



SMOKING CESSATION **戒烟**

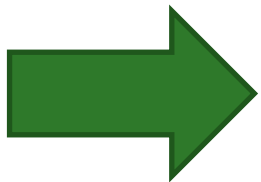
NICOTINE TTS for China
中国市场—尼古丁透皮贴(TTS)

Executive Summary

内容概要



- Globally growing number of smokers 全球烟民数量呈上升趋势
- In China approx. 300 mio. smokers, mostly male 在中国大约有3亿吸烟者，且男性为主
- Increasing awareness on smoking health hazards 吸烟有害健康的意识在逐渐提高
Regulations and “smoke-free cities” implemented; stop smoking encouraged
→ need for smoking cessation therapies growing “无烟城市”等法规的出台，鼓励禁烟→戒烟产品需求增加
- NICOTINE TTS are a well established and viable therapy of smoking cessation 尼古丁透皮贴是已经成熟且非常可行的戒烟治疗途径
- Global sales of NICOTINE TTS ca. 600 mio\$ (predominantly USA, EU) 尼古丁透皮贴全球年销售额约6亿美金（主要是美国和欧洲市场）
- LTS is important and experienced player in NICOTINE TTS business (CDMO, CMO)
LTS是尼古丁透皮贴领域重要且经验丰富的厂家（合同研发生产商，合同生产商）



