



AGENiX Bio-Pharmaceutical (Shanghai) Co. Ltd.

SHRG Bio-Pharma Development, Inc.

YSY Pharmaceutical Co., Ltd.

December 2007





AGENiX(SH) – SHRG – YSY

- AGENiX
- AGENiX Bio-pharmaceutical (Shanghai) Co., Ltd.
- SHRG Biopharma Development, Inc.
- SHRG pipeline
- YSY Pharmaceutical
- YouHeDing background
- YouHeDing marketing





AGENiX

- Agenix is a public traded company, listed on ASX since 1987 and it employs a strategic blend of biotechnology investment in research and development of ThromboView®, an innovative blood-clot imaging technology.



AGENiX at Brisbane





AGENiX (Shanghai)

- AGENiX formed a Wholly Owned Foreign Enterprise (WOFE) - AGENiX (Shanghai), in Shanghai, China on May 25, 2007.
- AGENiX (Shanghai) reorganized SHRG Biopharma and YSY Pharmaceutical in June, 2007.
- AGENiX (Shanghai) manages representative offices in Beijing, Shanghai, Guangzhou and Chongqing (in planning), China.
- AGENiX (Shanghai) with SHRG Biopharm is to work with first class medical universities to strengthen its R&D in anti-viral and anti-cancer fields.





