

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



2018/12/20



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

智財權保護

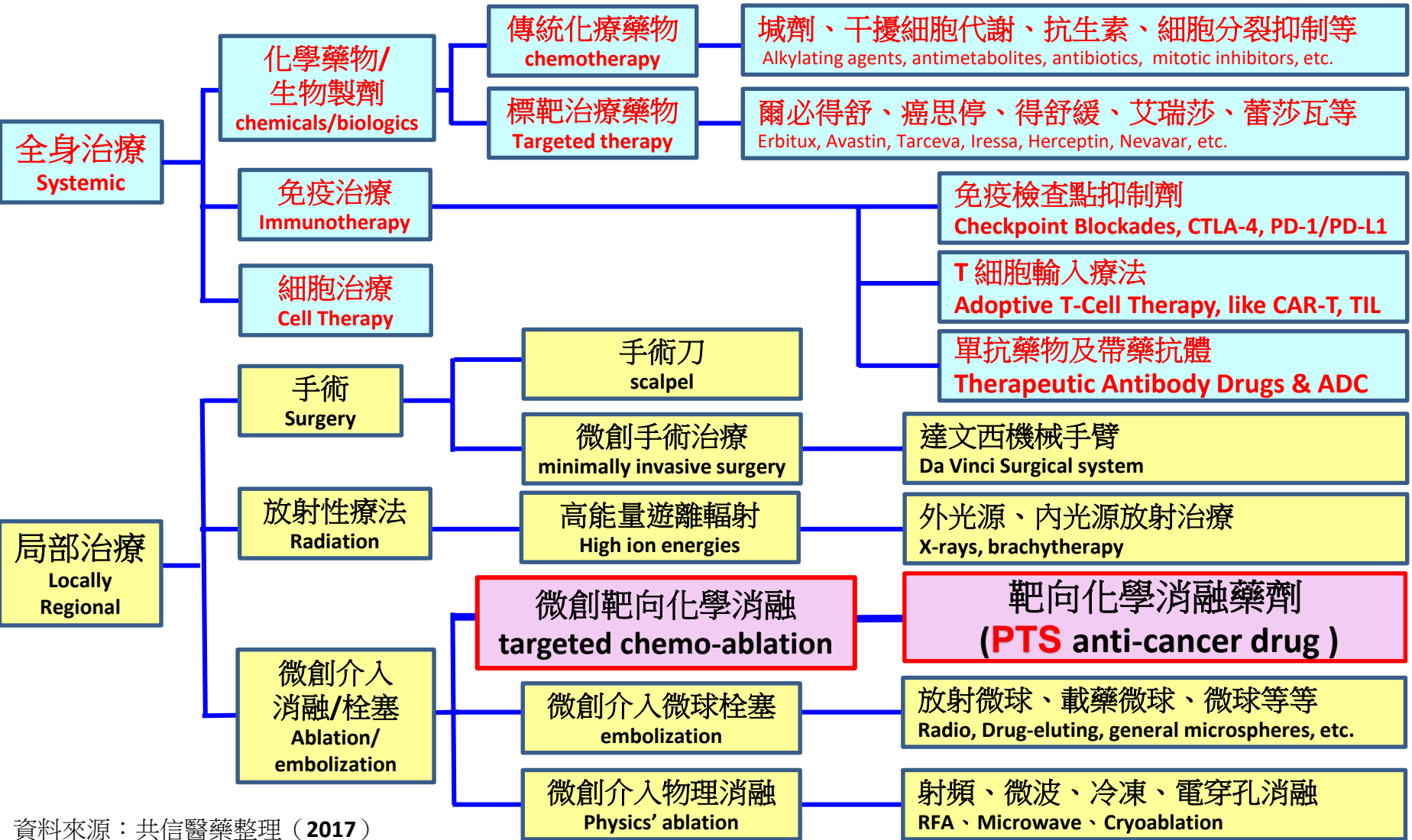


專利名稱	方向	申請日期	送件國家	送件案號	目前狀態
Toluene Sulfonamide-Containing Anti-Tumor Composition And Method Of Use Thereof	產品特性	2001.04.16	USA/全球	6/727,287	有效中 6/727,287
A type of Sulfonamide pharmaceutical composition	創新製程	2015.01.06	China/PCT	104473914A	有效中 104473914A
Novel benzenesulfonamides compositions for treatment 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

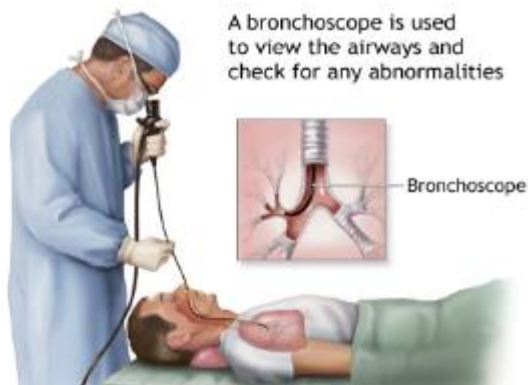


資料來源：共信醫藥整理（2017）



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



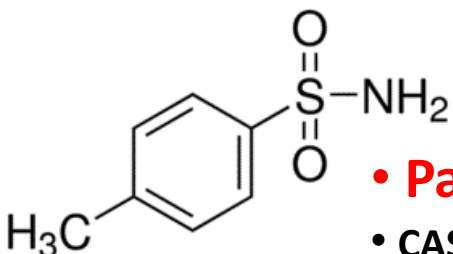
肝癌超音波經皮穿刺治療



PTS抗癌新藥



PTS100注射液



- **Para-toluene sulfonamide**
- CAS Number [70-55-3](#)
- Linear Formula $\text{CH}_3\text{C}_6\text{H}_4\text{SO}_2\text{NH}_2$
- Molecular Weight 171.22

