共信醫藥科技控股股份有限公司
股票代碼：6617

誠信.創新.專業.關懷

共信醫藥科技股份有限公司
Gongwin Biopharm Co., Ltd.

日　期：Dec-19-2018

「共信-KY」的里程碑

1980'S | Present

- ✓ 吳宜莊先生與石家舜博士首次發現PTS作為抗癌藥物之潛力。
- ✓ 1994年，在中國廣州執行人體臨床探索性研究，多達數百案例。開始執行PTS藥物的前臨床細胞與動物實驗。
- ✓ 2000年，於美國成立 PTS International Inc.。
- ✓ 2004年，送審美國FDA IND核准。
- ✓ **2017年，取得美國FDA於腺樣囊性癌之孤兒藥認定。**

2000 | Present

- ✓ 2011年，完成中央型嚴重氣道阻塞肺癌III期臨床試驗。
- ✓ 2012年，成立天津紅日健達康公司，建立PTS的生產線。
- ✓ **2018年，CFDA查驗登記歸類為1類新藥，特殊&優先審批。**
- ✓ **2018年，共信-KY通過天津紅日健達康預計辦理現金增資人民幣2,000萬元案。**

2014 | Present

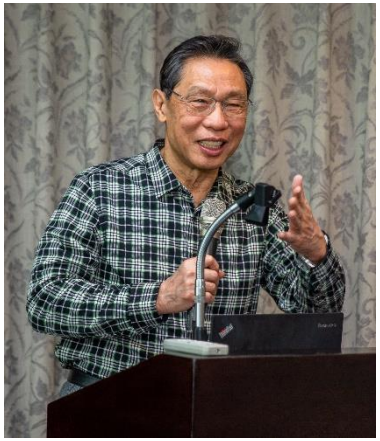
- ✓ 2014年，成立共信醫藥科技控股股份有限公司。
- ✓ 2015年，重組後將PTS Int'l併入控股公司，成為子公司。
- ✓ 2017年，共信-KY正式公開發行，2月8日上興櫃。
- ✓ 2017年，PTS100 取得新藥公司認定。
- ✓ **2018年，於臺大醫院進行PTS100肝癌臨床二期試驗。**
- ✓ **2018年，科技部核准新竹科學園區投資案。**
- ✓ **2018年，於五股新北產業園區購置不動產，預計建置研發中心。**
- ✓ **2018年，完成現金增資，募集資金共2.97億元。**
- ✓ **2018年，GW-1205配方海外授權。**

Lead Investigator of PTS: Dr. NanShan Zhong
（鍾南山 院士）

- 2011 完成 **PTS302** 的三期臨床試驗
- 2005 擔任中華醫學會會長
- 2003 成為中國的抗 **SARS** 英雄
- 2002 開始擔任中國的人大代表
- 1999 參與 **PTS** 的臨床研究計畫
- 1992 **中國廣州醫學院院長**
  初次接觸 PTS

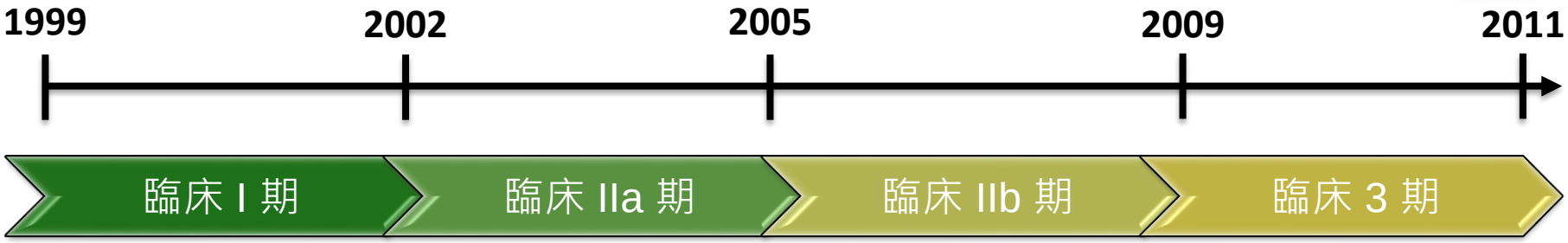
計畫主持人會議，福州
2017.09

Chinese anti-SARS Hero



Fields:
呼吸疾病
Alma Mater:
畢業於英國愛丁堡大學
Institute:
中華人民共和國全國人大代表
中華醫學會23rd會長
廣州呼吸疾病研究所所長
廣州市科協主席
廣東省科協副主席

PTS – 三期臨床實驗完成



- 收案人數：54
- 臨床設計：
  表淺、肺癌、肝癌 、乳癌患者
  每週1-5次給藥
  療程1週
- 成果：
  建立藥動模型
  建立單次給藥安全劑量
  建立多次給藥安全劑量
- Daily Max 10 ml

早期乳腺癌
腫瘤內/局部注射
(N= 41)

第一/二期頭頸鱗癌
腫瘤內/局部注射
(N= 22)

晚期惡性表淺實體腫瘤
腫瘤內/局部注射
(N= 114)

晚期非小細胞肺癌
腫瘤內注射
(N= 94)

晚期肝癌
腫瘤內注射
(N= 83)

中央型肺癌
嚴重氣道阻塞
局部腫瘤內注射
(N= 89)

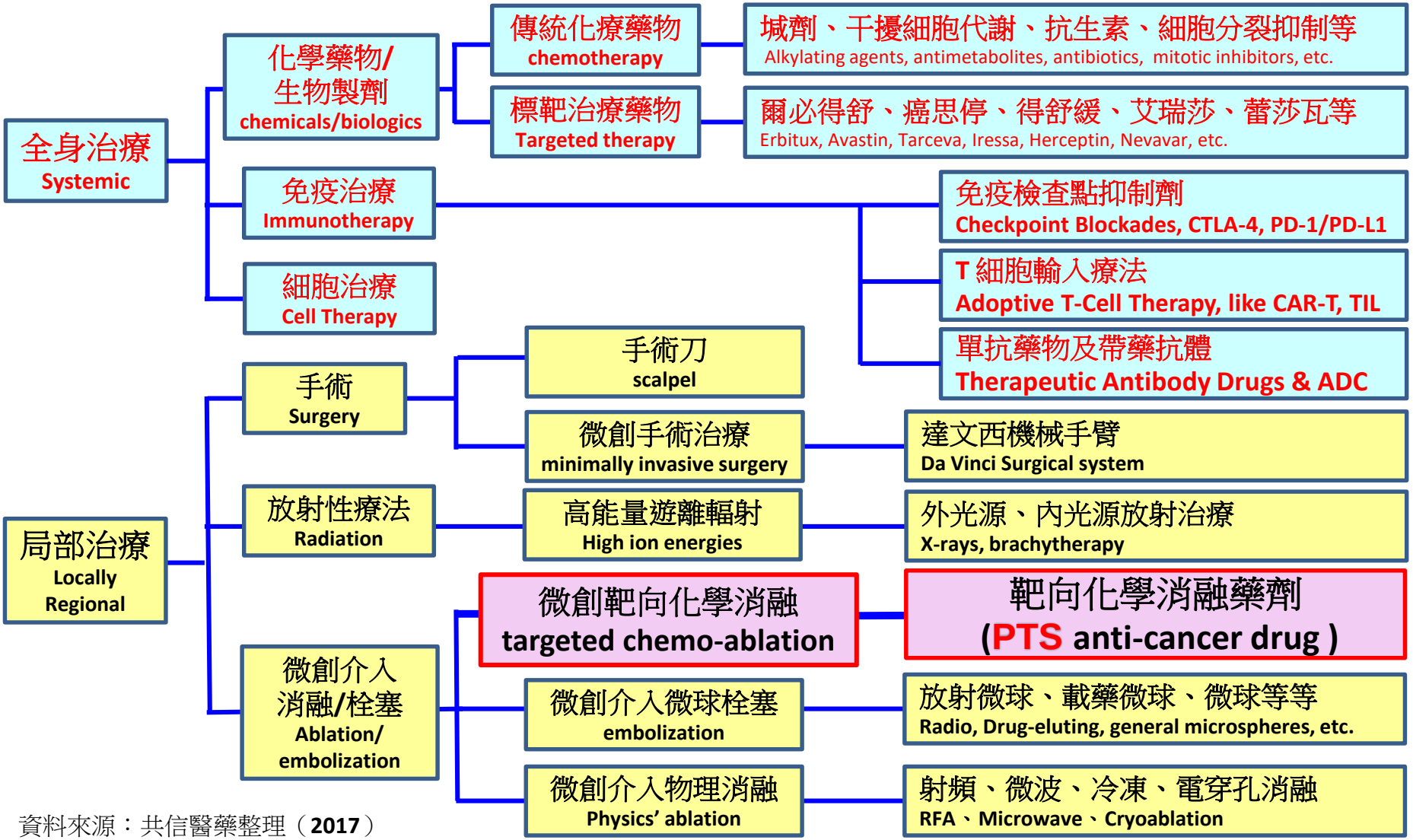
中國CFDA化學藥品
1 類新藥藥證申請中

智財權保護

專利名稱	方向	申請日期	送件國家	送件案號	目前狀態
Toluene Sulfonamide-Containing Anti-Tumor Composition And Method Of Use Thereof	**產品特性**	2001.04.16	USA/全球	6/727,287	有效中 **6/727,287**
A type of Sulfonamide pharmaceutical composition	**創新製程**	2015.01.06	China/PCT	104473914A	有效中 **104473914A**
Novel benzenesulfonamides compositions for treatment of malignant pleural effusions	**新適應症**	2016.06.10	USA/PCT	15/179,153	有效中 **US 9,668,990 B1**
Novel pharmaceutical compositions of benzenesulfonamide derivatives for treatment of adenoid cystic carcinoma	**新適應症**	2016.12.21	USA/PCT	15/387,221	有效中 **US 9,782,370 B2**
Pharmaceutical composition exhibiting anti-tumor activity, method for treating patient suffering from cancer and method for inhibiting tumor growth	**擴充抗癌應用**	2016.08.23	USA/PCT	15/245,170	審查中
Pharmaceutical composition containing benzenesulfonamide derivatives for the prevention or treatment of cancer	**新劑型/配方**	2016.12.30	USA	62/440,536	審查中
TOPICAL FORMULATION AND METHOD FOR PREVENTING OR TREATING ACNE	新用途	2017.12.29	USA	15/858,617	審查中
BENZENESULFONAMIDE DERIVATIVES AND METHOD FOR MODULATING LIPID RAFT	**藥效作用 分子標的**	2017.12.29	USA	62/612,028	審查中
BENZENESULFONAMIDE DERIVATIVES AND METHOD FOR TREATING CANCER	**新衍生物**	2018.06.21	USA	16/014,295	審查中