AGENiX (Shanghai) Office Locations

BJ



BJ office

SH



SH office

GZ

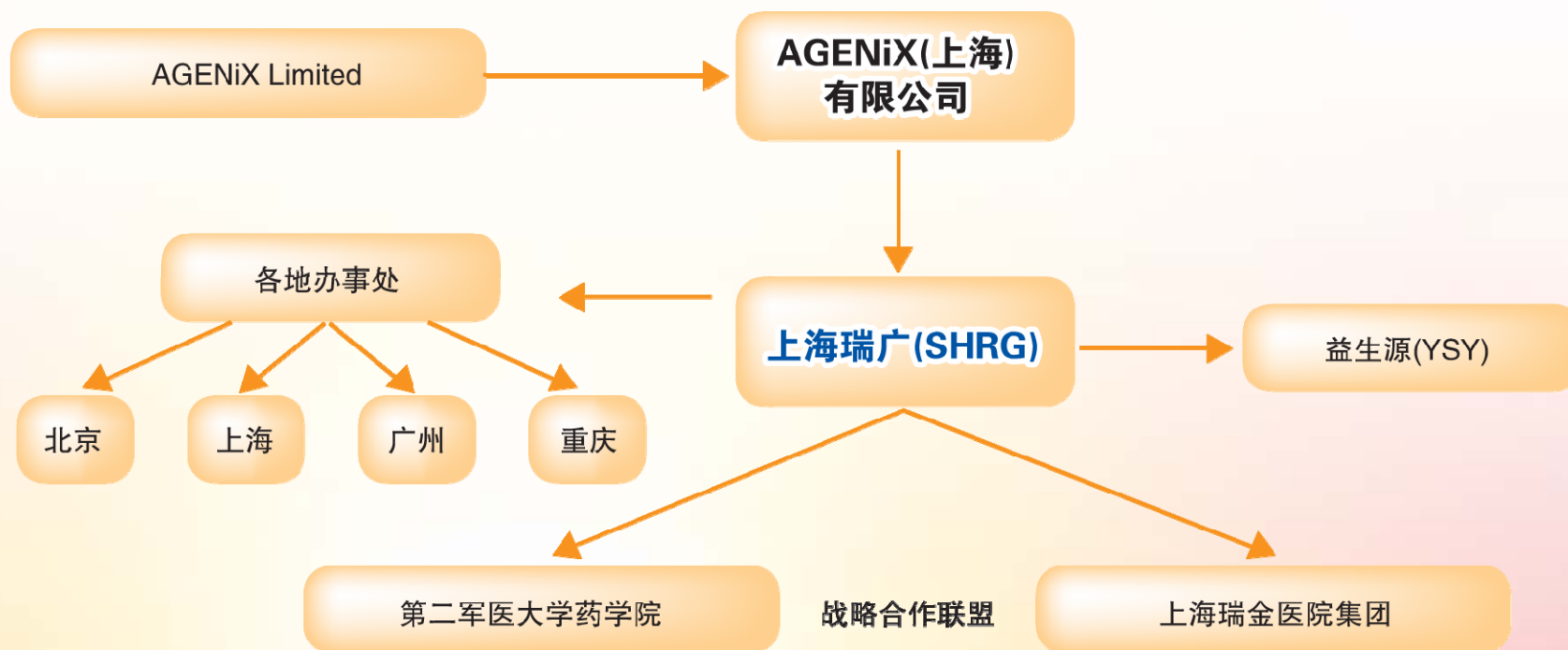


GZ office





AGENiX(Shanghai) - SHRG





SHRG Biopharma

- SHRG was incorporated in July 2001 in Shanghai, China.
- SHRG is focused on new drug development with specialties in clinical, regulatory management and marketing research.
- SHRG consists of skilled professionals in synthetic process, clinical planning and commercialization partnering.
- Since 2001, SHRG has built a strategic alliance with Pharmacy College of Shanghai 2nd Military Medical University and Shanghai Ruijin Hospital Group in anti-viral research and development.
- With joint efforts, SHRG has successfully developed and manufactured a patent protected product for anti-HBV, 优贺丁™.





AGENiX(Shanghai)- SHRG pipeline

Product	Type Drug	Stage of Development	Initiate Ph. I Trails	File New Drug Reg w/SFDA	Market Product Launch
YouHeDing (anti-HBV drug)	Adefovir Dipivoxil	Approved	2003	2005	2007
Anti-HBV drug program	L-nucleotide	Pre-clinical	2008	2009 / 2010	2010
Anti-liver cancer drug candidate (BEL-7402)	Acyclic nucleotide	Pre-clinical	2009	2011	2012
Anti-colon cancer drug candidate (HCT-116)	Acyclic nucleotide	Pre-clinical	2009	2011	2011
Anti-HIV drug candidate (TG-10)	Natural product integrase inhibitor	Pre-clinical	2010	2012	2013
Anti-flu/avian flu	Neuraminidase inhibitor	Pre-clinical	TBD	TBD	TBD





AGENiX(Shanghai)- SHRG Manufacturing site - YSY

- GMP in August 2005.
- YSY is conveniently located outskirts of Shanghai, (about 45 minutes from downtown)
- Size:
 - 33.6 acres of land or 22,378 M²
 - 45% green areas
 - 4 main buildings totaling of 8,387 M²
- Capacity:
 - 4 production lines: tablet, oral liquid, granule and aerosol
 - 50 million tablets for 优贺丁™



equipment



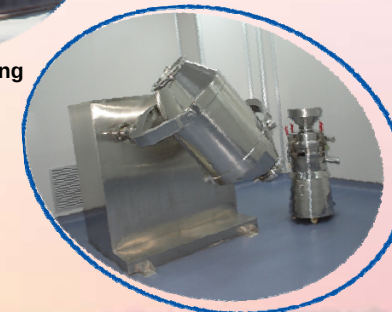
GMP plant



Admin. building



QC lab



Equipment





AGENiX(Shanghai)-SHRG

优贺丁™
(an adefovir dipivoxil tablet)





优贺丁™ R&D process

- Preclinical is completed by Pharmacy College of Shanghai 2nd Military Medical University;
- Phase I clinical is completed by Peking Union Hospital of China Medical University;
- Phase II/III clinical is managed and completed by Shanghai Ruijin Hospital Group;
- Large quantity manufacturing is developed with Pharmacy College of Shanghai 2nd Military Medical University.





优贺丁™ work flow

- August 2002: applied and classified by SFDA as Category I new drug for clinical research.
- December 2002: filed for patent with SIPO.
- April 2003: SFDA approved for clinical.
- June 2003: 3 patents entered disclosure agreement process with SIPO.
- April 2003 – October 2003: Phase I completed.
- February 2004 – June 2005: Phase II/III completed.
- March 2004: 3 patents issued by SIPO.
- October 2007: new drug approval granted by SFDA.
- November 2007: entered exclusive distribution with Sinopharm(SH) for RMB50 million for 2008.