LTS offers a clear NICOTINE TTS

with enhanced features for the Chinese Market

LTS为中国市场带来性能更好的CLEAR（透明）尼古丁透皮贴

Agenda 议题

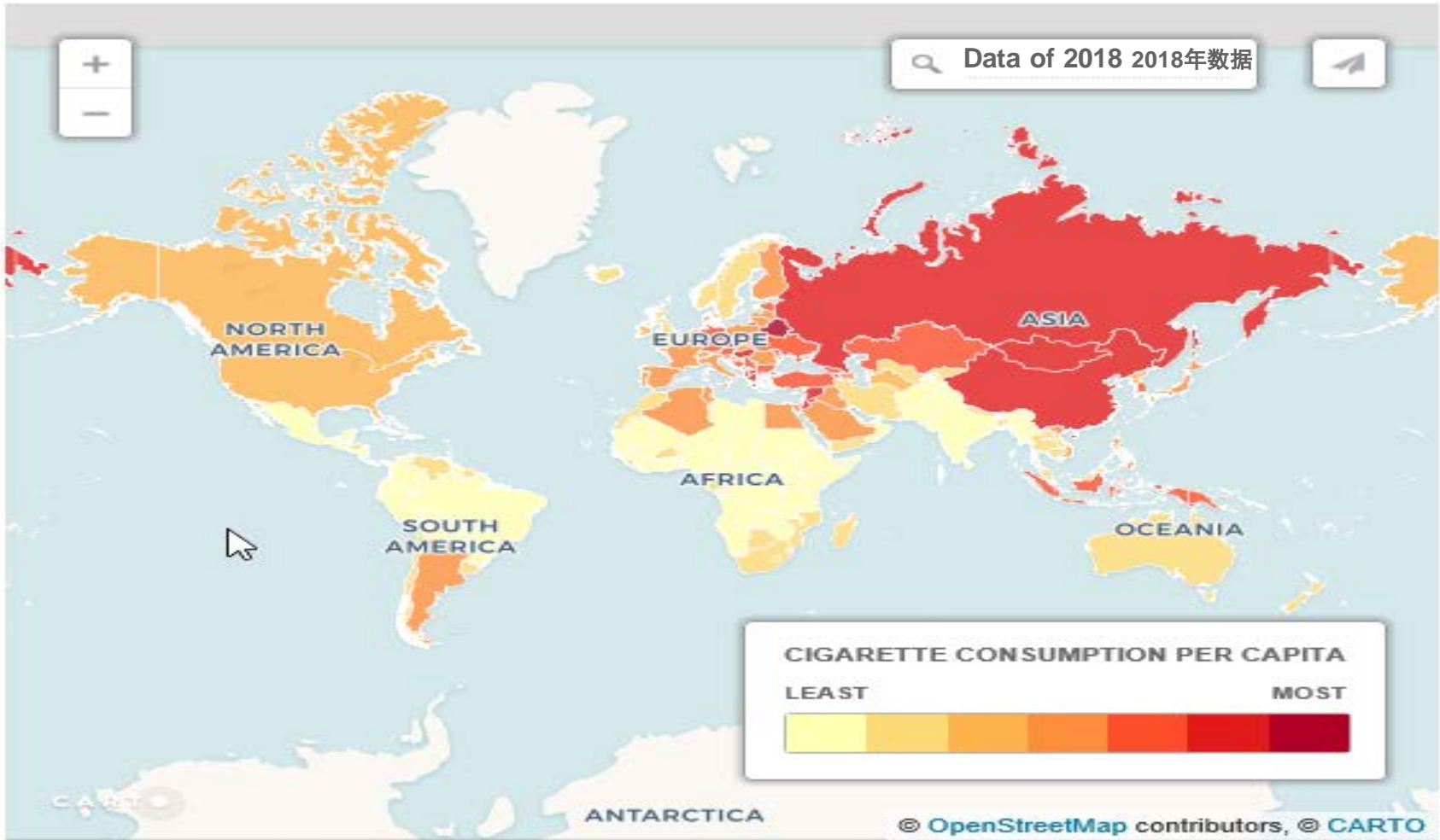


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 - Smoking cessation therapy by NICOTINE TTS
尼古丁透皮贴用于戒烟治疗
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全球尼古丁透皮贴市场
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GLOBAL SMOKING 全球吸烟率