PTS新藥技術

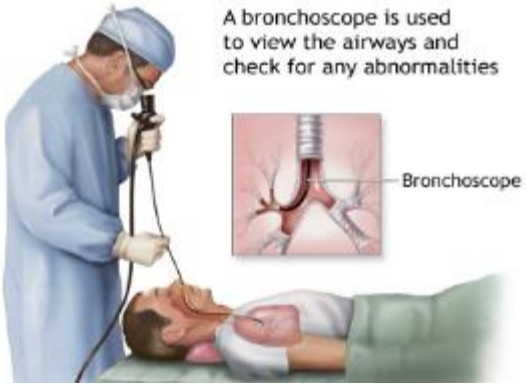
PTS在癌症治療的定位



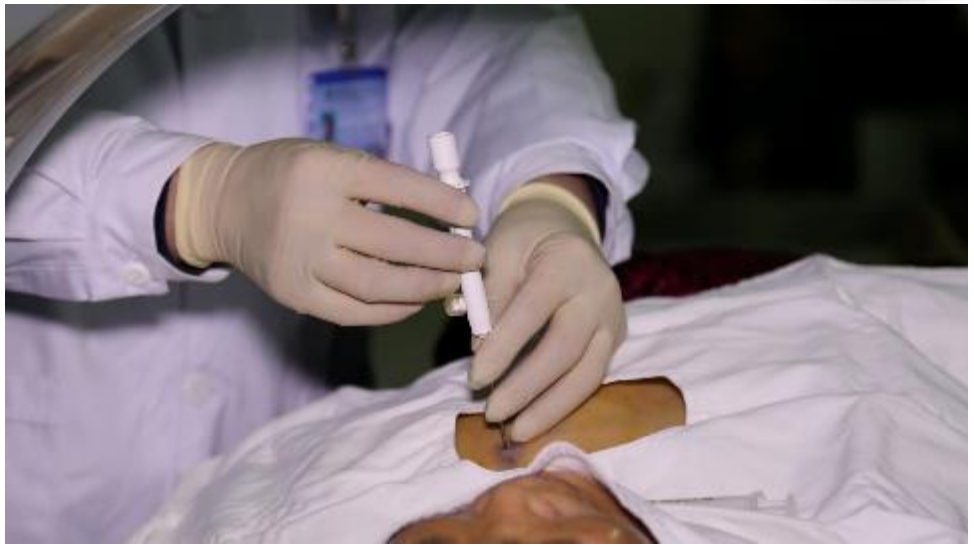
資料來源：共信醫藥整理（**2017**）

經由影像定位技術，將PTS注射到癌細胞

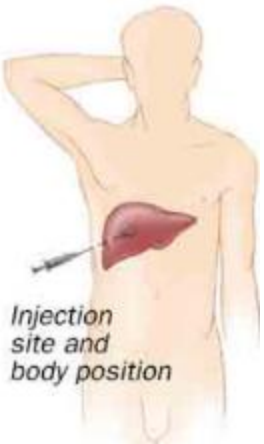
呼吸介入的診斷與治療



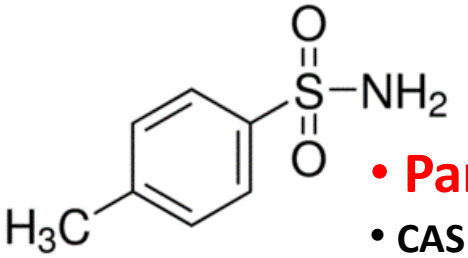
周圍型肺癌經皮穿刺治療



肝癌超音波經皮穿刺治療



PTS抗癌新藥



- **Para-toluene sulfonamide**
- **CAS Number 70-55-3**
- **Linear Formula $CH_3C_6H_4SO_2NH_2$**
- **Molecular Weight 171.22**

PTS100注射液

安全性

- PTS對癌細胞/正常細胞之間具有的選擇性的進入。
- 透過影像定位技術，直接將PTS注射到癌細胞，具相對安全性。

有效性

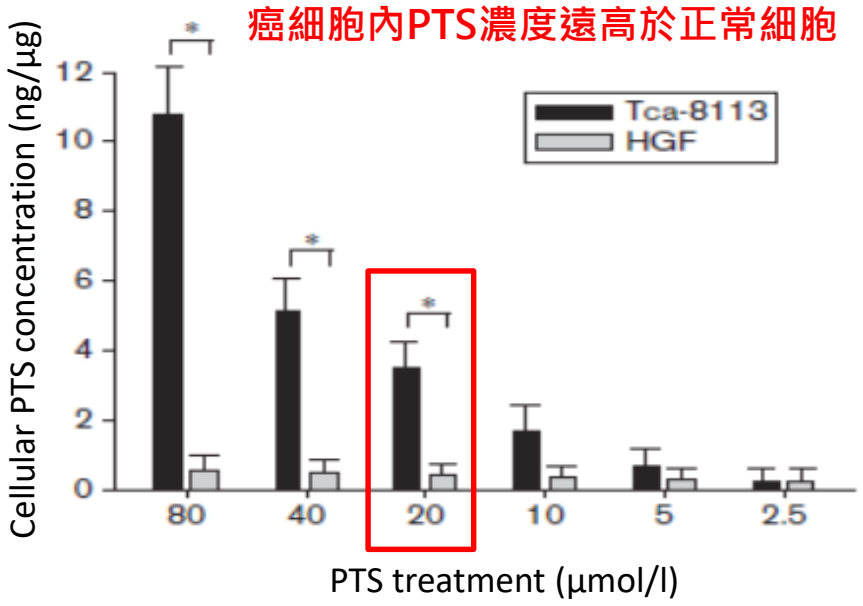
- 作為腫瘤內注射的靶向化學消融藥，PTS能有效的在注射後數小時內使腫瘤產生壞死/凋亡的作用。

廣效性

- 在過去的臨床經驗，PTS已證明對多種實體腫瘤，包括頭頸癌/乳癌/肺癌/肝癌等皆有明顯的療效。
- 可與現行癌症治療方法進行合併治療。

選擇性-1：細胞試驗的研究成果

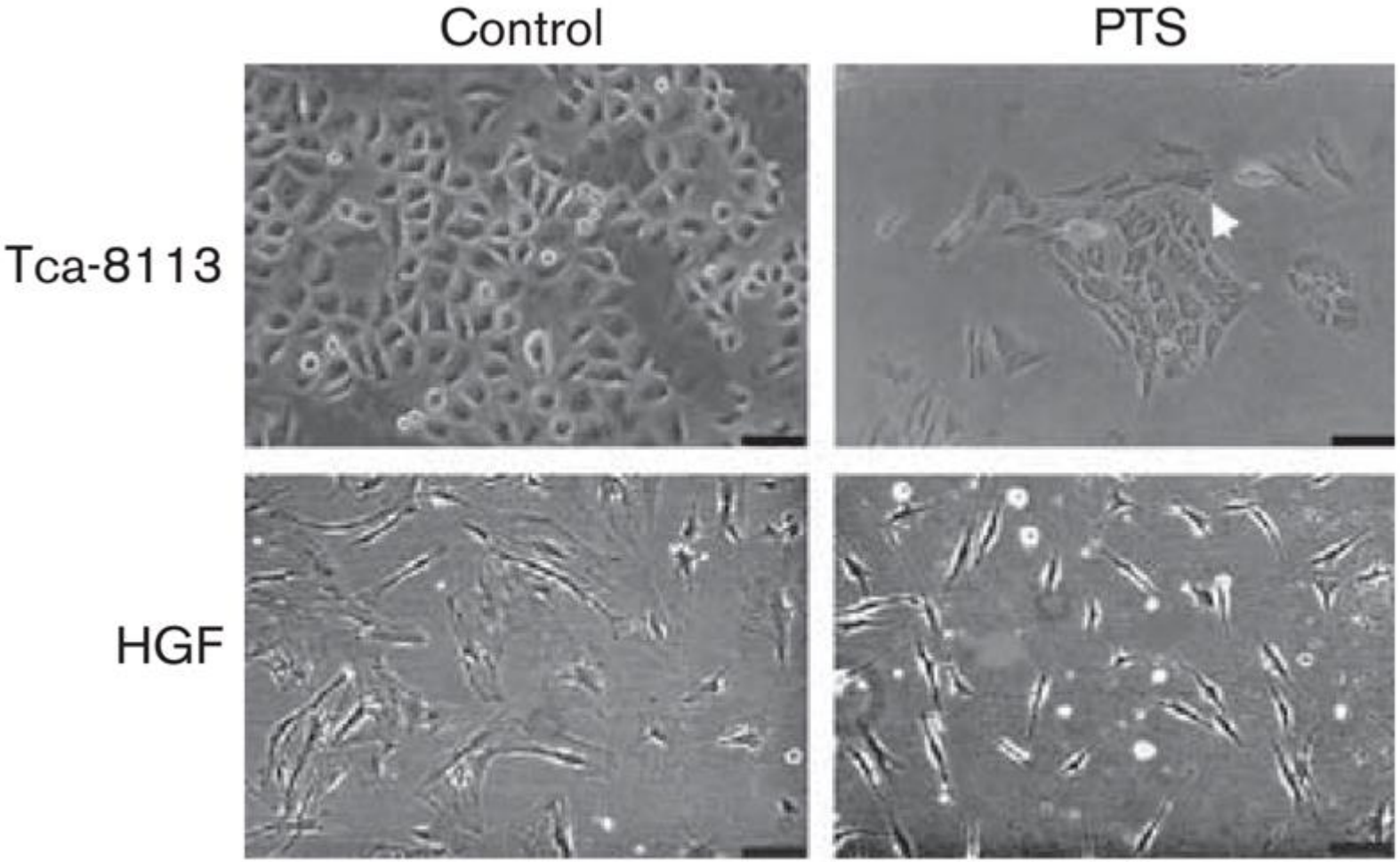
HPLC measuring cellular PTS concentration in normal and cancer cells upon increasing PTS treatments



> 10 folds PTS selectively accumulated in cancer cells than normal cells

Liu et al., Anticancer Drugs. 2015 Nov;26(10):1026-33.