Patents

中国第一个获得自主知识产权的阿德福韦酯

Triclinic crystal structure

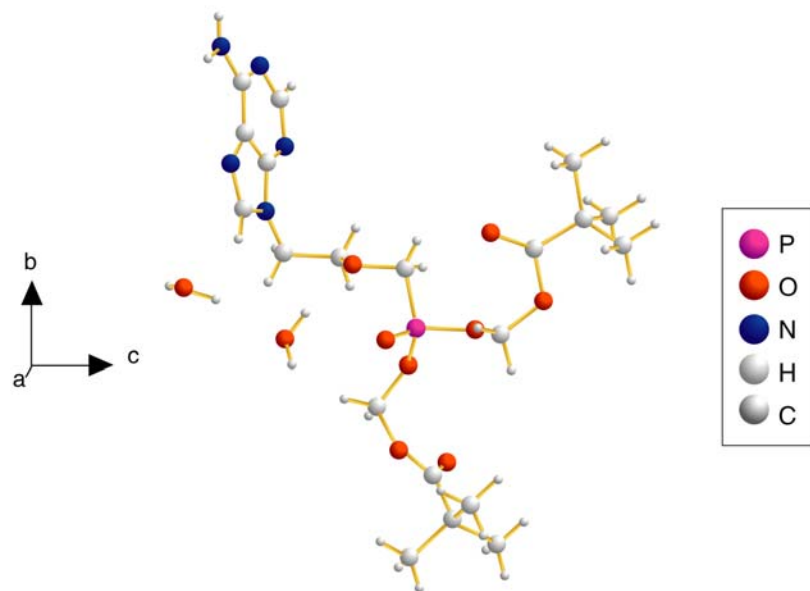


拥有自主知识产权的成熟合成工艺

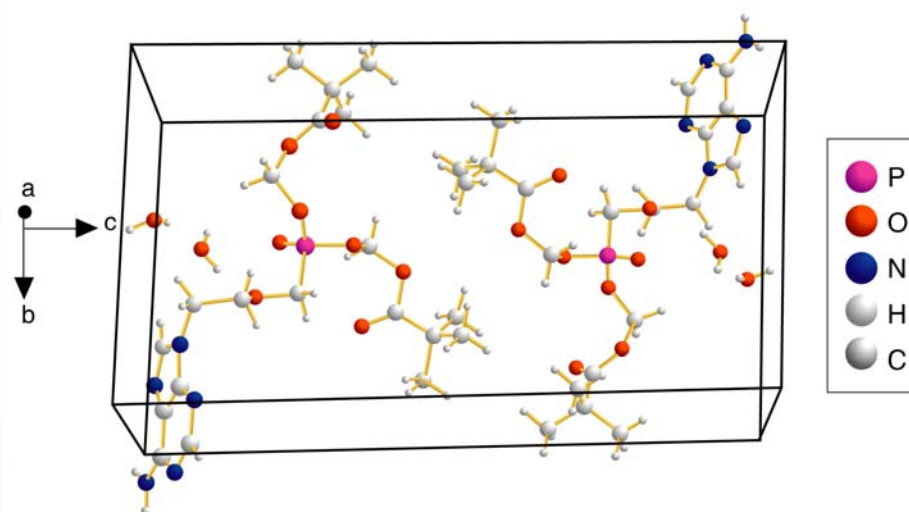
Unique synthetic process



优贺丁™ structures



阿德福韦酯单晶原子排列图



阿德福韦酯单晶的单位晶胞堆积图



优贺丁™ Development Awards

- 2005 – awarded by Shanghai High-Tech Development Commission
- 2004 – awarded by **project 863*** from Ministry of Science and Technology
- 2003 – received science grant from Shanghai Science Development Fund
- 2002 – R&D project of the year by Shanghai Science Commission
 - **Project 863:** The National High Technology Research and Development Program of China (863 Program) was launched in March 1986 by the government of China with the aim of enhancing China's international competitiveness and improving China's overall capability of R&D in high technology.