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。

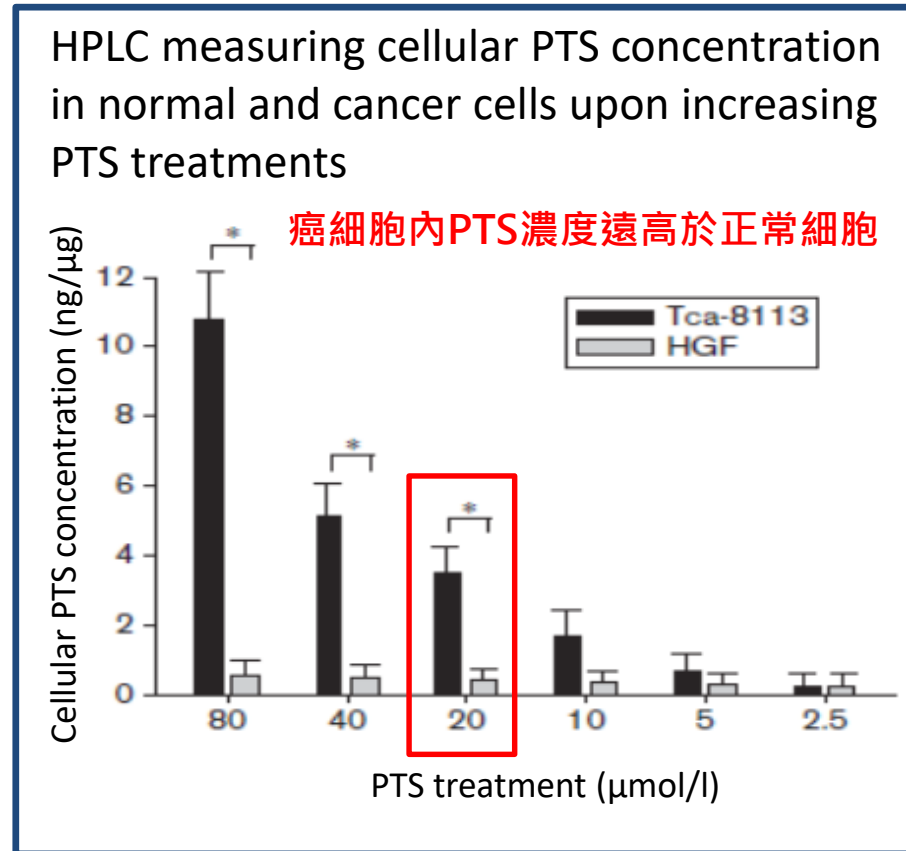
有效性

- 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



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

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

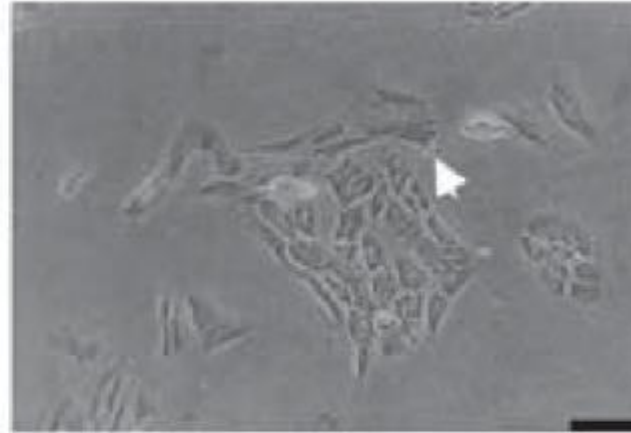
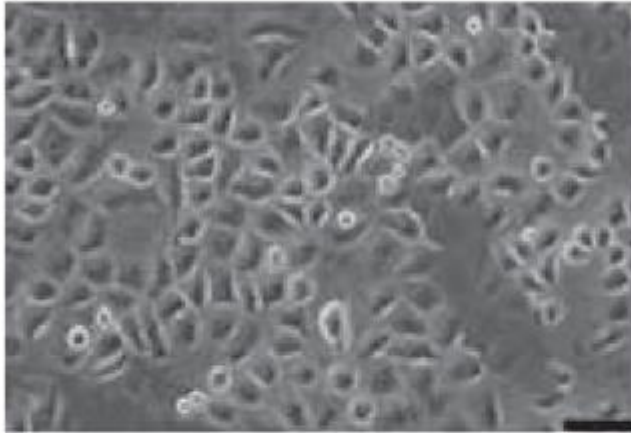
選擇性-2：細胞試驗的研究成果