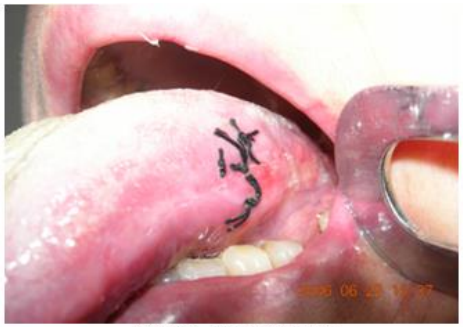
選擇性-2：細胞試驗的研究成果



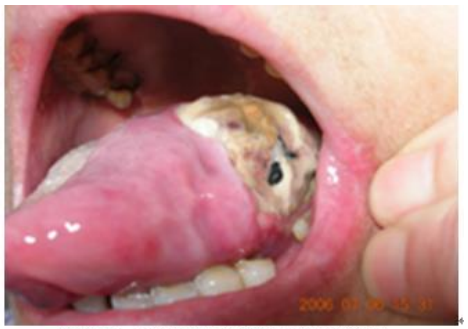
Source: **Anti-Cancer Drugs 2015, 26:1026-1033**

選擇性-3：人體臨床試驗證明

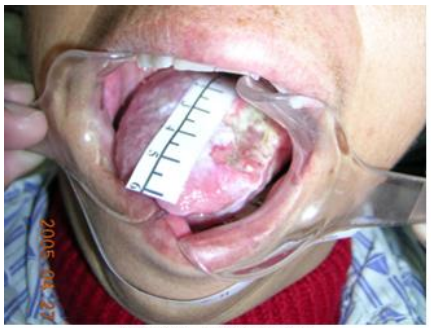
- 致腫瘤壞死靶向選擇性明顯
- 瘤周圍正常組織未見明顯損傷
- 本藥可突出顯示腫瘤邊緣, 有利更好的選擇手術切緣 (clean margin)



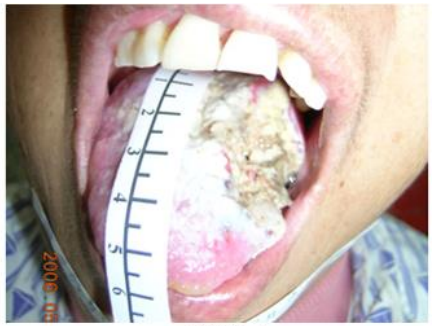
治疗前　肿瘤大小位置
肉眼难准确判断



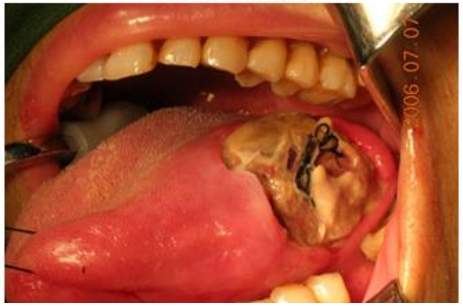
治疗中　肿瘤组织发生明显坏死退变
突显肿瘤的大小和位置

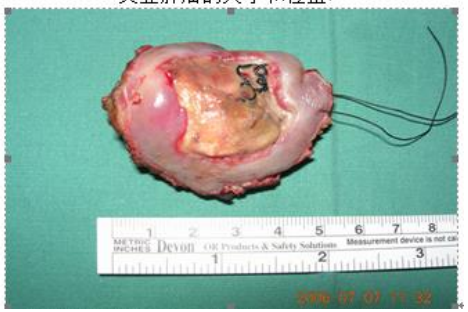


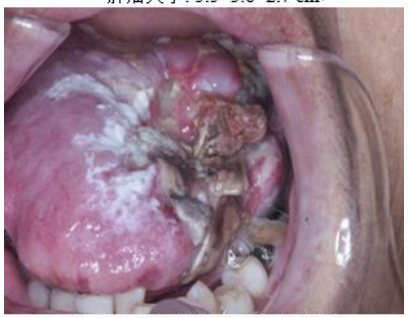
治疗前：鳞状细胞癌
肿瘤大小: 5.5×3.8×2.7 cm



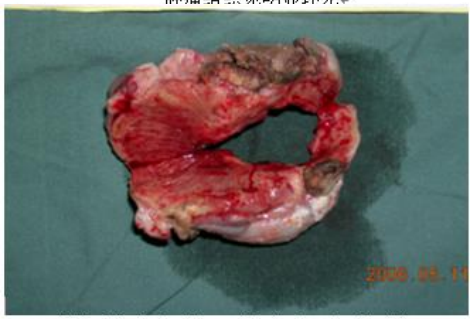
治疗中
肿瘤组织见明显坏死





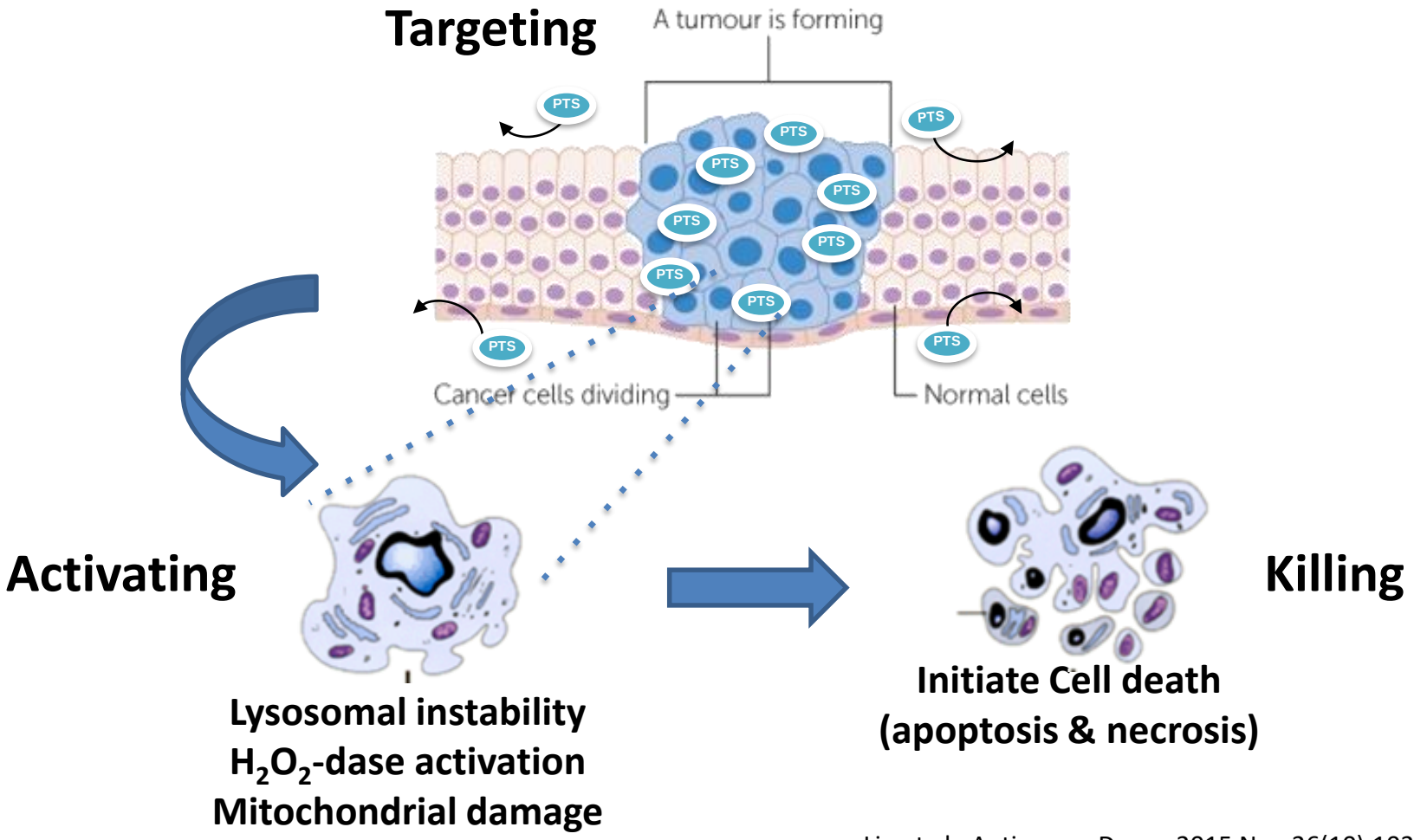


治疗中 坏死组织大部分脱落且与
正常组织分开脱离效果极为良好



沿长径剖开图，显示肿瘤组织已经基本坏死。
周围正常组织未有改变

有效性-1：PTS 作用機轉及療效



Liu et al., Anticancer Drugs. 2015 Nov;26(10):1026-33.

PTS會破壞舌癌鱗狀細胞 溶酶體 的穩定性而導致癌細胞死亡（Anti-Cancer Drugs, 2015）

OPEN

Preclinical report 1

Para-toluenesulfonamide induces tongue squamous cell carcinoma cell death through disturbing lysosomal stability

Zhe Liu[a,b], Chenyuan Liang[a,b], Zhuoyuan Zhang[a,b], Jian Pan[b,c], Hui Xia[a,b], Nanshan Zhong[d] and Longjiang Li[a,b]

Para-toluenesulfonamide (PTS) has been implicated with anticancer effects against a variety of tumors. In the present study, we investigated the inhibitory effects of PTS on tongue squamous cell carcinoma (Tca-8113) and explored the lysosomal and mitochondrial changes after PTS treatment *in vitro*. High-performance liquid chromatography showed that PTS selectively accumulated in Tca-8113 cells with a relatively low concentration in normal fibroblasts. Next, the effects of PTS on cell viability, invasion, and cell death were determined. PTS significantly inhibited Tca-8113 cells' viability and invasive ability with increased cancer cell death. Flow cytometric analysis and the lactate dehydrogenase release assay showed that PTS induced cancer cell death by activating apoptosis and necrosis simultaneously. Morphological changes, such as cellular shrinkage, nuclear condensation as well as formation of apoptotic body and secondary lysosomes, were observed, indicating that PTS might induce cell death through disturbing lysosomal stability. Lysosomal integrity assay and western blot showed that PTS increased lysosomal membrane permeabilization associated with activation of lysosomal cathepsin B. Finally, PTS was shown to inhibit ATP biosynthesis and induce the release of mitochondrial cytochrome *c*. Therefore, our findings provide a novel insight into the use of PTS in cancer therapy. ***Anti-Cancer Drugs*** 00:000–000

Anti-Cancer Drugs 2015, **00**:000–000

Keywords: apoptosis, lysosome, mitochondria, para-toluenesulfonamide, tongue squamous cell carcinoma