优贺丁™ Advantages

- **First awarded national patent in China**
- **Innovatively medically used crystal structure**
 - Unique triclinic structure
 - Single x-ray diffraction by Fudan University Analytical Testing Center: P-1 space with triclinic structure
- **New synthetic process**
 - high recovery rate: 5 step vs. conventional 7 step
- **Low toxicity in animal testing**
- **Only Adefovir Dipivoxil project awarded and financially funded by project 863 by Ministry of Science and Technology.**
- **Continuously suppression in viral development**
- **Safely tolerated**





优贺丁™ Clinical Summary





优贺丁™ Phase I





Clinical Sites

- **Peking Union Hospital of China Medical University**
- **Southern Hospital of 1st Military Medical University**
 - Both are SFDA certified clinical trial sites.





Phase IA

- A single center, randomized, double-blind, placebo-controlled tolerance phase I study, with a single, gradually-increased dose in Chinese healthy male adult volunteers to evaluate YouHeDing's safety and tolerance after an oral administration of a 5mg, 10mg, 20mg, 30mg and 60mg single dose of YouHeDing.
- 40 healthy volunteers were randomized into 5 groups of different doses, 8 people per group. Blood and urine samples were taken from each participant at 24 hours, 96 hours after administration of a single dose of adefovir dipivoxil tablet for safety analysis.
- The conclusion from this trial was that all participants tolerated well single dose oral administration of YouHeDing with dosage from 5mg to 60mg.





Phase IB

- The pharmacokinetics of YouHeDing were evaluated in 12 healthy Chinese volunteers that were given a single dose of adefovir dipivoxil (5mg, 10mg. And 30mg cross).
- The absorption, distribution and elimination of YouHeDing in human bodies was evaluated. This randomized, open, 3-dosage (5mg, 10mg, and 30mg), 3x3 cross-cycle safety pharmacokinetic study in 12 healthy male volunteers (4 people each group) provided data for rational dosage design of the phase II/III study.
- The YouHeDing plasma concentration at 0 tp 48 hours after medication was processed with software WinNonLin.
- The conclusion from this trial was that YouHeDing was well tolerated among 12 participants at a single dose of 3 different dosages (5mg, 10mg, and 30mg).





Phase IC

- Randomized, double-blind, placebo-controlled, single-center, phase I pharmacokinetic study evaluated the pharmacokinetics of multiple-dose YouHeDing (10mg, oral, once daily) in healthy volunteers, compared pharmacokinetic difference of single dose YouHeDing and multiple dose YouHeDing, and evaluated the safety and tolerance of continuous multiple dose YouHeDing in healthy volunteers.
- 12 of 15 healthy volunteers were given 10mg YouHeDing once daily 6 consecutive times within 7 days, with 3 of them on placebo. 2 of 8 male volunteers were given placebo. 1 of 7 female volunteers was given a placebo. Blood and urine samples were taken at 48 hours after administration, the 4th day of the study, and 48 hours after last administration for safety analysis.
- The conclusion from this trial was that 10mg dose of YouHeDing, given once-daily for 6 days (60mg adefovir dipivoxil in total) was safe and well-tolerated among 12 participants.





优贺丁™ Phase II/III





Clinical Sites

- ChangZhou No. 3 Hospital (JiangShu)
- GuLou Hospital (JiangShu)
- HuaXi Hospital (Sichuan)
- Jilin University No. 1 Affiliated Hospital (JiLin)
- Nanjing Medical University No. 1 Affiliated Hospital (JiangShu)
- People's Hospital (Beijing)
- PLA 302 Hospital (Beijing)
- Renji Hospital (Shanghai)
- Ruijin Hospital (Shanghai)
- Tianjin Infectious Disease Hospital (Tianjin)
- Zhejiang University No. 1 Affiliated Hospital (ZheJiang)