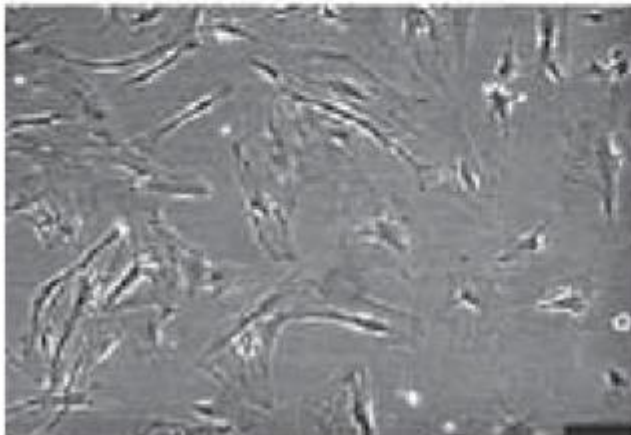
Control

PTS

Tca-8113



HGF



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

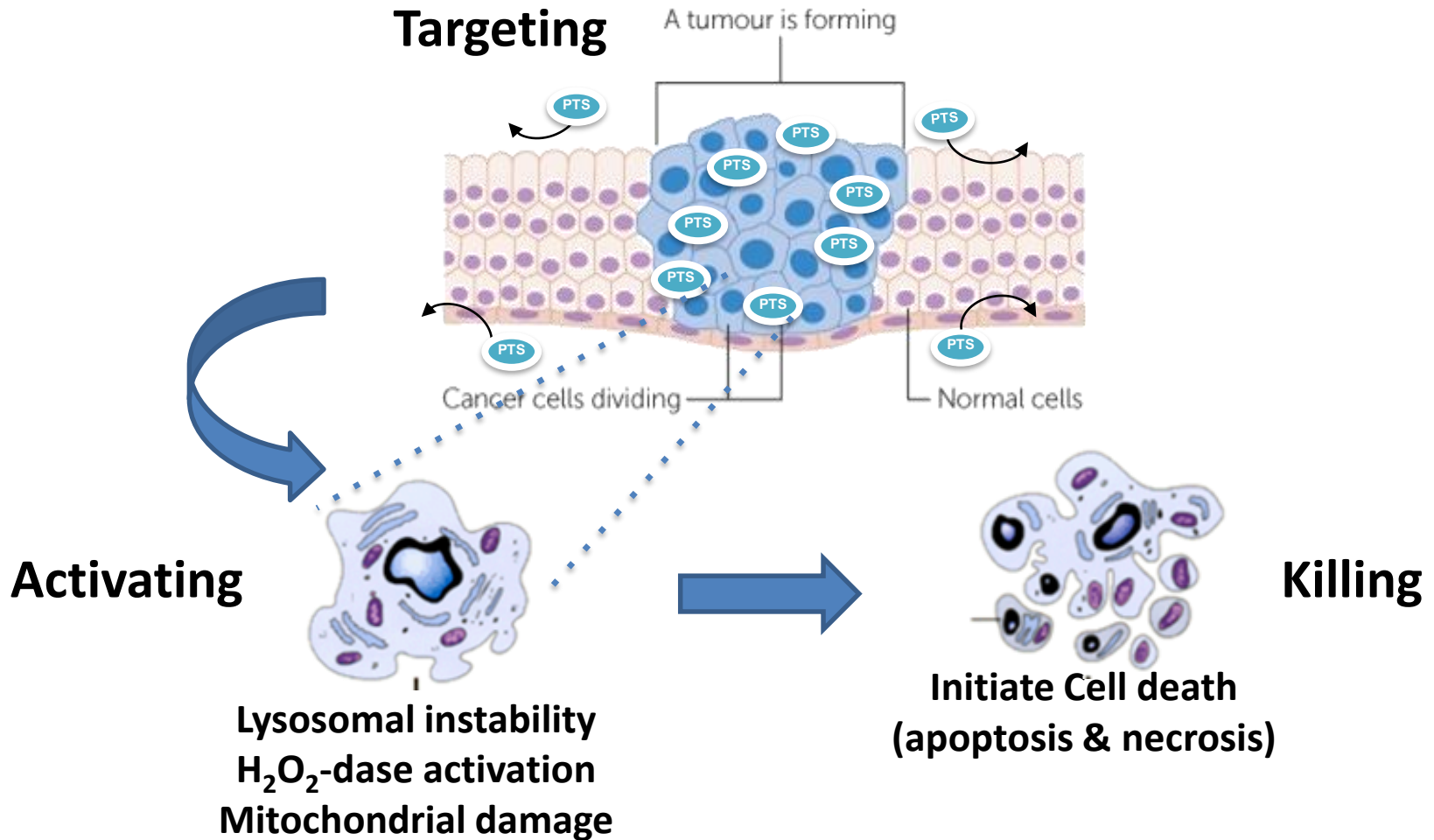


治疗中 坏死组织大部分脱落且与
正常组织分开脱离效果极为良好



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 Copyright © 2015 Wolters Kluwer Health, Inc. All rights reserved.

Anti-Cancer Drugs 2015, 00:000–000

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

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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 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



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

Jui-Ling Hsu¹, Wohn-Jenn Leu¹, Lih-Ching Hsu¹, Shih-Ping Liu², 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