Global Cigarette Consumption per Capita

全球人均香烟消耗量

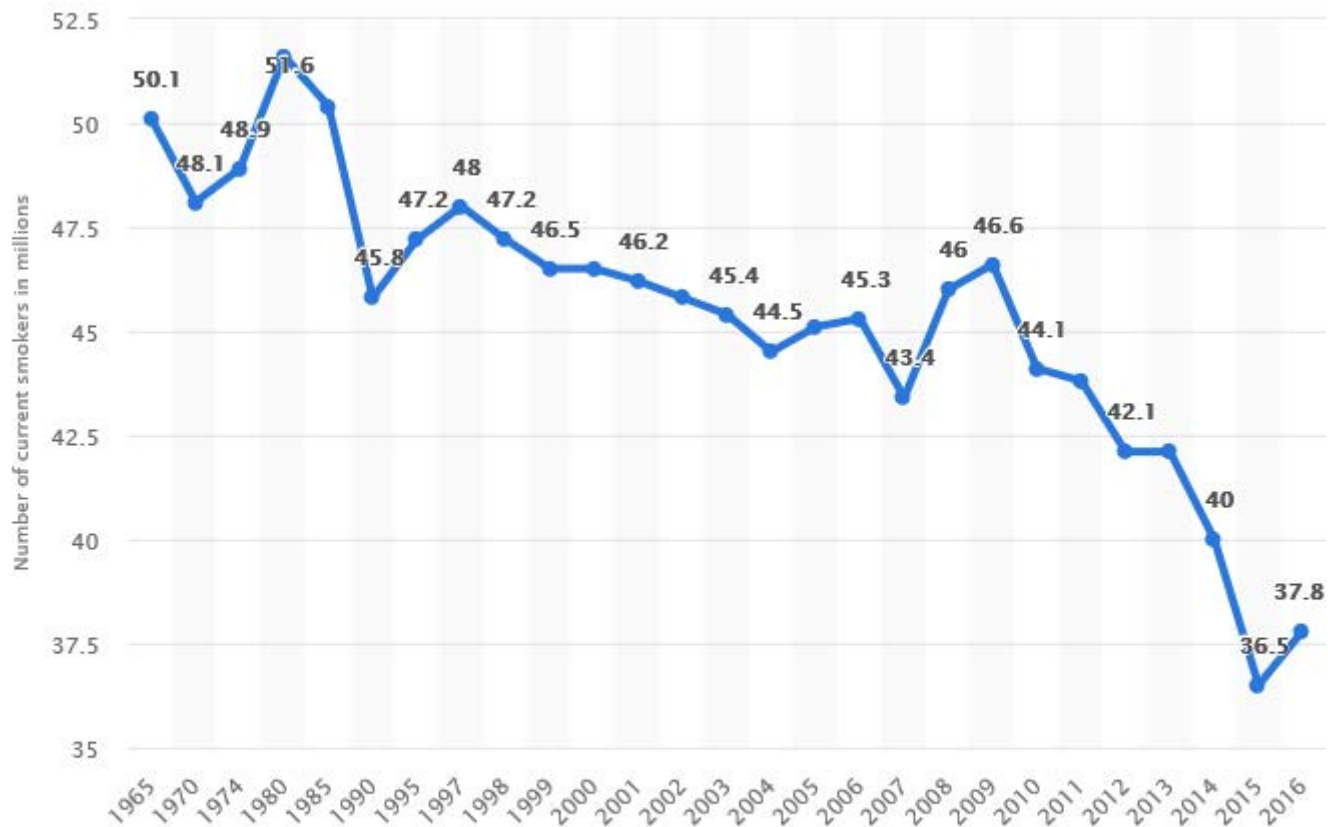


Map created by  telegraphtravelmaps