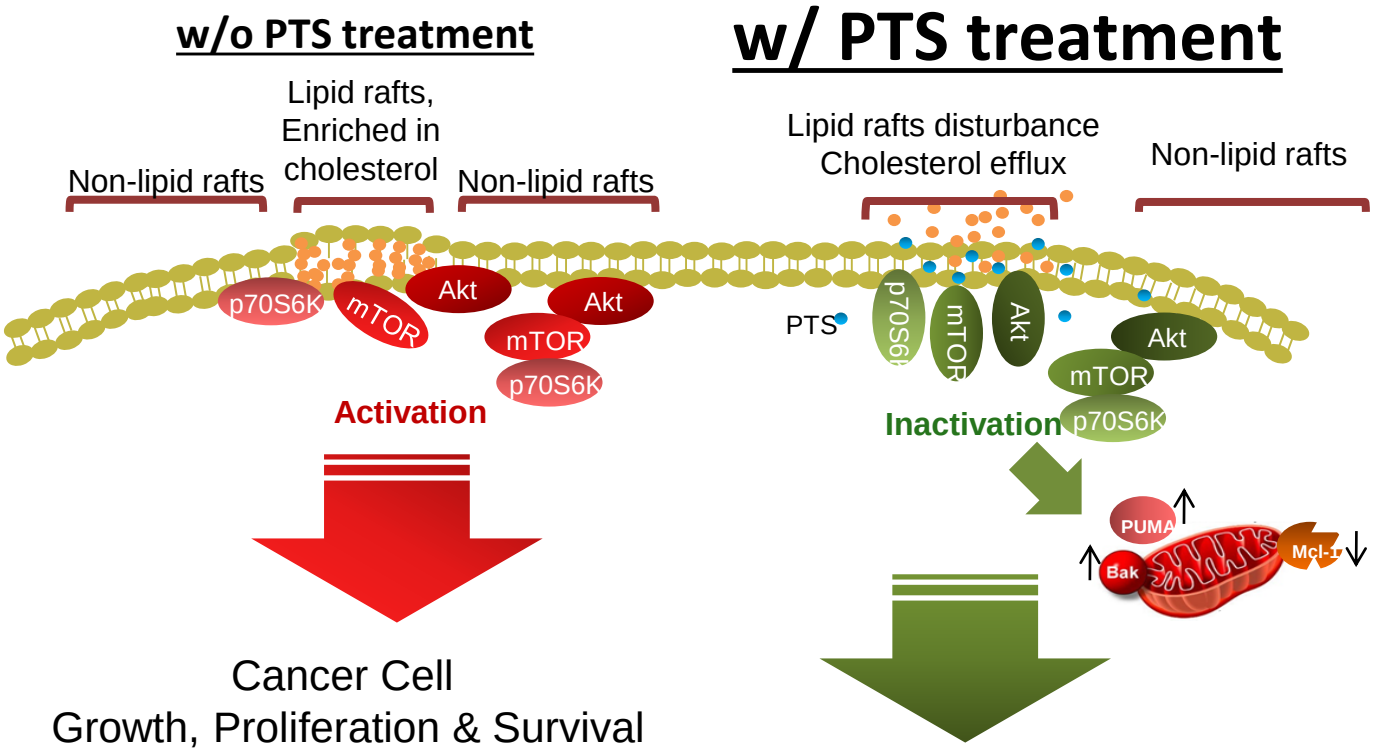
[a]Department of Head and Neck Oncology, [b]State Key Laboratory of Oral Diseases, [c]Department of Oral and Maxillofacial Surgery, West China Hospital of Stomatology, Sichuan University, Chengdu and [d]State Key Laboratory of Respiratory Disease, Guangzhou Institute of Respiratory Diseases, First Affiliated Hospital, Guangzhou Medical University, Guangzhou, China

Correspondence to Longjiang Li, DDS, PhD, Department of Head and Neck Oncology, West China Hospital of Stomatology, Sichuan University, 14#, 3rd Section of Renmin South Road, Chengdu 610041, China
Tel/fax: +86 28 85501428; e-mail: muzili63@163.com

Received 15 April 2015 **Revised form accepted** 23 July 2015

PTS Advantages- Mechanism of Action

PTS reduces lipid-raft associated pathways & necrotize cancer cells



Jih-Hwa Guh et al., Front. Pharmacol, 2018.
Illustrated Gongwin Biopharm

PTS 會破壞癌細胞膜上異常的膽固醇結構、進而干擾脂筏(Lipid raft)的穩定，阻斷下游癌細胞存活、增生和轉移之訊息傳遞

frontiers in Pharmacology

ORIGINAL RESEARCH
published: 13 November 2018
doi: 10.3389/fphar.2018.01223

Para-Toluenesulfonamide Induces Anti-tumor Activity Through Akt-Dependent and -Independent mTOR/p70S6K Pathway: Roles of Lipid Raft and Cholesterol Contents

Jui-Ling Hsu[1], Wohn-Jenn Leu[1], Lih-Ching Hsu[1], Shih-Ping Liu[2], Nan-Shan Zhong[3] and Jih-Hwa Guh[1]**

[1] School of Pharmacy, College of Medicine, National Taiwan University, Taipei, Taiwan, [2] Department of Urology, College of Medicine, National Taiwan University Hospital, Taipei, Taiwan, [3] State Key Laboratory of Respiratory Disease, National Clinical Research Center for Respiratory Disease, Guangzhou Institute for Respiratory Health, First Affiliated Hospital of Guangzhou Medical University, Guangzhou, China

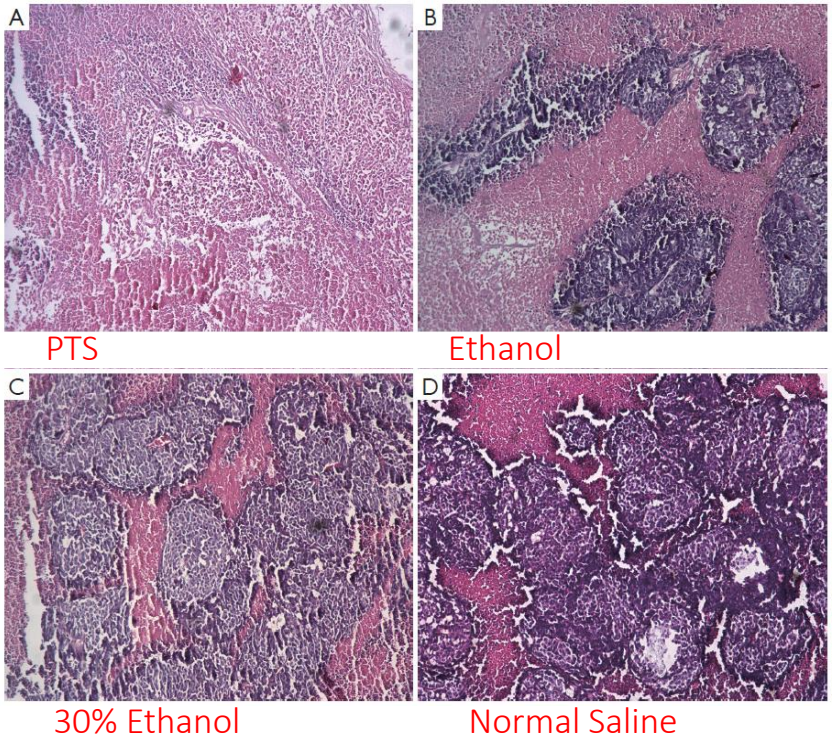
OPEN ACCESS

Castration-resistant prostate cancer (CRPC) cells can resist many cellular stresses to ensure survival. There is an unmet medical need to fight against the multiple adaptive mechanisms in cells to achieve optimal treatment in patients. Para-toluenesulfonamide (PTS) is a small molecule that inhibited cell proliferation of PC-3 and DU-145, two CRPC cell lines, through p21- and p27-independent G1 arrest of cell cycle in which cyclin D1 was down-regulated and Rb phosphorylation was inhibited. PTS also induced a significant loss of mitochondrial membrane potential that was attributed to up-regulation of both Bak and PUMA, two pro-apoptotic Bcl-2 family members, leading to apoptosis. PTS inhibited the phosphorylation of m-TOR, 4E-BP1, and p70S6K in both cell lines. Overexpression of constitutively active Akt rescued the inhibition of mTOR/p70S6K signaling in PC-3 cells indicating an Akt-dependent pathway. In contrast, Akt-independent effect was observed in DU-145 cells. Lipid rafts serve as functional platforms for multiple cellular signaling and trafficking processes. Both cell lines expressed raft-associated Akt, mTOR, and p70S6K. PTS induced decreases of expressions in both raft-associated total and phosphorylated forms of these kinases. PTS-induced inhibitory effects were rescued by supplement of cholesterol, an essential constituent in lipid raft, indicating a key role of cholesterol contents. Moreover, the tumor xenograft model showed that PTS inhibited tumor growth with a T/C (treatment/control) of 0.44 and a 56% inhibition of growth rate indicating the *in vivo* efficacy. In conclusion, the data suggest that PTS is an effective anti-tumor agent with *in vitro* and *in vivo* efficacies through inhibition of both Akt-dependent and -independent mTOR/p70S6K pathways. Moreover, disturbance of lipid raft and cholesterol contents may at least partly explain PTS-mediated anti-tumor mechanism.

Keywords: para-toluenesulfonamide, Akt/mTOR/p70S6K pathway, lipid raft, cholesterol, castration-resistant prostate cancer

Source: Front. Pharmacol., 13 November 2018
https://www.frontiersin.org/articles/10.3389/fphar.2018.01223/full

有效性-2：動物試驗



Source: J. Thorac Dis 2013; 5(4): 472-483

PTS具有對癌細胞壞死的選擇性
（Journal of Thoracic Disease, 2013）

ORIGINAL ARTICLE

Antitumor effect of para-toluenesulfonamide against lung cancer xenograft in a mouse model

Yang Gao[1], Yonghua Gao[2], Weijie Guan[1], Liyan Huang[2], Xiaoming Xu[1], Chenting Zhang[1], Xiuqing Chen[1], Yizhuang Wu[3], Guangqiao Zeng[1], Nanshan Zhong[1]

[1]State Key Laboratory of Respiratory Disease, [2]Guangzhou Institute of Respiratory Disease, First Affiliated Hospital of Guangzhou Medical University, Guangzhou 510120, China; [3]Beijing Vision Drugs Development Limited, Beijing 100020, China

ABSTRACT

Background: Conventional chemotherapy and radiation therapy against non-small cell lung cancer (NSCLC) are relatively insensitive and unsatisfactory. Para-toluenesulfonamide (PTS), a unique antitumor drug for local intratumoral injection, shows an efficacy of severely suppressing solid tumor growth with mild side effects in clinical trials. The aim of this study was to investigate the effect of PTS on lung cancer H460 cells *in vivo* in nude mice and its underlying mechanisms *in vitro*.

Methods: A lung cancer model for *in vivo* experiment was established in BALB/c nude mice using H460 cells to examine the effect of local injection of PTS on tumor suppression. We also assessed the injury to the normal tissue by subcutaneous injection of PTS. *In vitro*, PTS was diluted into different doses for study on its antitumor mechanisms. We evaluated the necrotic effect of PTS on H460 cells by PI and Hoechst 33342 staining. Cell viability and membrane permeability were also determined by using CCK-8 and LDH assays respectively. All these tests were conducted in comparison with traditional local injection of anhydrous ethanol.