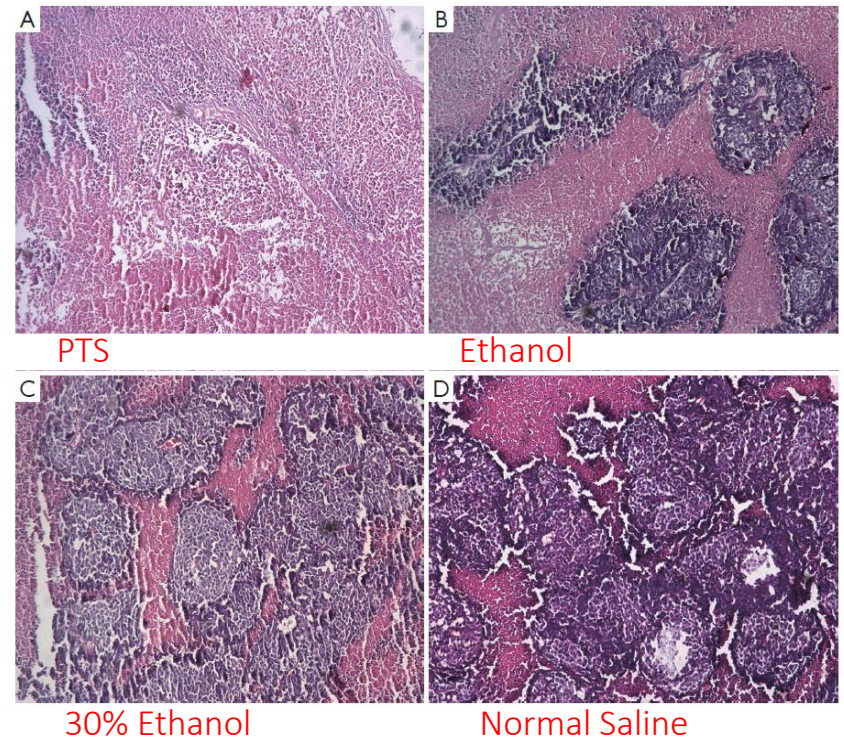
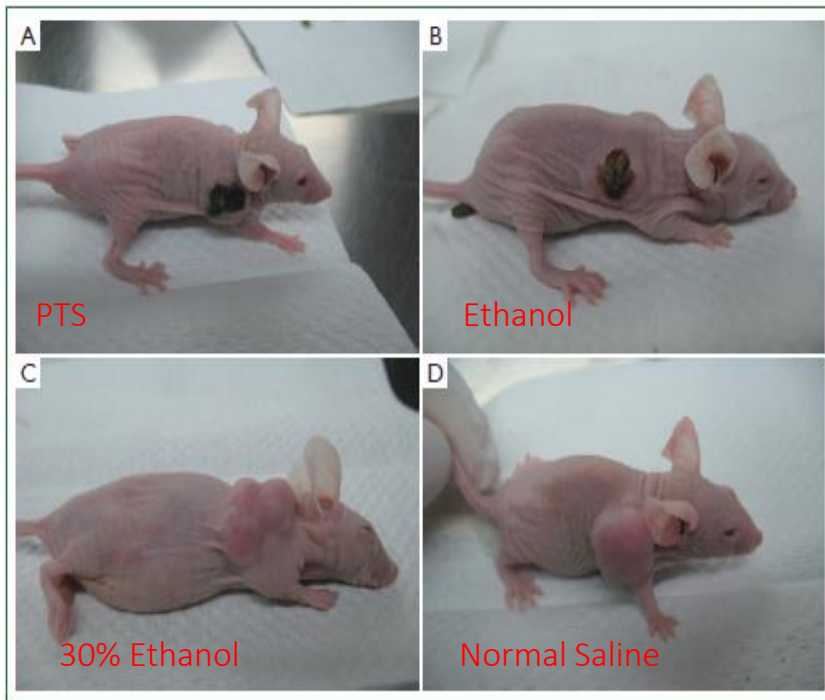
OPEN ACCESS

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

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

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 Gao¹, Yonghua Gao², Weijie Guan¹, Liyan Huang², Xiaoming Xu¹, Chenting Zhang¹, Xiuqing Chen¹, Yizhuang Wu³, Guangqiao Zeng¹, **Nanshan Zhong¹**

¹State Key Laboratory of Respiratory Disease, ²Guangzhou Institute of Respiratory Disease, First Affiliated Hospital of Guangzhou Medical University, Guangzhou 510120, China; ³Beijing 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 *in vitro* is stronger than that of ethanol.