GLOBAL SMOKING 全球吸烟率

Number of adult smokers in USA

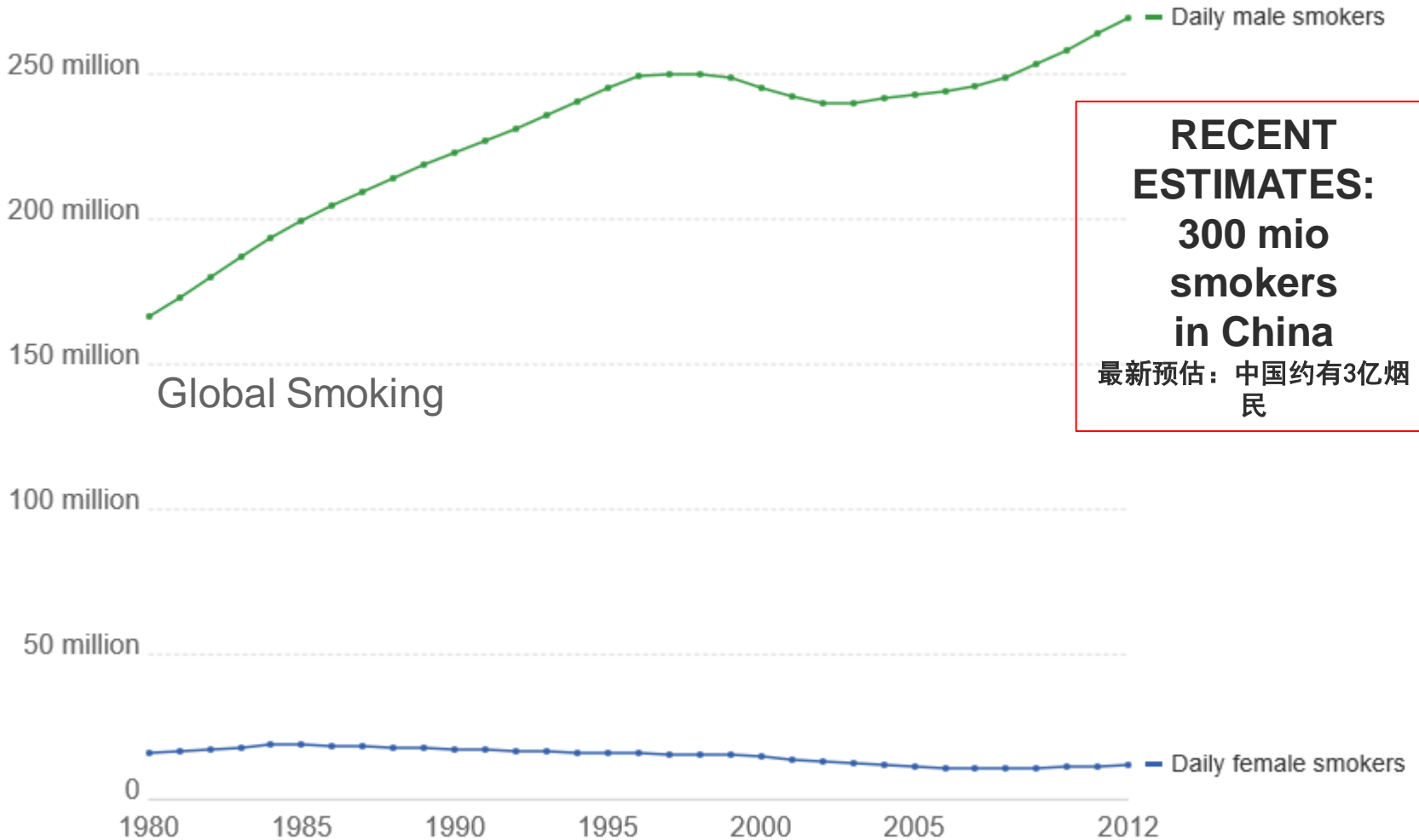
美国成年吸烟者数量 (单位:百万)