Results: PTS was shown to significantly inhibit the growth of H460 tumor xenografts in nude mice by inducing necrosis of the tumor histologically. Its effect on tumor growth was significantly stronger than that of anhydrous ethanol. By contrast, the injured normal tissue by PTS injection was less than that by ethanol. *In vitro*, PTS still demonstrated excellent necrotizing effect on H460 cells when diluted to a lower concentration. Detailed analysis of PTS on H460 cells indicated that PTS had a better effect on attenuating the cell viability and increasing the cell membrane permeability than ethanol at the same level.

Conclusions: PTS exhibits excellent inhibition effect on the growth of lung cancer by necrotizing tumor *in vivo* and *in vitro*, reducing tumor cell viability and augmenting the membrane permeability *in vitro*, with only mild injury to normal tissue. The antitumor effect of PTS on lung cancer *in vivo* and vitro is stronger than that of ethanol.

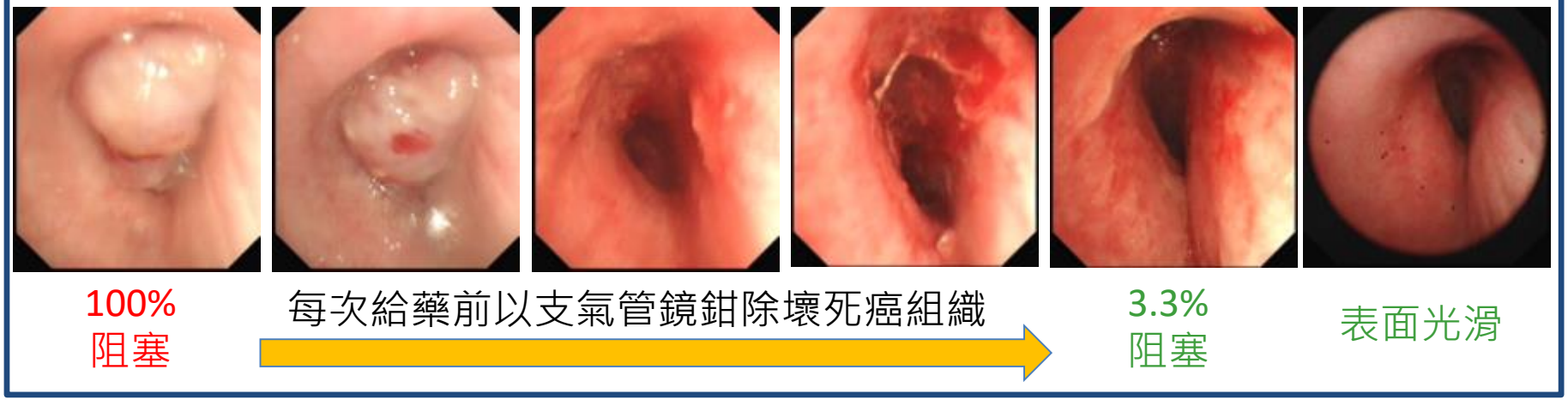
KEY WORDS Para-toluenesulfonamide (PTS); lung cancer; necrosis; therapy; antitumor agent

J Thorac Dis 2013 Aug 15. doi: 10.3978/j.issn.2072-1439.2013.08.28

有效性-3：PTS臨床治療的典型案例

右主支氣管低分化鱗狀上皮細胞癌，腫瘤分期 T3N2M1, 診斷為IV期肺癌患者

	Day 1	Day 4	Day 6	Day 8	Post 2 mo
檢查	第一次給藥	第二次給藥	第三次給藥	退出期	追蹤期
2010/05/28	2010/06/04	2010/06/07	2010/06/09	2010/06/11	2010/08/03



100% 阻塞

每次給藥前以支氣管鏡鉗除壞死癌組織

3.3% 阻塞

表面光滑

Li et al., Lung Cancer, 2016 Aug; 98:43-50. doi: 10.1016/

PTS展現有效緩解晚期肺癌患者可能危及生命之緊急狀況

PTS治療非小細胞肺癌/ 嚴重氣道阻塞的Ⅲ期試驗

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Article in Press

Effects of para–toluenesulfonamide intratumoral injection on non-small cell lung carcinoma with severe central airway obstruction: A multi-center, non-randomized, single-arm, open-label trial

Shi-yue Li[1], Qiang Li[1], Wei-jie Guan[1], Jiang Huang[1], He-ping Yang, Guo-ming Wu, Fa-guang Jin, Cheng-ping Hu, Liang-an Chen, Guo-liang Xu, Shou-zhi Liu, Chang-gui Wu, Bao-hui Han, Ying Xiang, Jian-ping Zhao, Jie Wang, Xin Zhou, Hui-ping Li, Nan-shan Zhong

[1] Drs. Shi-yue Li, Qiang Li, Wei-jie Guan, and Jiang Huang contributed equally to this study.

DOI: http://dx.doi.org/10.1016/j.lungcan.2016.05.012

Article Info

Abstract

Highlights

- The first multicenter clinical trial on PTS intrabronchial injection in NSCLC-SMAO.
- PTS leads to ameliorated dyspnea, improved lung function and prolonged survival.

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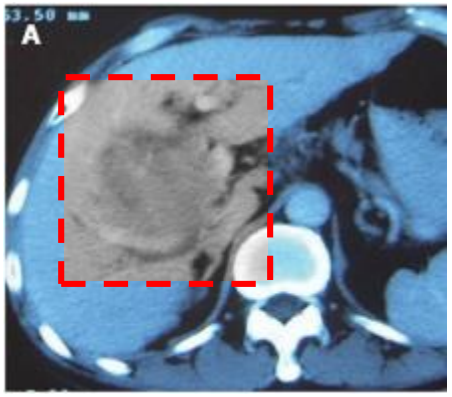
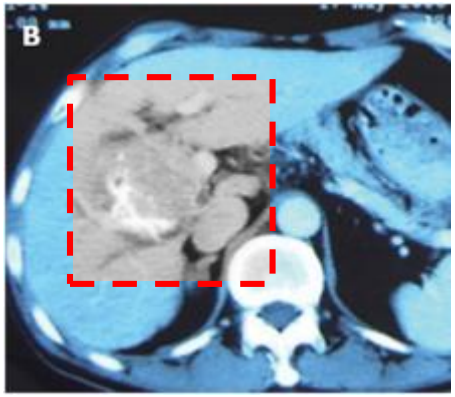
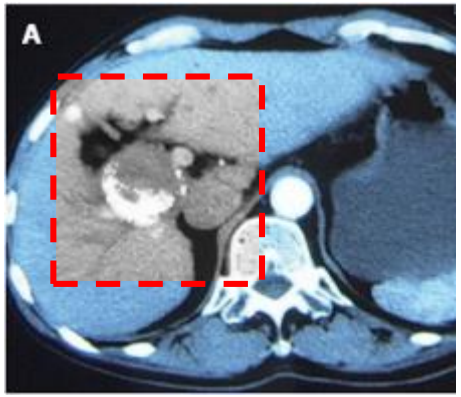
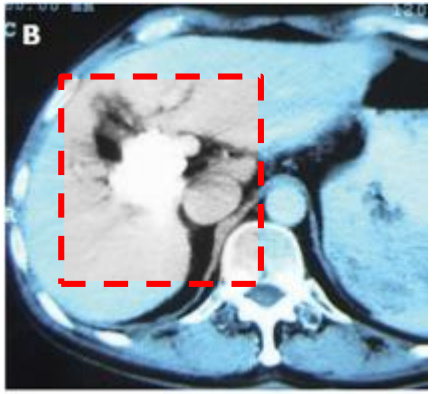
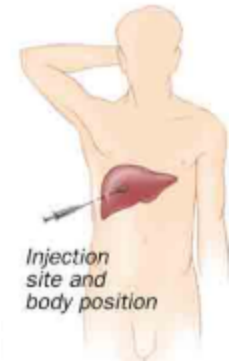
廣效性-1：晚期肝癌以PTS治療案例

下列為70歲晚期肝癌患者治療情形

2006-01	2006-02	2006-05	2006-08
治療前	TACE治療兩次後	注射 5次PTS	再追加 3次PTS
			
AFP >1210 ng/mL	AFP >1210 ng/mL	AFP =185 ng/mL	AFP =4.44 ng/mL

He et al., World J Gastroenterol. 2012 Dec 14; 18(46): 6861–6864.



對於肝癌中晚期化療栓塞失效之患者，提供嶄新治療契機。(此患者經追蹤四年尚無復發情形)

治療晚期肝癌的IIb期試驗研究個案發表

World Journal of Gastroenterology

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CASE REPORT

Puncture injection of para-toluenesulfonamide combined with chemoembolization for advanced hepatocellular carcinoma

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An-Ren Kuang, Department of Nuclear Medicine, West China Hospital of Sichuan University, Chengdu 610041, Sichuan Province, China
Author contributions: He Q and Kuang AR conceived and designed the study and prepared the manuscript; Guan YS and Liu YQ acquired and analyzed the data.
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Telephone: +86-28-85423270 Fax: +86-28-85423270
Received: July 22, 2012 Revised: September 11, 2012
Accepted: September 19, 2012
Published online: December 14, 2012

Abstract

Hepatocellular carcinoma (HCC) is difficult to eradicate due to its resilient nature. Portal vein is often involved in tumors of large size, which exclude the patient from surgical resection and local ablative therapy, such as percutaneous ethanol injection (PEI) and radiofrequency ablation (RFA) because they were considered neither effective nor safe. Currently, there is almost no effective treatment for HCC of such condition. As a unique antitumor agent in form of lipophilic fluid for local injection, para-toluenesulfonamide (PTS) produces mild side effects while necrotizing the tumor tissues quickly and efficiently. Being largely different from both PEI and RFA therapies, PTS can disseminate itself in tumors more easily than other caustic agents, such as alcohol. So PTS may offer additional benefit to HCCs with vascular involvement. We herein describe a 70-year-old HCC patient who was treated with the combination of PTS injection and transcatheter arterial chemoembolization, resulting in a significantly improved clinical prognosis.