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

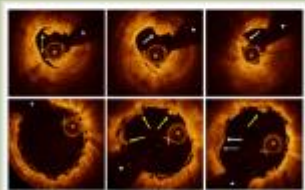
KEY WORDS

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

Vol 5, No 6 June 2013
ISSN 2072-1439
JOURNAL of
THORACIC
DISEASE



jd.amegroups.com

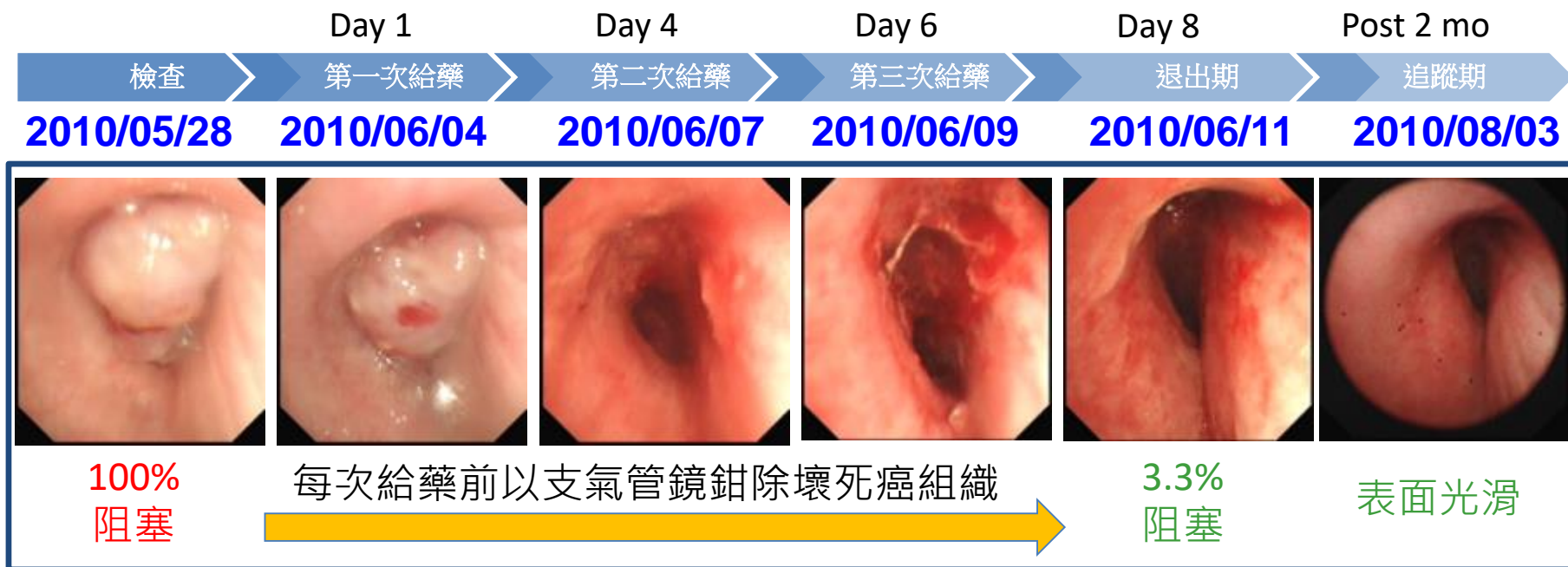


Indexed in
PubMed, ISI

有效性-3：PTS臨床治療的典型病例



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



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 Li¹, Qiang Li¹, Wei-je Guan¹, Jlang Huang¹, 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^{1,2}

¹ Drs. Shi-yue Li, Qiang Li, Wei-je Guan, and Jlang 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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Neoplasia

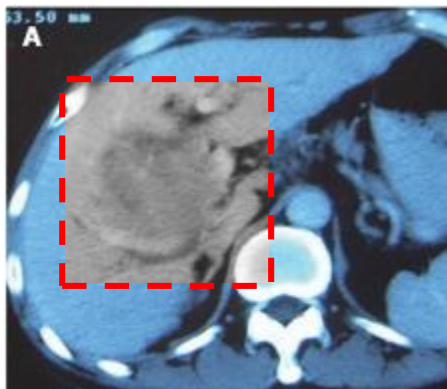
廣效性-1：晚期肝癌以PTS治療案例



下列為70歲晚期肝癌患者治療情形

2006-01

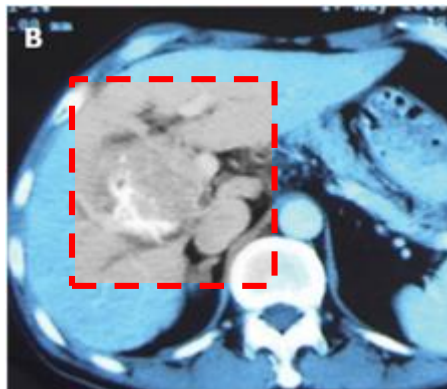
治療前



AFP >1210 ng/mL

2006-02

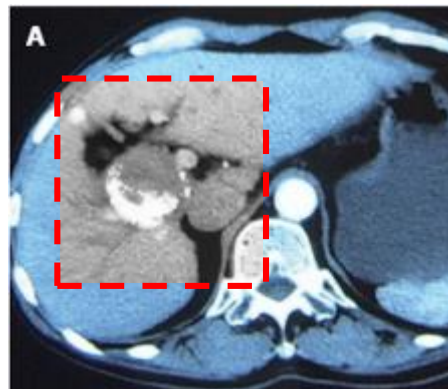
TACE治療兩次後



AFP >1210 ng/mL

2006-05

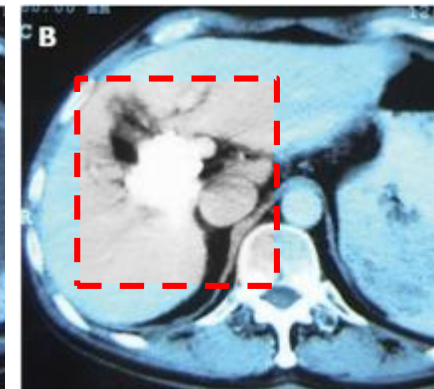
注射 5次PTS



AFP =185 ng/mL

2006-08

再追加 3次PTS



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TACE期試驗研究個案發表



World Journal of
Gastroenterology

Online Submission: <http://www.wjgnet.com/>
WJG@wjgnet.com
ISSN 1039-5426/WJG © 1984-2012

World Journal of Gastroenterology 2012; December 14; 18(50): 6861-6864
ISSN 1039-5426 (print) ISSN 2219-2510 (online)
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CASE REPORT

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

Qing He, An-Ren Kuang, Yong-Song Guan, Yue-Qing Liu

Qing He, Yong-Song Guan, Yue-Qing Liu, Department of Oncology, West China Hospital of Sichuan University, Chengdu 610041, Sichuan Province, China
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.

