	Pretax	<i>After Tax</i>	Pretax	<i>After Tax</i>
Q1+Q2	95,926	<i>76,156</i>	321,740	<i>281,251</i>	225,814	<i>205,095</i>
Q3+Q4	284,325	<i>219,680</i>	552,446	<i>453,717</i>	268,121	<i>234,037</i>
Total	380,251	<i>295,836</i>	874,186	<i>734,968</i>	493,935	<i>439,132</i>

Earning Distribution

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

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 Investors

2.09萬張(8.39%)



6.12萬張(24.63%)

Taiwan Investors

0.18萬張(0.74%)



1.91萬張(7.67%)

Individuals

0.12萬張(0.50%)

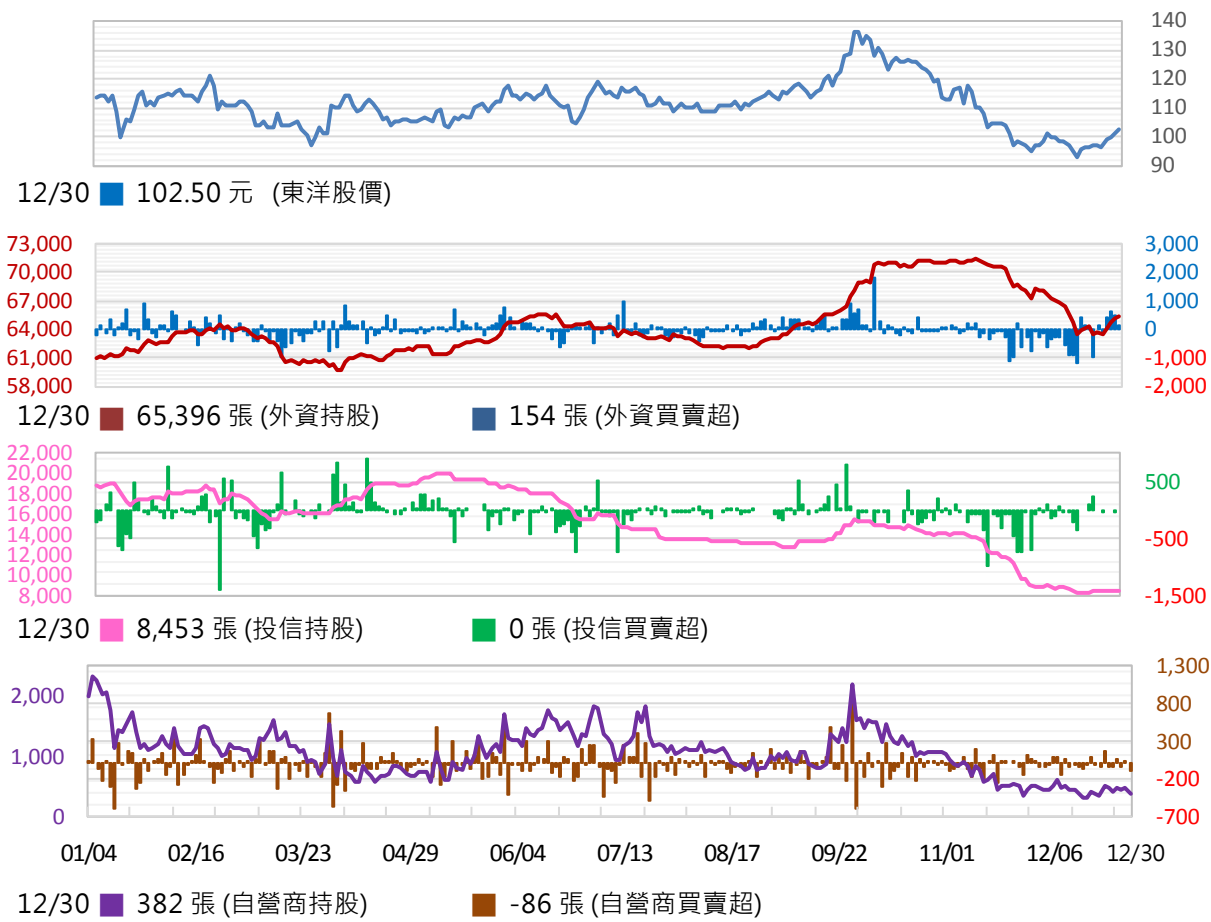


0.19萬張(0.79%)



3 Major Investors 20160104~20161230

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 Investors

6.10萬張(24.54%)



6.53萬張(26.30%)

Taiwan Investors

1.89萬張(7.59%)



0.84萬張(3.40%)

Individuals

0.20萬張(0.80%)

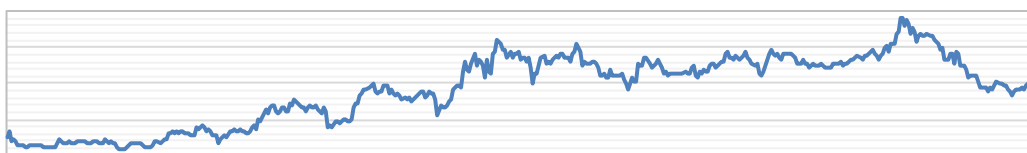


0.03萬張(0.15%)