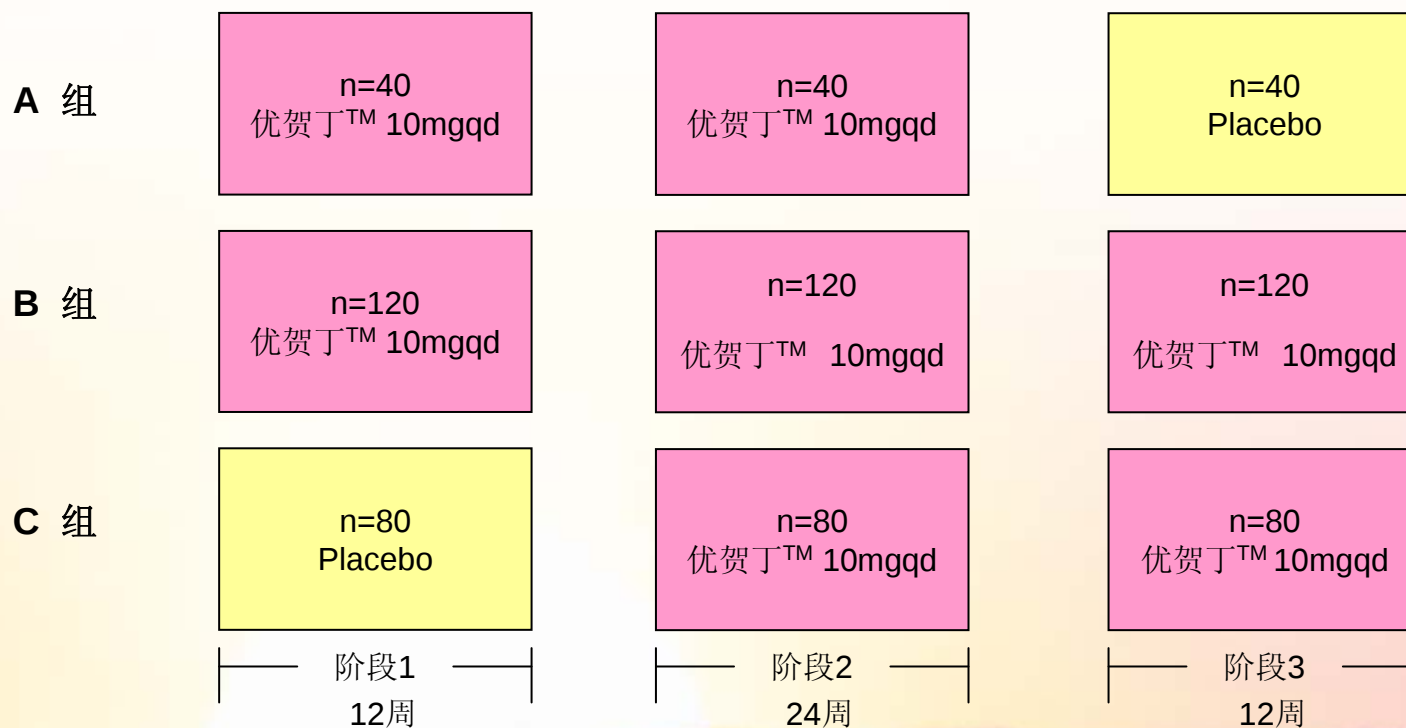
Clinical Design

- Phase II/III clinical trial for YouHeDing was designed as a multi-center, randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy and safety of 10mg Adefovir Dipivoxil tablet (YouHeDing) with placebo for the treatment of chronic hepatitis B (CHB). The total treatment lasted 48 weeks and was divided into 3 periods
 - Period 1 – multi-center, randomized, double blind, placebo-controlled clinical trial design. Patients were randomized into a “trial group” (n=160) or a “placebo group” (n=80) in a 2:1 ratio of 10mg of YouHeDing or placebo orally, once daily, for 12 weeks.
 - Period 2 – the YouHeDing and placebo treatment groups were all given open-labeled YouHeDing with 10mg tablets orally, once daily, for 12 weeks.
 - Period 3 – double blind again. Here the “trial group” patients from Period 1 were randomized to YouHeDing (n=120) or placebo (n=40) at a ratio of 3:1, and “placebo group” patients from Period 1 (n=80) continued on 10mg of YouHeDing daily. This phase of the trial lasted 24 weeks.
- Patients were divided into 3 groups according to the treatment order of YouHeDing or placebo they received:
 - Group A (n=40) were given YouHeDing + YouHeDing + placebo (YYP);
 - Group B (n=120) were given YouHeDing + YouHeDing + YouHeDing (YYY);
 - Group C (n=80) were given placebo + YouHeDing + YouHeDing (PYY).