Global Smoking 全球吸烟率

Number of daily smokers, men and women, China

Estimates of the number of men and women who smoke cigarettes at least daily (all ages).



Source: Institute for Health Metrics and Evaluation (IHME) (2012)

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GLOBAL SMOKING 全球吸烟率

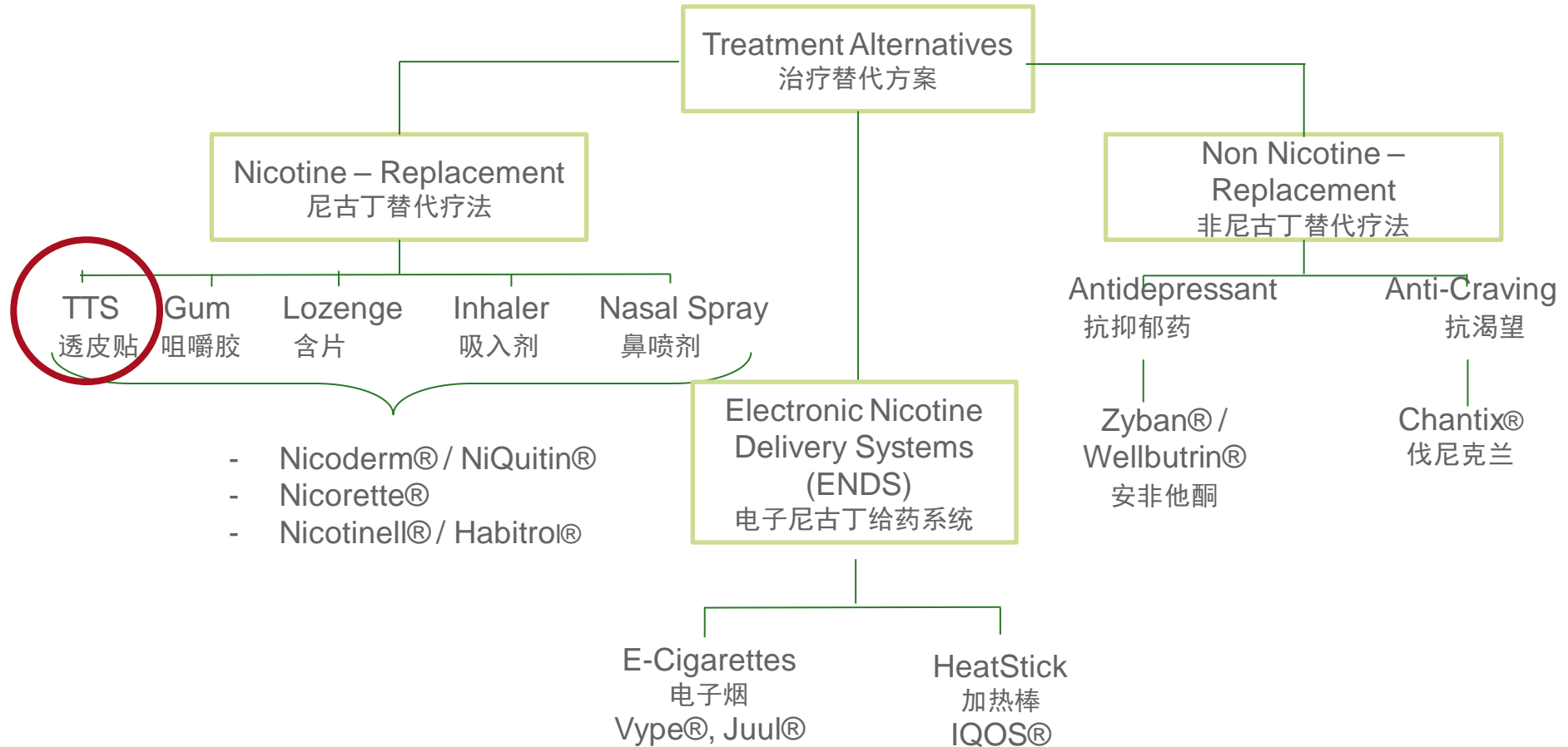
Global Smoking Cessation 全球戒烟趋势

- ▶ Overall increasing number of smokers 烟民数量总体上升
 - ▶ Ban on smoking in public places 公众场所要求禁烟
 - ▶ Increasing government initiatives, WHO supported 世卫组织支持及越来越多的政府倡议
 - ▶ Increasing awareness about health hazards caused by smoking, i.e. lung cancer, cardiac diseases, respiratory disorders 吸烟导致健康危害意识提升: 如肺癌, 心血管疾病和呼吸系统疾病
- ▶ Need for smoking cessation therapies growing 对戒烟产品需求持续增加