Key words: Hepatocellular carcinoma; Para-toluenesulfonamide; Antitumor agent; Transcatheter arterial chemoembolization; Therapy

Peer reviewers: Alessandro Cucchetti, MD, Liver and Multiorgan Transplant Unit, Policlinico S.Orsola-Malpighi, University of Bologna, PAD 23., Via Massarenti 9, 40138 Bologna, Italy; Zenichi Morise, MD, PhD, Professor, Chairman, Department of Surgery Ranbunnana Hontokukai Hospital, Fujita Health University School of Medicine, 3-6-10 Onohashi Nakagawa-ku, Nagoya, Aichi 454-8509, Japan

He Q, Kuang AR, Guan YS, Liu YQ. Puncture injection of para-toluenesulfonamide combined with chemoembolization for advanced hepatocellular carcinoma. *World J Gastroenterol* 2012; 18(46): 6861-6864 Available from: URL: http://www.wjgnet.com/1007-9327/full/v18/i46/6861.htm DOI: http://dx.doi.org/10.3748/wjg.v18.i46.6861

INTRODUCTION

Transcatheter arterial chemoembolization (TACE) has become the standard treatment for unresectable hepatocellular carcinoma (HCC). Nonetheless, clinical outcomes are often unsatisfactory, especially for recurrent cases. As a novel anticancer agent, para-toluensulfonamide (PTS) is completely different from genetic, classical chemical and molecular targeted drugs, and has shown amazing antitumor effect in animal HCC experiments[1-3]. Primary pharmacological studies suggest that PTS inhibits tumor growth by acting as a tumor necrosing agent[1,2]. PTS may strengthen the effect of TACE in advanced HCC. We herein report a patient with refractory HCC who was treated with PTS injection after TACE, which resulted in a very good clinical prognosis.

CASE REPORT

The patient was a 70-year-old man. A mass was found in his right lobe of the liver in May 2004. He refused

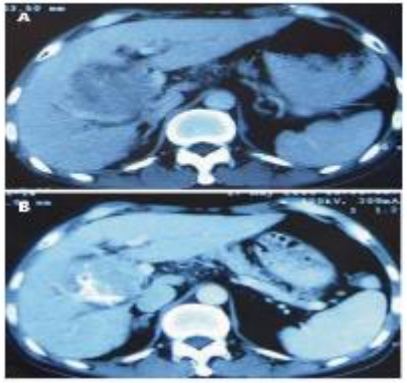

Figure 1 Trans-catheter arterial chemoembolization had little effect on the hepatocellular carcinoma, but restrict the size of tumor mass. A: Contrast computer tomography (CT) before the procedure showed a huge hypodense mass with remarkable enhancement and portal vein embolus; B: Two months after the initial 2 series of transcatheter arterial chemoembolization, contrast CT still found a hypodense nodule with partial contrast enhancement and portal vein invasion.

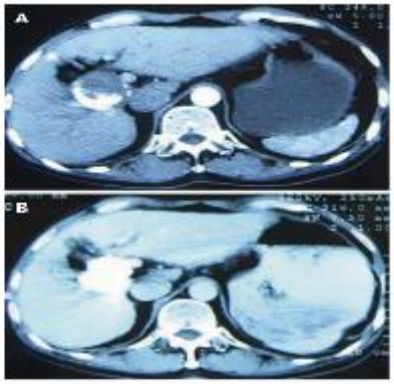

Figure 2 The following para-toluenesulfonamide injections resulted in a significantly improved clinical prognosis. A: Contrast computer tomography (CT) after the first 5 para-toluenesulfonamide (PTS) injections demonstrated a decreased nodule with partial retention of lipiodol. Remarkable necrosis and no blood supply were found in the rest part of the tumor; B: Two months after the last 3 PTS injections, contrast CT revealed homogeneous dense retention of lipiodol within the entire tumoral mass and no recurrent lesion was identified.

mixture, portal vein thrombosis, and hemothorax[4,5]. Because most anticancer drugs are corrosive and extremely toxic, they will destroy both cancer cells and normal cells when given locally at high concentrations. PTS is a local therapeutic drug that is injected directly into the tumors and has been shown to cause selectively necrosis in a variety of cancers with minimal damage to normal tissues[1,2,6].

Local ablative therapies share similar difficulties with surgical resection. The size, site and number of tumors, vascular and extrahepatic involvement as well as liver function of the patient pose a relatively minor effect on the usage of PTS[4,5]. PTS is a more readily available alternative to the local ablative therapies.

PTS, in form of lipophilic fluid, kills tumor cells by a rodent model. Local and intratumoral injection is the optimal route of PTS delivery. Being largely different from both alcohol and RFA therapies, PTS can disseminate itself in tumors more easily than other caustic agents, such as alcohol. Therefore, a successful PTS administration is to approach to the anatomically dangerous or hard to reach areas and diffuse to the target area and induce injury to the tumor tissues. This might be the mechanism as to why PTS combined with TACE could effectively treat the HCC with vascular invasion. As a locoregional antitumor agent, PTS is safe[1,2,6]. But up to date, PTS is still only a locally used antitumor agent. It is intended mainly for the treatment of a limited number of detectable tumors. PTS is not suitable to be used alone for the treatment of multifocal HCCs.

This case report demonstrated that PTS is effective in treating liver cancer by intratumoral injection, which was hypothesized to enhance the effect of TACE. This combined therapy may prove to be useful in the treatment of patients with refractory and recurrent HCC. Therefore, subsequent large, multi-center, randomized controlled studies are needed to facilitate the introduction of PTS as a novel modality for the treatment of cancers.

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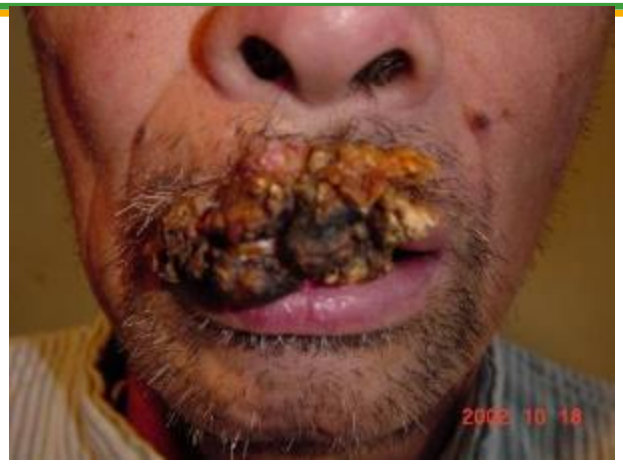
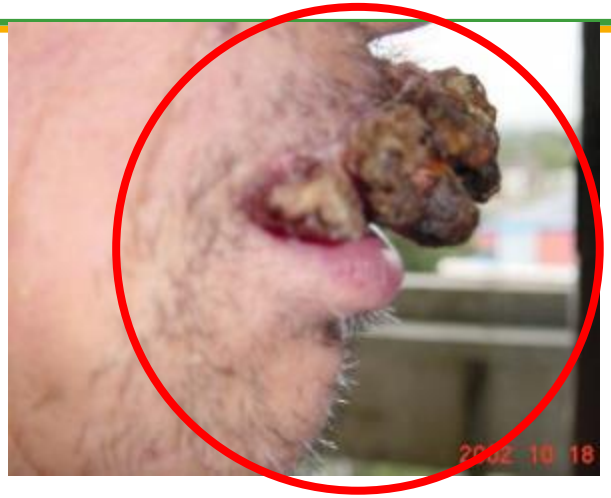
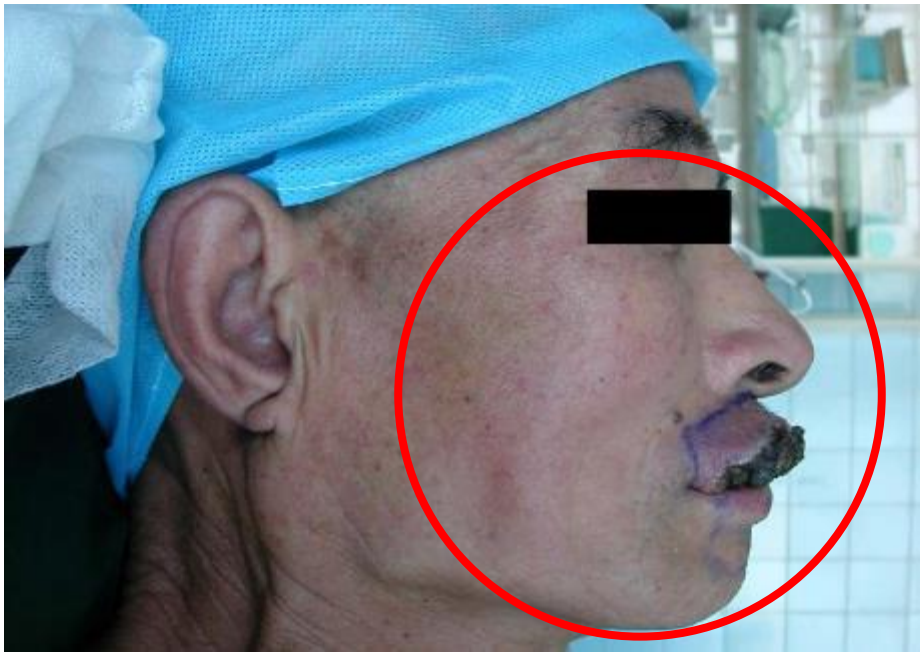
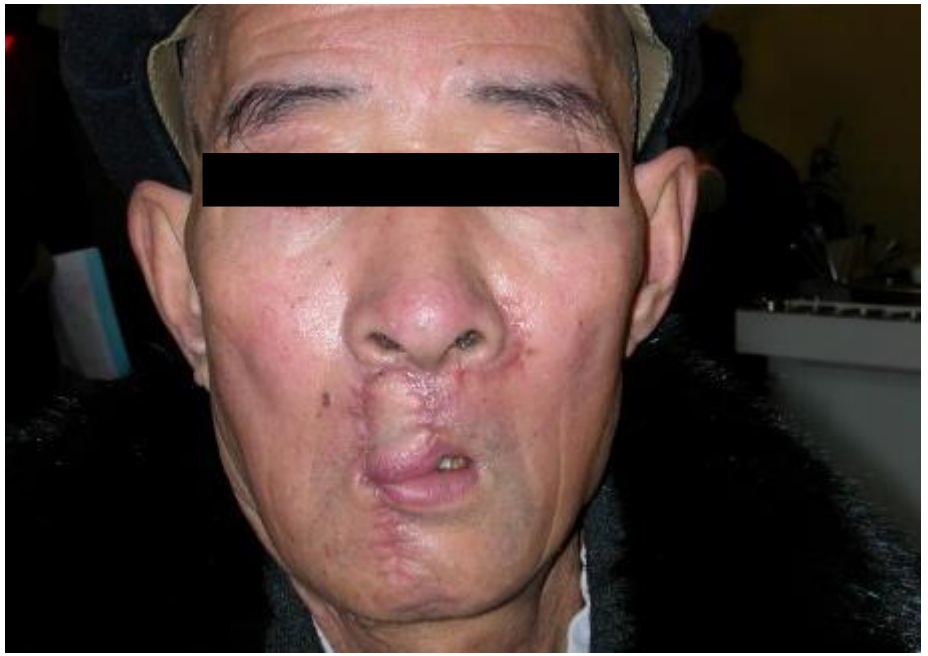
廣效性-2：頭頸癌的治療典型案例，與手術合併治療