Clinical Design





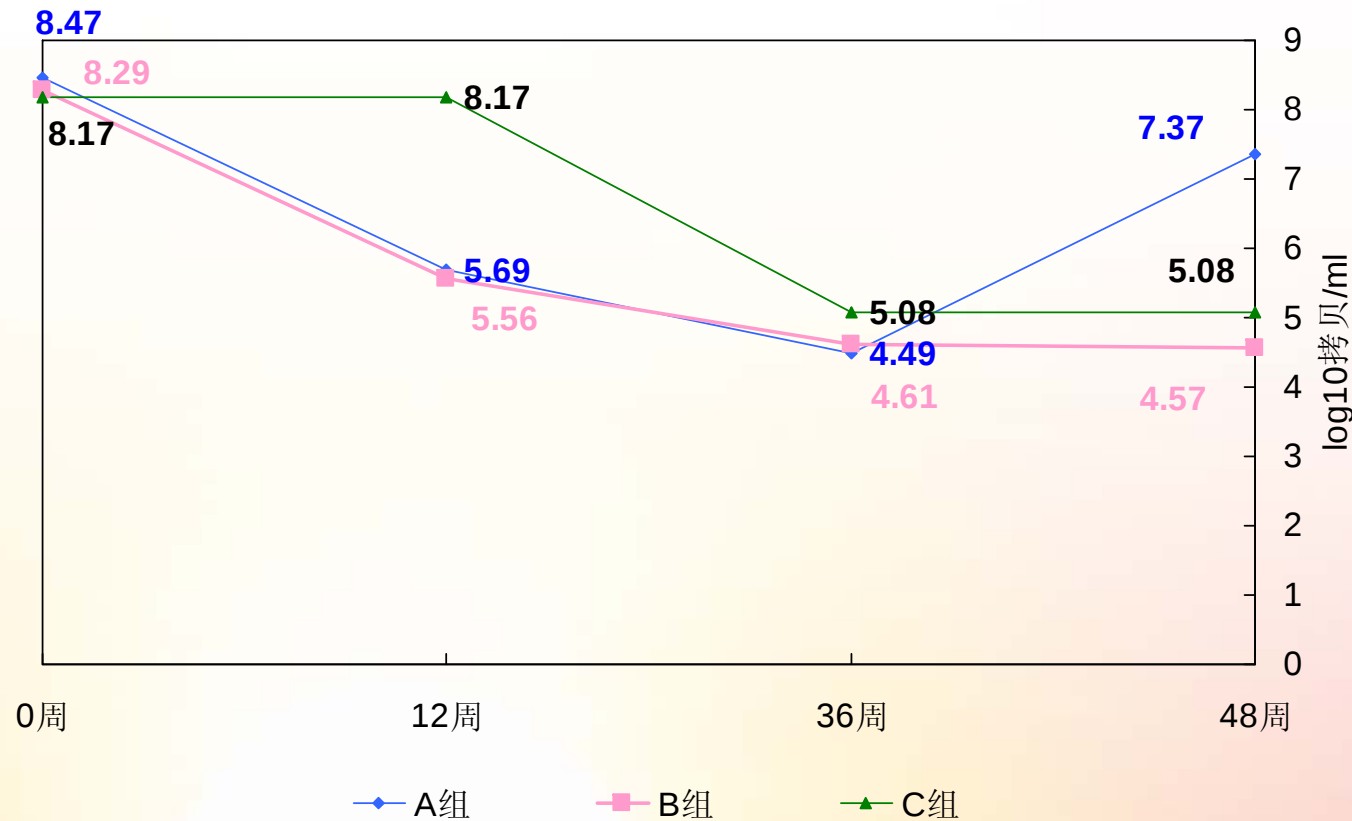
Primary Efficacy Endpoints

- Mean change in serum HBV DNA from baseline
- Inhibition of HBV DNA
- HBV DNA undetectable