SMOKING CESSATION THERAPIES 戒烟产品

Treatment Alternatives in USA/EU/JAPAN

美国/欧洲/日本市场治疗方案



SMOKING CESSATION THERAPIES戒烟方案

Comparison of Treatment Alternatives

不同戒烟方案对比

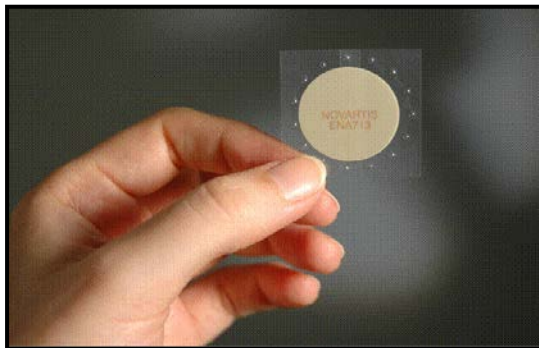


| | TTS 透皮贴剂 | Gum 咀嚼胶 | Lozeng 含片 | Inhaler 吸入剂 | Nasal spray 鼻喷剂 | Bupropion 安非他酮 | Varenicline 伐尼克兰 |
|---|--------------------------|---|------------------------------------|--|---|---|--|
| Duration 疗程 | 8 - 12 weeks | ≤12 weeks | ≤ 12 weeks | 6 - 12 weeks | 3 – 6 months | 12 weeks | 12 weeks |
| Frequency 用药频率 | 1 / day 一日一次 | multiple / day 一日多次 | multiple / day 一日多次 | 6 – 16 / day 一日6~16次 | multiple / day 一日多次 | 2 / day 一日两次 | 2 / day 一日两次 |
| Availability 市场状态 | OTC* / Rx* | OTC* | OTC* | Rx* | Rx* | Rx | Rx |
| Onset of Action 起效(给药)快慢 | Slow 慢 | Fast 快 | Fast 快 | Fast 快 | Fast 快 | Slow 慢 | Slow 慢 |
| Control of sudden cravings 对突发渴望的控制 | no | yes | yes | yes | yes | no | yes |
| Side Effect 不良反应 | Skin Irritation 皮肤刺激性 | Mouth Irritation, Nausea 口腔刺激性, 恶心 | Nausea, Indigestion 恶心, 消化不良 | Coughing, Mouth Irritation 咳嗽, 口腔刺激性 | Watery eyes, Coughing, Nasal Irritation 泪眼, 咳嗽, 鼻腔刺激 | Dry mouth, Insomnia, Mental Health Issues, Suicidal Thoughts 口干, 精神健康问题, 自杀倾向 | Nausea, Depressed Mood, Suicidal Thoughts. 恶心, 情绪抑郁, 自杀倾向 |
| Costs per Unit (€)** 单片价格 (欧元) ** | 2,2 - 3 | 0,35 - 0,5 | 0,35 | 1 - 1,5 | 0,25 - 0,3 | 1,8 - 2,2 | 2 - 2,2 |
| Daily Therapy Costs (€)** 每日治疗费用 (欧元) ** | 2,2 - 3 | 4,2 – 12 | 4,2 – 7 | 6 – 18 | 4,5 – 10,8 | 3,6 - 4,4 | 4 - 4,4 |

* 根据当地法规监管要求分类 ** 美国/欧洲零售价格

SMOKING CESSATION BY TTS 透皮贴剂用于戒烟

How to apply a TTS? 如何使用透皮贴剂

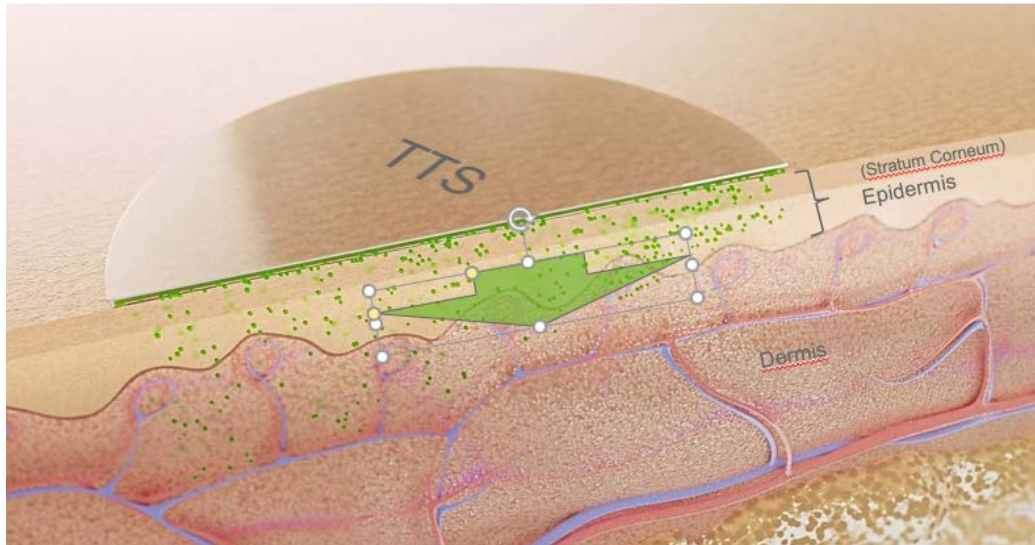


- Easy self-application 非常方便自己给药
- Recommended application sites: a) upper arm 上臂
建议给药位置 b) torso 躯干
- NICOTINE TTS LTS offers is a clear TTS = discreet
LTS提供的尼古丁是一款透明的透皮贴，更加不引人注目

SMOKING CESSATION BY TTS透皮贴剂用于戒烟

How does a NICOTINE TTS work?

尼古丁透皮贴如何起效?