Correspondence to: Dr. An-Ren Kuang, Department of Nuclear Medicine, West China Hospital of Sichuan University, Chengdu 610041, Sichuan Province, China. Email: arkuang@scsuh.com

Telephone: +86-28-85423270 Fax: +86-28-85423278

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 neutralizing 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.

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

Peer reviewers: Alessandro Cucchetti, MD, Liver and Multorgan Transplant Unit, Policlinico S.Orsola-Malpighi, University of Bologna, PAD 22, Via Massarenti 9, 40138 Bologna, Italy; Zenaido Morise, MD, PhD, Professor, Chairman, Department of Surgery, Banbutsuwa Hospital, Fujita Health University School of Medicine, 3-6-10 Onobashi Nakagawa-ku, Nagoya, Aichi 464-8305, 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(50): 6861-6864. Available from: URL: [http://www.wjgnet.com/1039-5426/18\(50\)/6861.htm](http://www.wjgnet.com/1039-5426/18(50)/6861.htm) DOI: <http://dx.doi.org/10.3746/wjg.v18.i50.6861>

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-toluenesulfonamide (PTS) is completely different from genetic, classical chemical and molecular targeted drugs, and has shown amazing antitumor effect in animal HCC experiments^[1]. Primary pharmacological studies suggest that PTS inhibits tumor growth by acting as a tumor necrosis factor agent^[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 male. A mass was found in his right lobe of the liver in May 2004. He refused

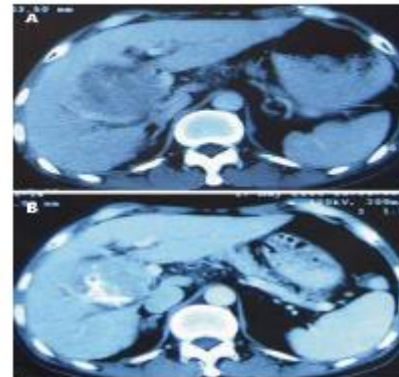


Figure 1. Transcatheter arterial chemoembolization had little effect on the hepatocellular carcinoma, but restrict the size of tumor mass. A: Contrast computer tomography (CT) before the procedure showed a large hypodense mass with metastatic enhancement and portal vein embolism; B: Two months after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

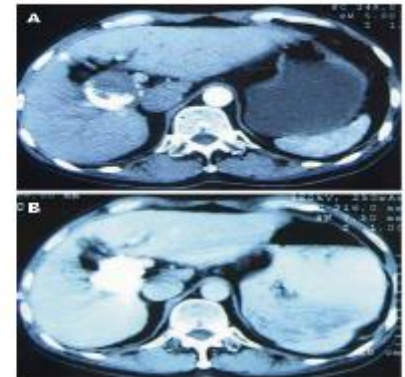


Figure 2. The following para-toluenesulfonamide injections resulted in a significantly improved clinical prognosis. A: Contrast computer tomography (CT) after the first 3 para-toluenesulfonamide (PTS) injections demonstrated a decreased nodule with partial retention of lipid. Enhancement necrosis and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

structure, portal vein thrombosis, and hemorrhage^[3]. Because most anticancer drugs are cytotoxic 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 tumor and has been shown to cause selective necrosis in a variety of cancers with minimal damage to normal tissues^[4,5].

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^[6]. PTS is a more readily available alternative to the local ablative therapies.

PTS, in form of lipophilic fluid, kills tumor cells by a rodent mode. 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 areas and induce injury to the cancer tissues. This might be the mechanism as to why PTS combined with TACE could effectively treat the HCC with vascular invasion. As a locoregional anticancer agent, PTS is safe^[6,7,8]. But up to date, PTS

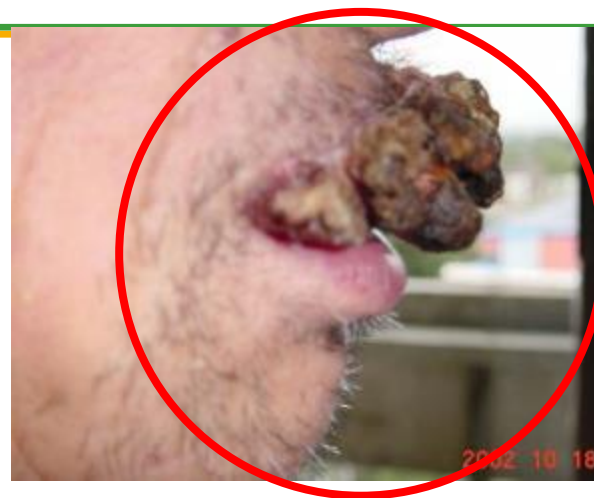
is still only a locally used anticancer agent. It is intended mainly for the treatment of a limited number of detectable tumors. PTS is not suitable to be used alone for the treatment of multifocal HCCs.