Mean change in serum HBV DNA



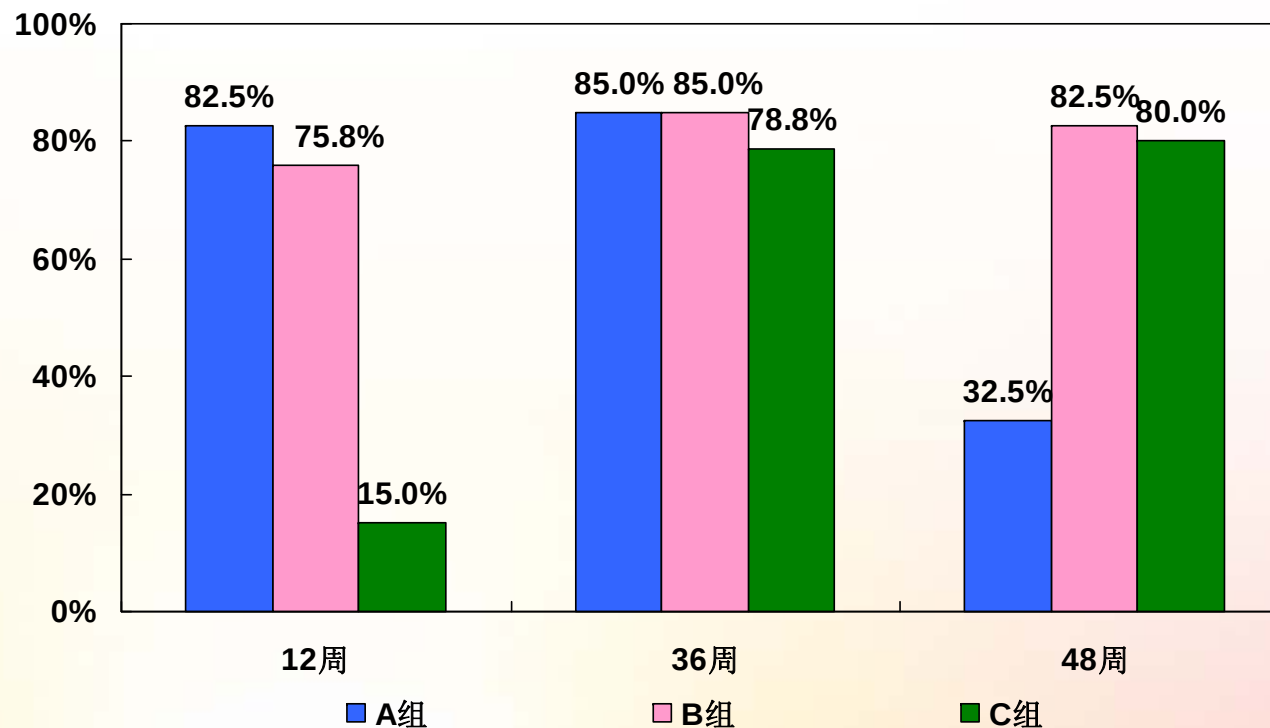
治疗组在**48周时 (B组)**

- HBV DNA中位数水平较基线时显著下降**3.58 log10 copies/ml** ($P < 0.01$)





Inhibition of HBV DNA*



治疗组在48周时 (B组)