- Application of TTS once a day 每天一贴尼古丁透皮贴
- Application period 24h 作用24小时
- Sustained release of Nicotine during 24h 24小时内持续递送尼古丁

REPLACE NICOTINE
UPTAKE FROM SMOKING
取代吸烟摄入尼古丁

APPLICATION of TTS to SKIN
将透皮贴贴于皮肤上

RELEASE of NICOTINE
via SKIN
into BLOODSTREAM
通过皮肤释放尼古丁使其进入血液

NICOTINE from TTS decreases
CRAVINGS and
WITHDRAWAL SYMPTOMS
when not smoking

当停止吸烟时透皮贴中的尼古丁降低吸烟渴望和戒断症状

HELP SMOKER
QUIT SMOKING
帮助吸烟者戒烟

SMOKING CESSATION BY TTS透皮贴剂用于戒烟 Therapy Approach 治疗方式



- Stepwise reduction of Nicotine dose to wean smoker off Nicotine 逐步减少尼古丁的剂量，使吸烟者摆脱尼古丁依赖
- Three different TTS sizes (21mg/24h, 14mg/24h, 7mg/24h)*三种不同尺寸透皮贴剂*



Example above: smoker consumes more than 20 cigarettes a day

如上方案举例适用于：每日吸烟量超过20支

Lighter smokers start with 14mg dose as step 1 and switch to 7mg for step 2/3

轻度吸烟者可从14mg 作为步骤1起始，以7mg作为步骤2/3剂量进行用药

SMOKING CESSATION BY TTS 透皮贴剂用于戒烟

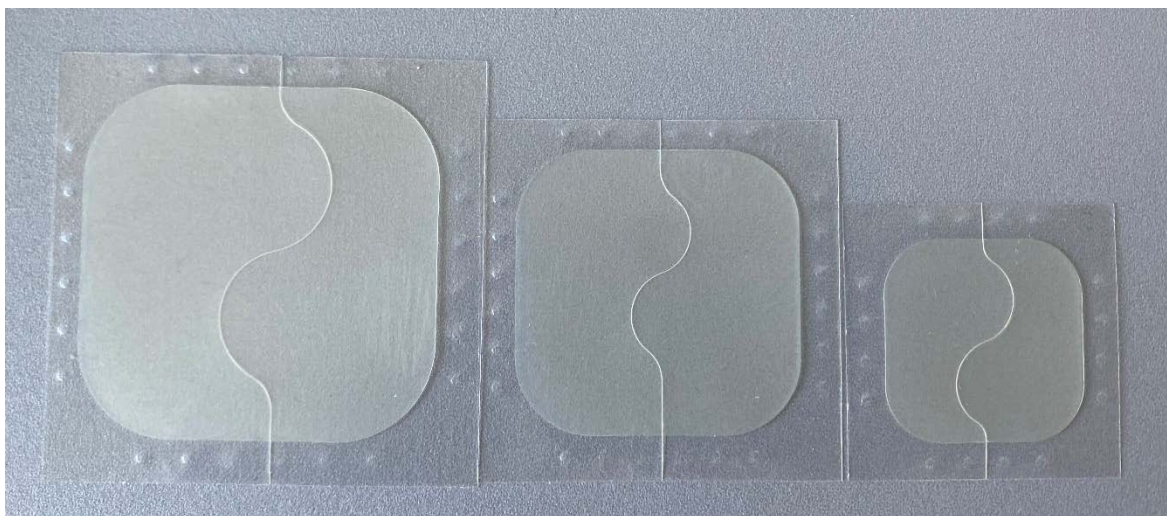
Global NICOTINE TTS market 全球尼古丁透皮贴市场



- Global NICOTINE TTS market* 全球尼古丁TTS市场*
 - > 600 mio\$ 大于6亿美金
 - CAGR 4.1% 年均复合增长率4.1%
 - predominantly USA, EU, Japan 主要市场：美国，欧洲，日本
 - major players: J&J, GSK, Perrigo 主要销售厂家：J&J, GSK, Perrigo
- High market potential in China 中国具有很大的市场潜力
- Rx/OTC: 市场状态
 - USA OTC 美国为OTC
 - JAPAN initially Rx, now both OTC & Rx 日本初期为处方药，现在为OTC/Rx双跨品种
 - EU OTC - reimbursement via smoking cessation programs 欧洲为OTC, 且可报销
- Regulatory: NICOTINE TTS requires approval by Health Authority**
法规：尼古丁透皮贴需要相关卫生监管部门批准**
- LTS > 25 years experience as supplier of NICOTINE TTS***
LTS拥有超过25年的尼古丁透皮贴供应商经验***