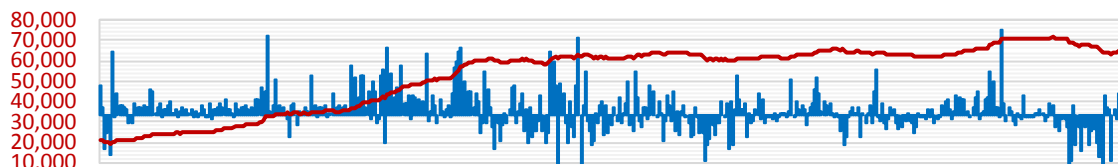


3 Major Investors 20150106~20161230

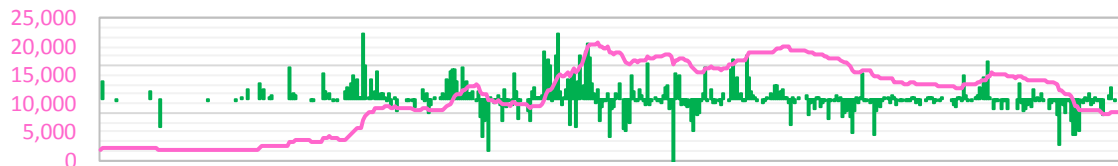
台灣東洋(4105)法人持股走勢圖



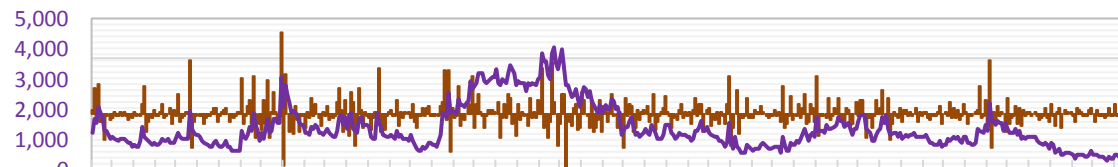
12/30 ■ 102.50 元 (東洋股價)



12/30 ■ 65,396 張 (外資持股) ■ 154 張 (外資買賣超)



12/30 ■ 8,453 張 (投信持股) ■ 0 張 (投信買賣超)



12/30 ■ 382 張 (自營商持股) ■ -86 張 (自營商買賣超)

2015/1/6 →
2016/12/30 Shift

3 Majors

2.39萬張(9.63%)



7.42萬張(29.85%)

Foreign Investors

2.09萬張(8.39%)



6.53萬張(26.30%)

Taiwan Investors

0.18萬張(0.74%)



0.84萬張(3.40%)

Individuals

0.12萬張(0.50%)

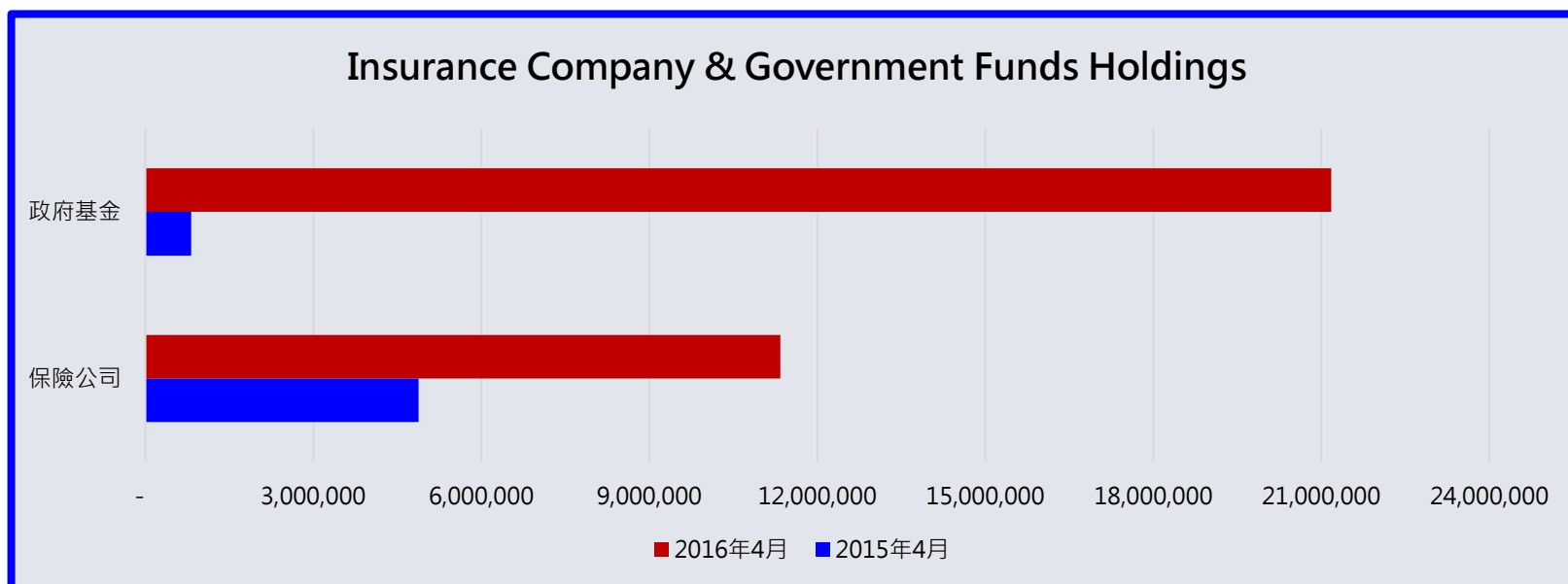


0.03萬張(0.15%)



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%
Total	5,697,821	2.29%	32,516,843	13.08%





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