This case report demonstrated that PTS is effective in treating liver cancers 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



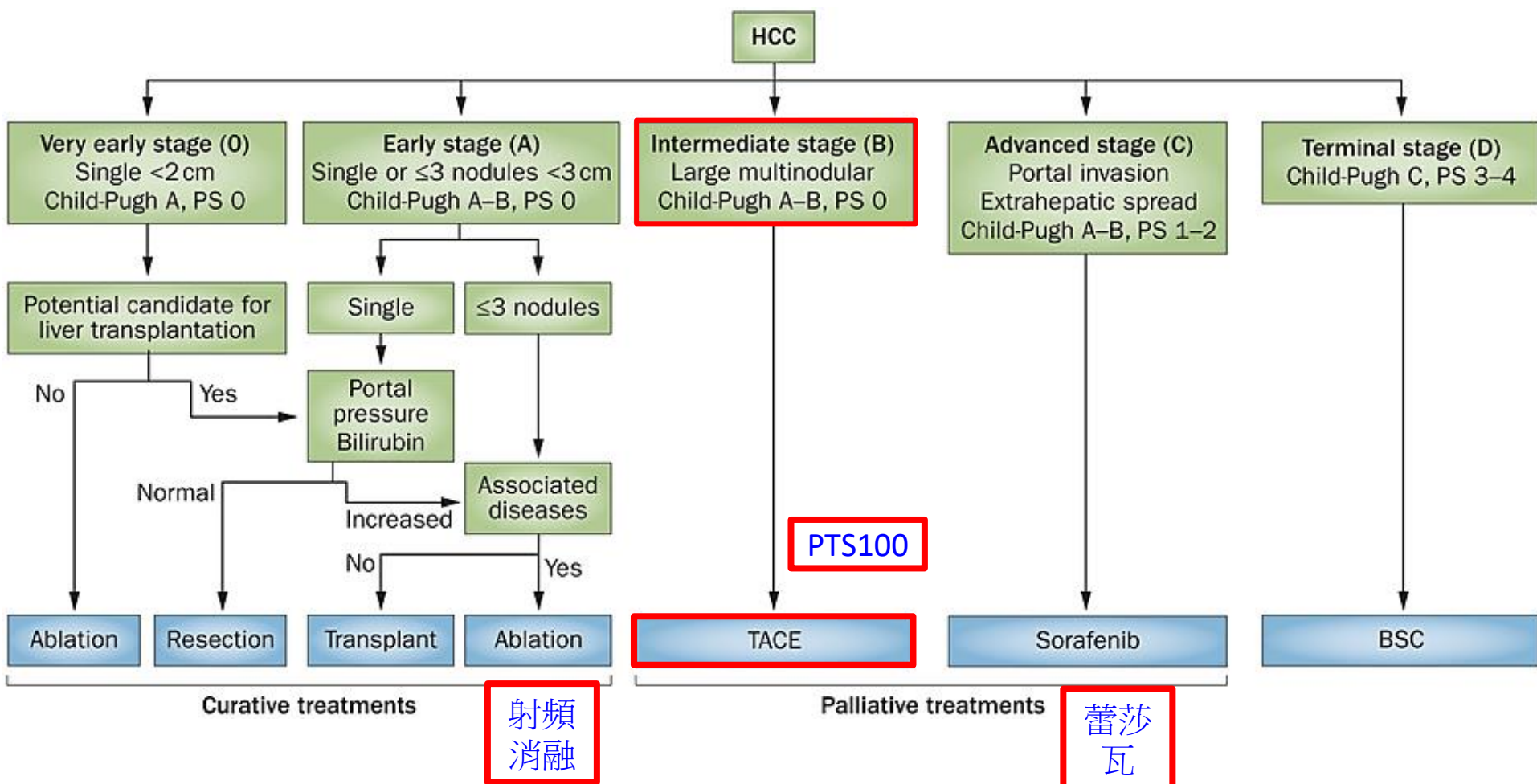


PTS302與現有呼吸介入治療比較

	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

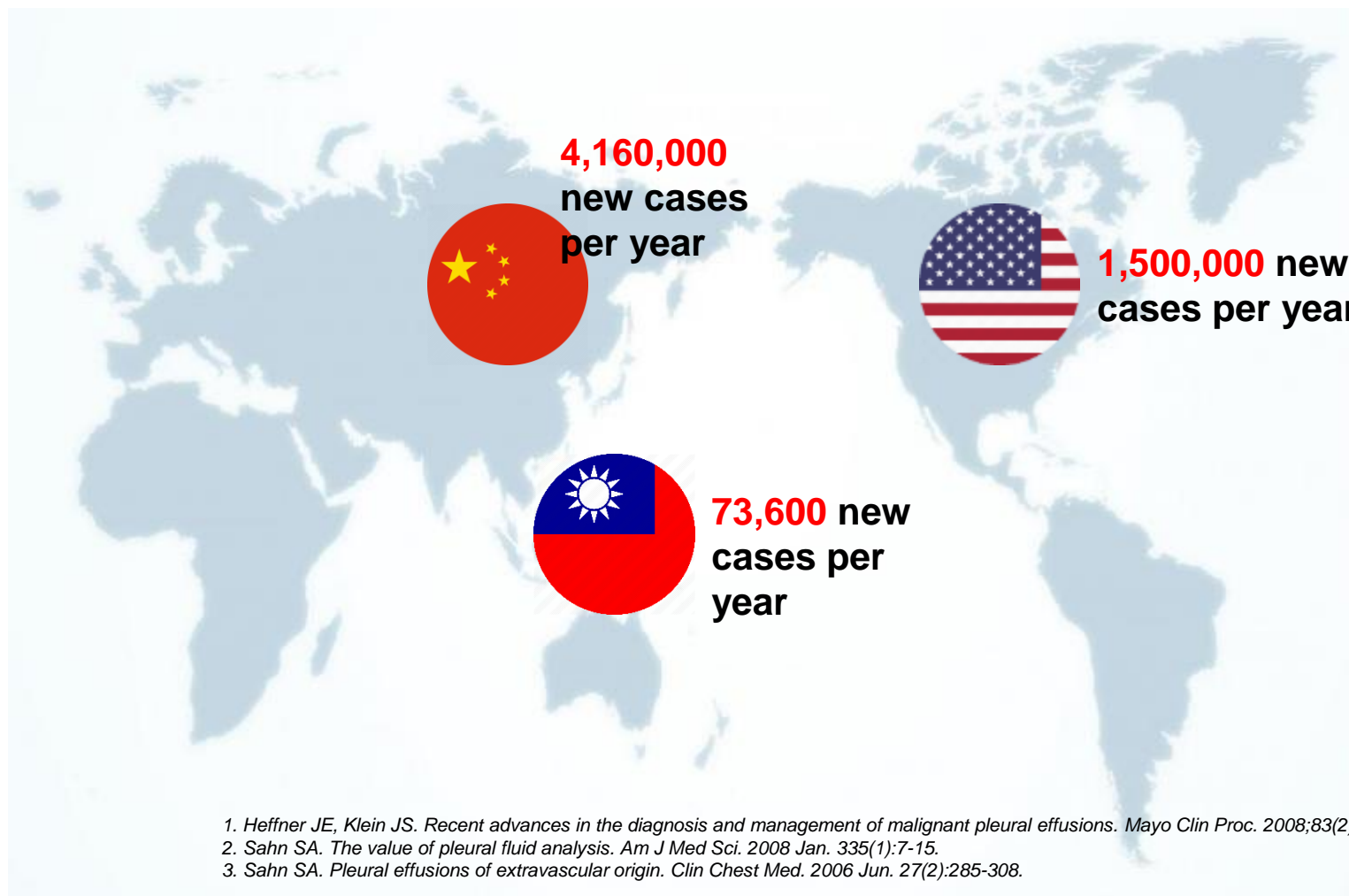


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Global MPE Market Scale: 6 million Patients/Year

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



PTS302

中央型肺癌
氣管阻塞

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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



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

中國製造/銷售

紅日健達康醫藥科技有限公司
(天津)

PTS International Inc.

臨床研究

臨床研究

健達康新藥開發公司
(北京)

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(台灣)

研發/臨床/製造技術

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(HK)

臨床研究

GW1205 美妝原料