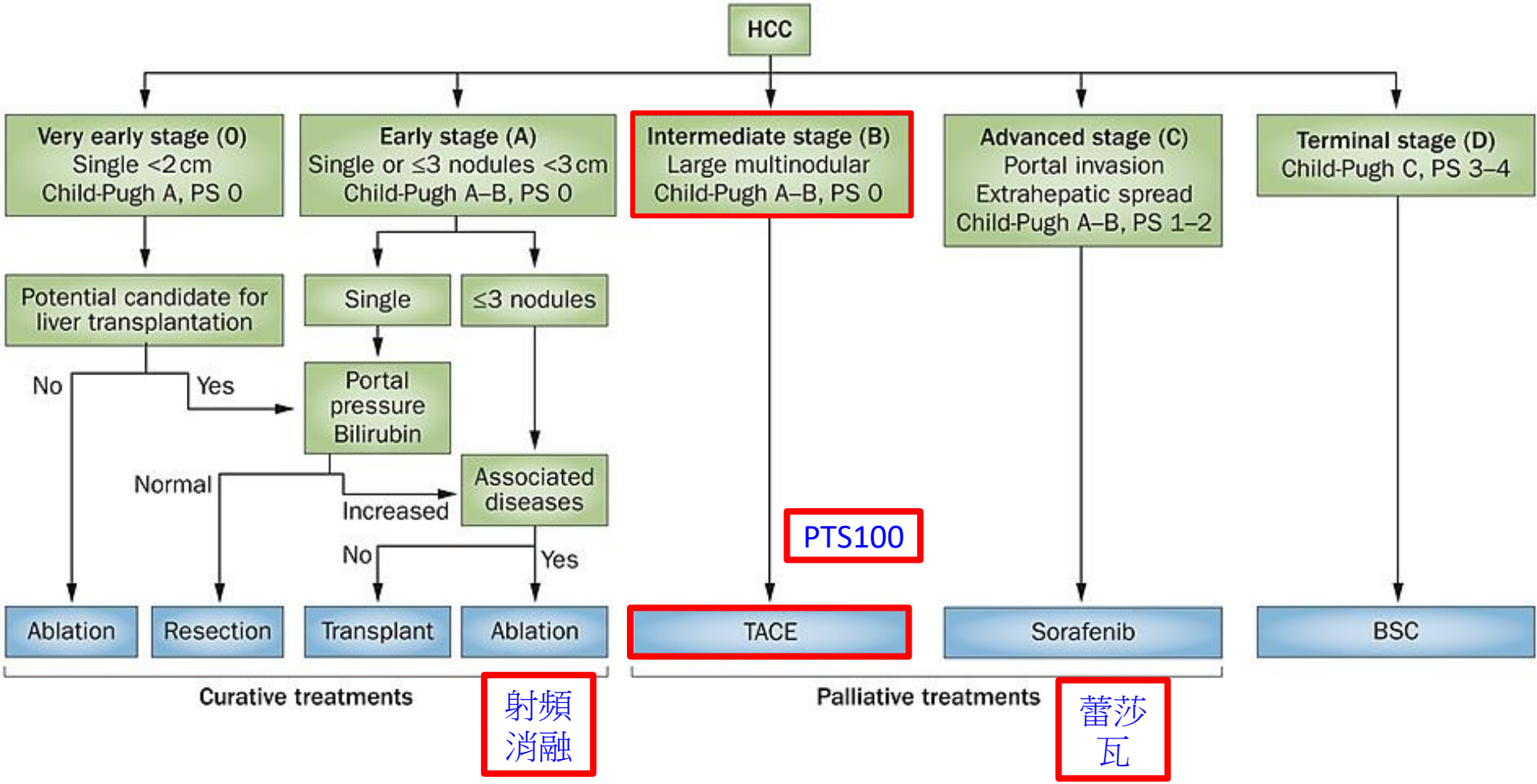




PTS302與現有呼吸介入治療比較

	PTS	雷射	氬氣刀 APC	冷凍	支架植入
安全性	高	低	高	中等	高
起效時間	中等	快	快	慢	快
設備要求	低	高	高	中等	中等
說明	不受限於醫院設備；大小腫瘤皆可治療	容易造成氣道著火	適用於小腫瘤	起效慢；有出血的風險	維持氣管暢通，但無法縮小腫瘤

PTS100的潛在治療定位



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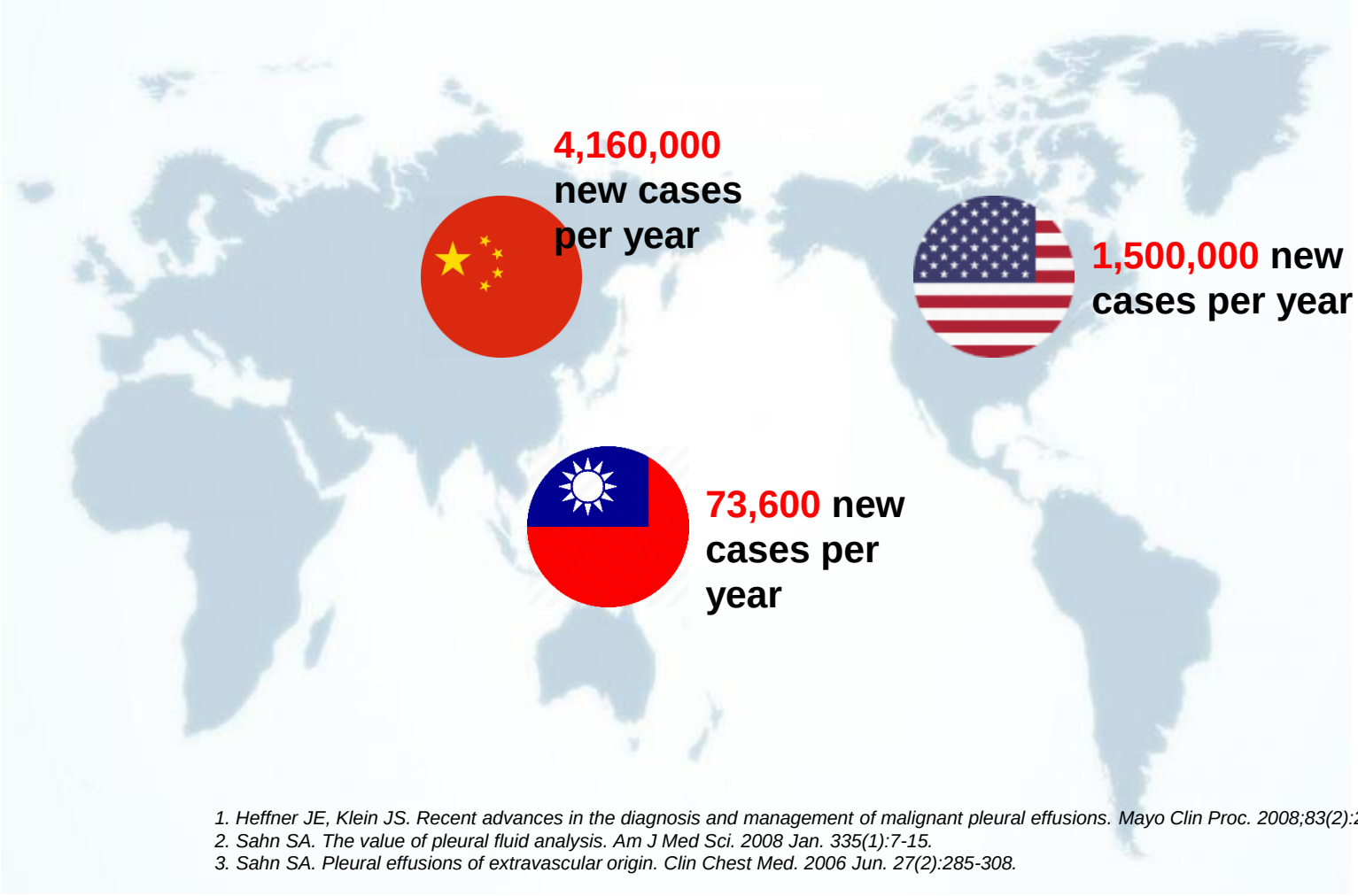
Global MPE Market Scale: 6 million Patients/Year
PTS Has Great Potential to Improve their Quality of Life