NEW NICOTINE TTS - A CLEAR TTS

新一代尼古丁透皮贴 一款透明的透皮贴剂



Clear TTS
=
Discreet
Application
透明透皮贴=更加不引人
注意的给药

| Patch sizes 贴剂尺寸 | Release rate 释药速率 |
|----------------------|----------------------|
| 6.8 cm ² | 7 mg/24h |
| 13.5 cm ² | 14 mg/24h |
| 20.3 cm ² | 21 mg/24h |

NEW CLEAR NICOTINE TTS新透明尼古丁透皮贴

Product Characteristics 产品特性



Enhanced
Product
Features
增强产品功能

- Enhanced TTS design*透皮贴剂增强了设计*
 - Clear TTS (clear vs. opaque/skin color) ✓透明TTS(透明 vs.不透明/肤色)
 - Thin patch (ca. 210 μm , $\approx 45\%$ vs. competitor) ✓更薄(约210 μm ,约45% vs. 竞品)
 - Flexible patch ✓弹性贴
 - Rectangular design with rounded corners ✓带圆角的矩形设计
 - Smaller patch size (20 cm^2 , 1/3 smaller than competitor) ✓更小的尺寸(20 cm^2 ,竞品1/3大小)
 - Lower Nicotine loading (1/3 less than competitor) ✓更低尼古丁载药量(比竞品载量少1/3)
- Supportive pilot PK and stability data available ✓有支持性PK试验数据和稳定性数据
- Formulation/manufacturing based on LTS` know-how ✓处方/生产基于LTS know-how

* Reference products: various key products in global smoking cessation TTS market
参比产品：全球戒烟透皮贴各重点品种

NEW CLEAR NICOTINE TTS新透明尼古丁透皮贴

Product Characteristics 产品特性



- Target 目标

- Bioequivalent to Nicotinell® (Habitrol®)
跟Nicotinell® (Habitrol®) 生物等效
- Skin irritation & sensitization at least as tolerable as Nicotinell® (Habitrol®)
皮肤刺激性&敏感度至少等同于Nicotinell® (Habitrol®)
- Skin adhesion improved compared to Nicotinell® (Habitrol®)
相比Nicotinell® (Habitrol®)，提高了皮肤黏附度
- 3 years shelf life
3年有效期

Enhanced
Product
Features
增强产品功能

NEW CLEAR NICOTINE TTS 新型透明尼古丁透皮贴 Activities ongoing at LTS 本公司正在进行的项目



- Manufacturing process/qualification established 建立生产工艺/质量确认
- Pilot clinical trial scheduled for 12/2021/ 初步临床研究计划于2021年12月开始
- Design regulatory strategy to meet requirements of major health authorities 设计法规策略以满足主要药监部门要求
- Onboarding of Pharma Partner to advance the project together 招募医药合作伙伴，共同推进项目

NEW CLEAR NICOTINE TTS新型透明尼古丁透皮贴



Offer by LTS 本公司将提供

TRANSDERMAL. MARKETLEADER.

- ▶ CLEAR NICOTINE TTS with enhanced product features with formulation & manufacturing based on LTS` know-how
透明尼古丁透皮贴在LTS专有技术的基础上增强了产品特性处方和生产工艺
- ▶ Partnership of LTS and Chinese Pharma Company to bring CLEAR NICOTINE TTS to the Chinese market: Chinese Pharma Company to become the Licensing/Marketing-/Distribution-Partner for CLEAR NICOTINE TTS for China

LTS期待与中国医药公司合作，将CLEAR NICOTINE TTS引入中国市场：中国医药公司将成为CLEAR NICOTINE TTS在中国的许可/市场/分销合作伙伴。