PTS100 台灣二期臨床
PTS-02 美國 IND
PTS500 跨國臨床研究
PTS037 研發新劑型
PTS040 研發新配方

Phentac Solution (澳洲)

Best Friend Ltd. (澳洲)

簽訂授權合約

簽訂授權備忘錄



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

預估PTS上市後
每年銷售額：

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

人民幣
12億

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

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



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

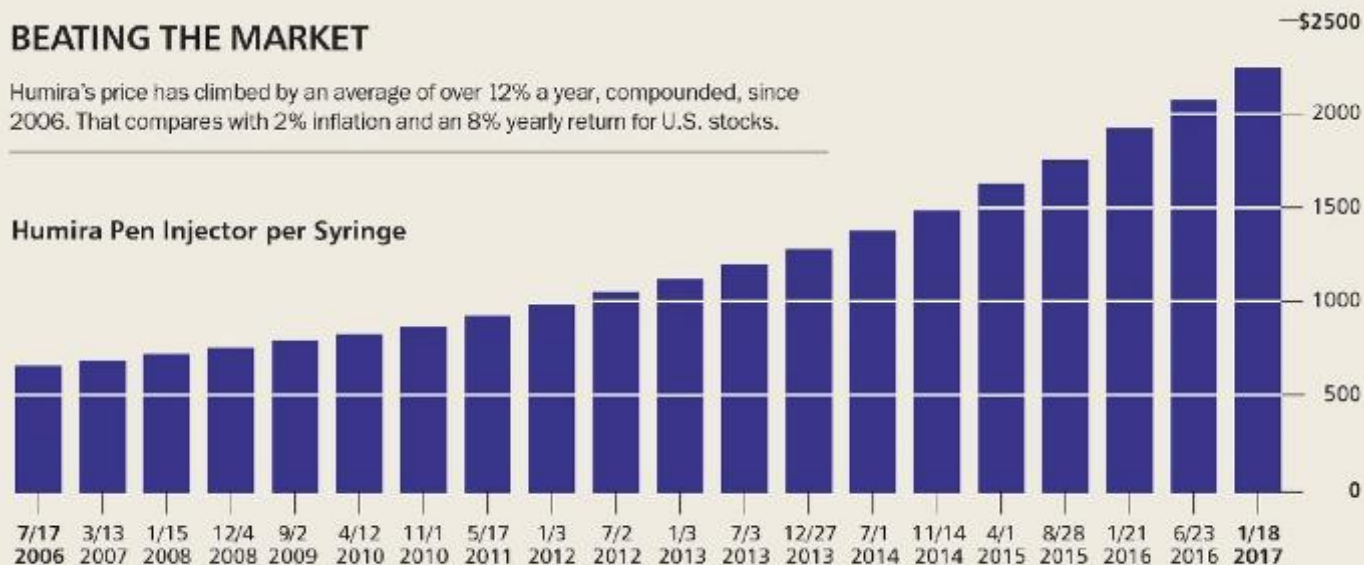
PTS 的適應症

- 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

BEATING THE MARKET

Humira's price has climbed by an average of over 12% a year, compounded, since 2006. That compares with 2% inflation and an 8% yearly return for U.S. stocks.

Humira Pen Injector per Syringe



Source: Raymond James



Thanks for your participation

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