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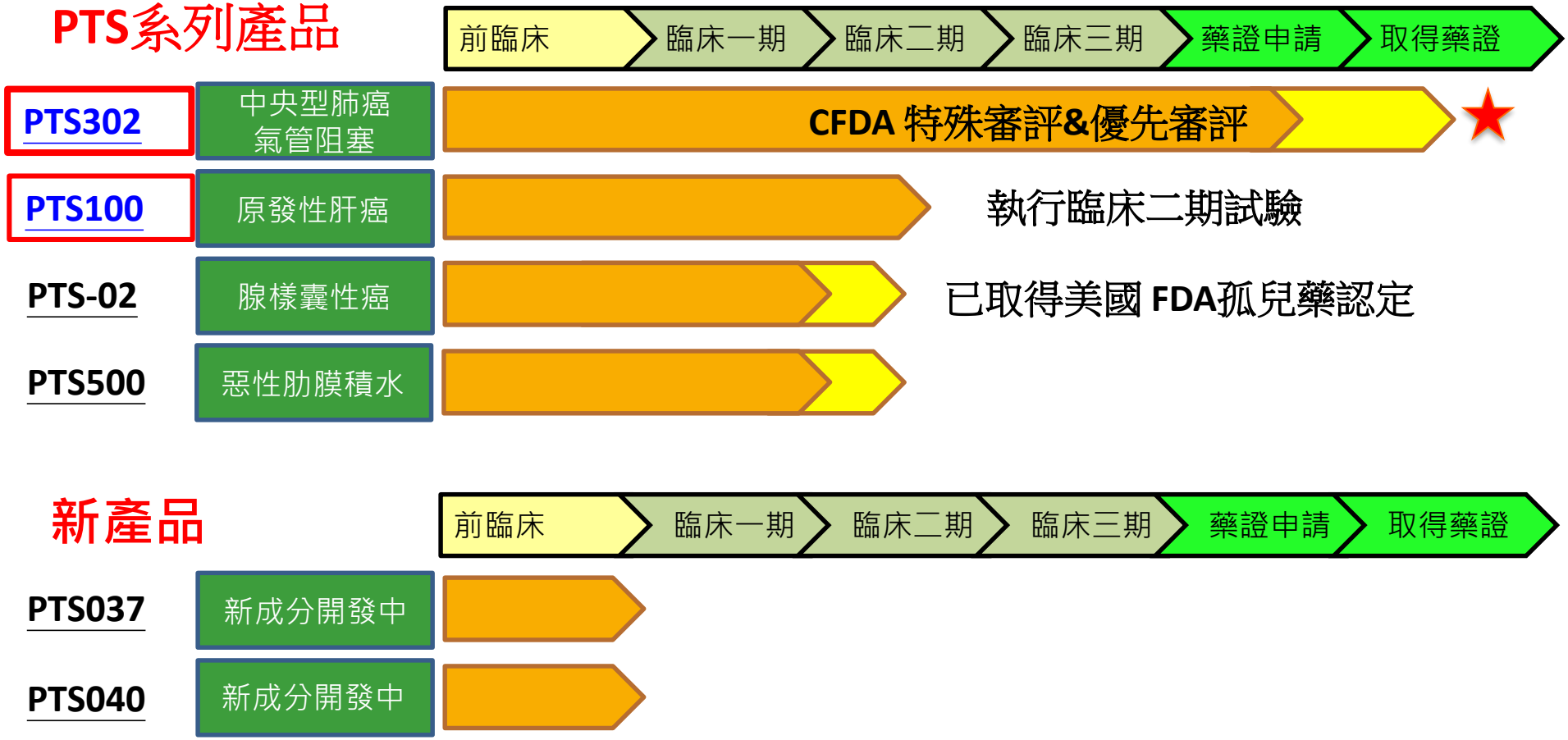
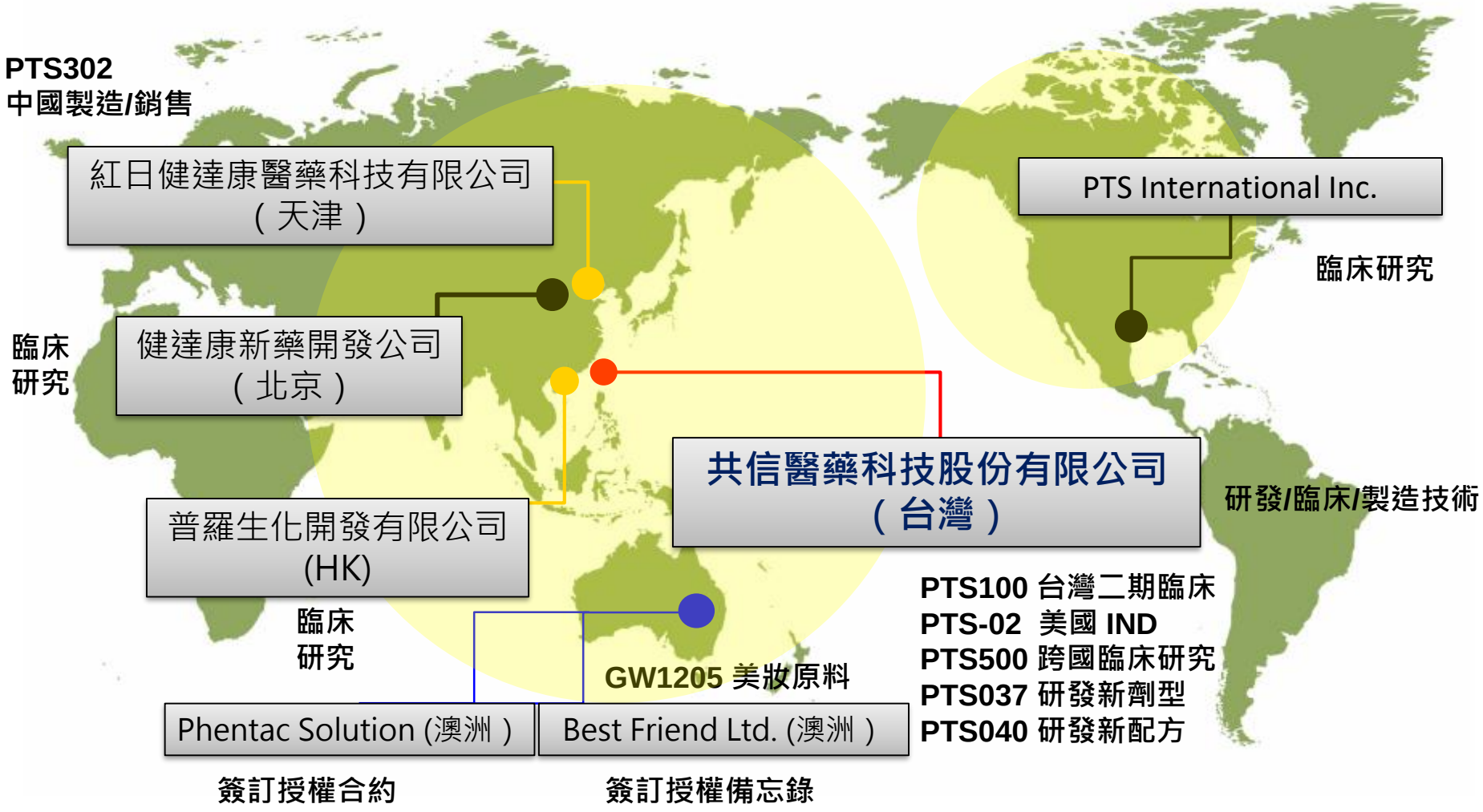
PTS新藥佈局

PTS產品線進度


PTS系列產品
前臨床
臨床一期
臨床二期
臨床三期
藥證申請
取得藥證
PTS302
中央型肺癌
氣管阻塞
CFDA 特殊審評&優先審評
PTS100
原發性肝癌
執行臨床二期試驗
PTS-02
腺樣囊性癌
已取得美國 FDA孤兒藥認定
PTS500
惡性肋膜積水
新產品
前臨床
臨床一期
臨床二期
臨床三期
藥證申請
取得藥證
PTS037
新成分開發中
PTS040
新成分開發中

「共信-KY」的全球佈局

台灣研發/製造技術、中國行銷、跨國臨床研究的戰略佈局



PTS302目標市場

8萬人 嚴重氣道阻塞(主氣管與左右支氣管)，無法手術之患者總數/年

根據IMS市調分析，PTS新藥取得中國藥證之後，並無相似瘤內注射化學藥物的競爭者

33萬人 中國非小細胞肺癌之患者中，中央氣道阻塞病人總數/年

84萬人 中國非小細胞肺癌之病人總數/年

預估PTS上市後每年銷售額：

人民幣 12億

http://img.epochtimes.com/i6/1301290250011459.jpg

海外授權布局

1. 新藥授權:

   2016年12月，Gongwin holdings與澳洲Phentac簽訂PTS新藥授權合約。

2. 配方授權:

   2018年11月，共信醫藥科技股份有限公司與澳洲Best Friend International Ltd.簽訂GW1205合作備忘錄。

Humira的銷售額模式 vs PTS

Humira Revenue	
Year	Cumulative revenue (in millions)
2003	$280
2004	$852
2005	$1,500
2006	$2,000
2007	$3,000
2008	$4,500
2009	$5,500
2010	$6,508
2011	$7,932
2012	$9,265
2013	$10,659
2014	$12,543
2015	$14,012
2016	$16,078
2017Q1	$4,118
2017Q2	$4,716
Total	**$103,463**

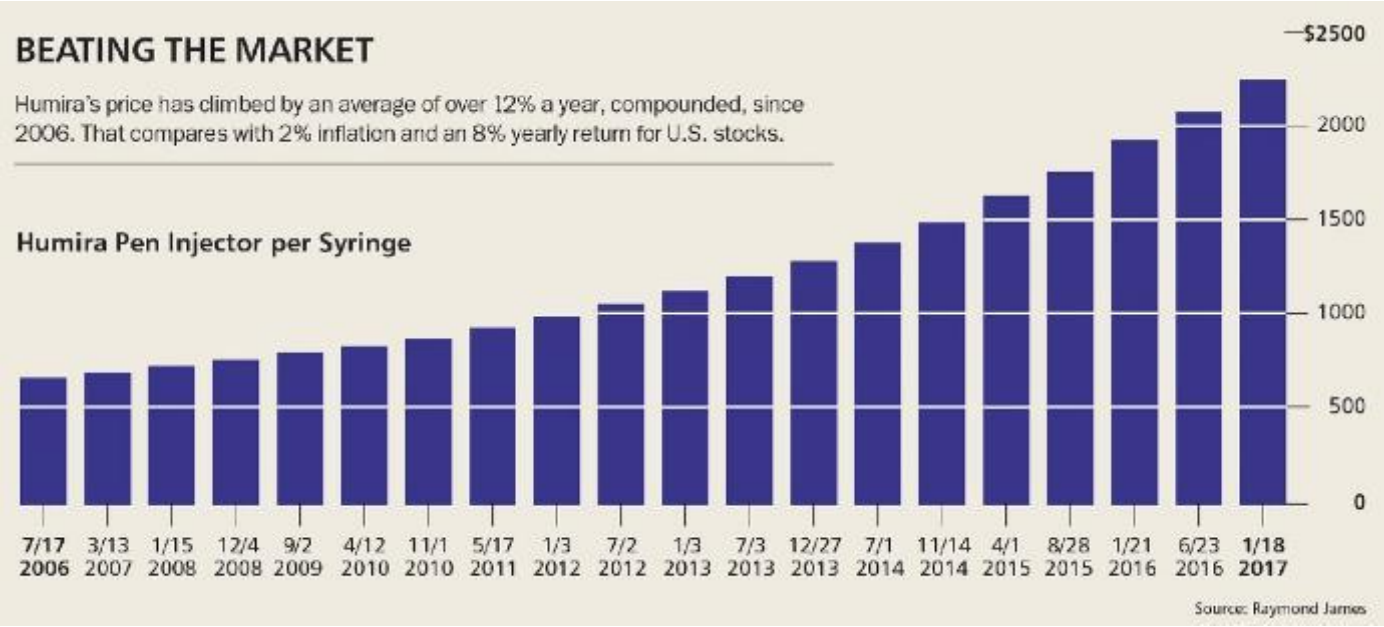
Data gathered from SEC filings

Adalimumab (Humira) 的適應症

- 類風濕性關節炎
- 乾癬性關節炎
- 僵直性脊椎炎
- 克隆氏症
- 乾癬
- 幼年型自發性多關節炎
- 潰瘍性結腸炎
- 腸道貝西氏症
- 化膿性汗腺炎
- 小兒克隆氏症

PTS 的適應症

- PTS302，肺癌氣道阻塞
- PTS100，肝癌
- PTS-02，腺樣囊性癌
- PTS500，惡性胸腔積液
- 頭頸癌
- 皮膚癌
- 乳腺癌
- 胰臟癌
- 其他實體腫瘤



Thanks for your participation

卓越 .科學 .創新 .永續

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