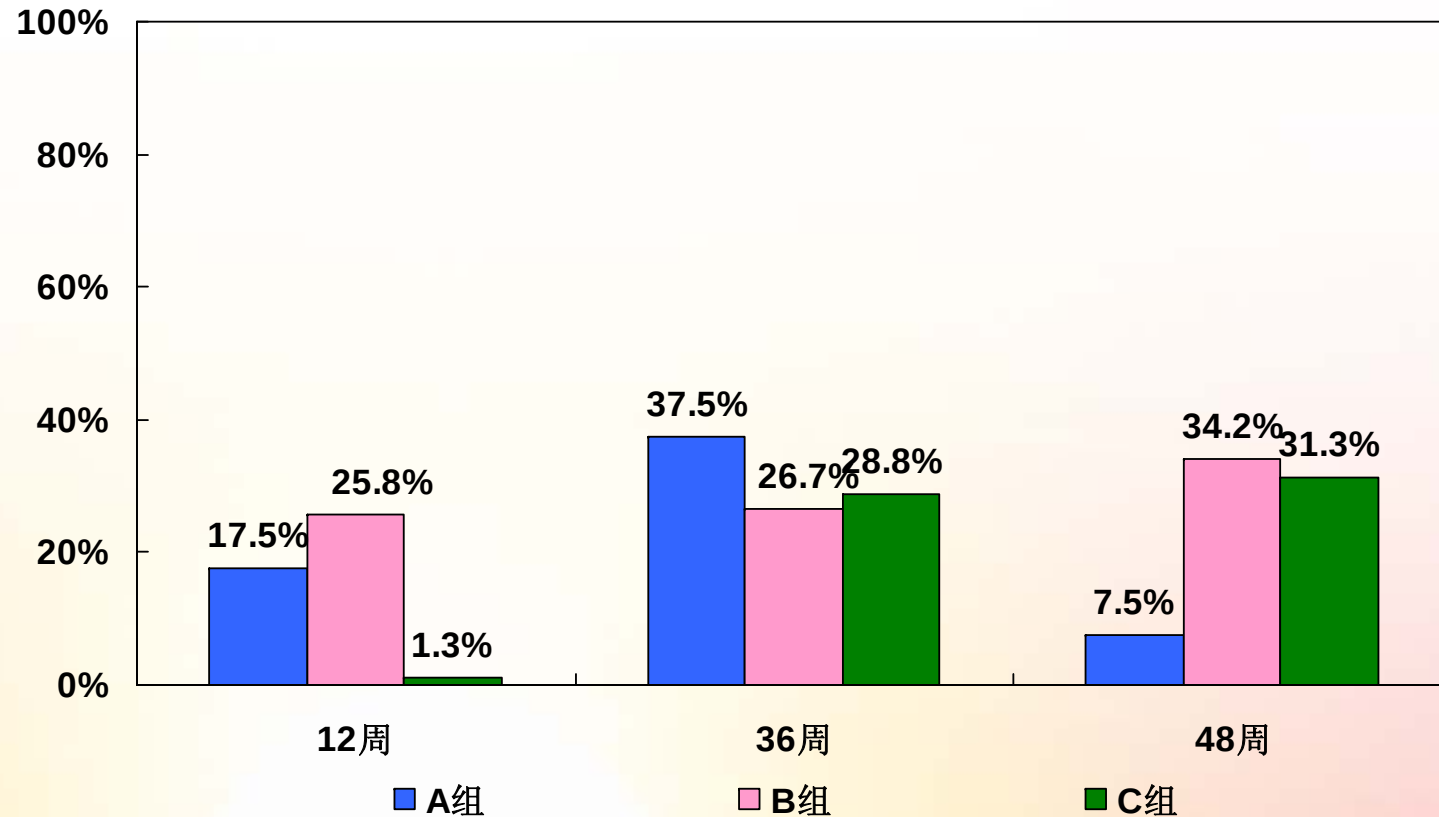
- HBV DNA 有效抑制达 82.50% ($P < 0.01$)

*HBV DNA 有效抑制: HBV DNA水平下降到 $\leq 10^5$ 拷贝/ml或下降 $\geq 2\log_{10}$ 的病人比例





HBV DNA undetectable**



治疗组在48周时 (B组)

- HBV DNA 转阴率 34.17% ($P < 0.01$).

**HBV DNA转阴: < 1000 拷贝/ml





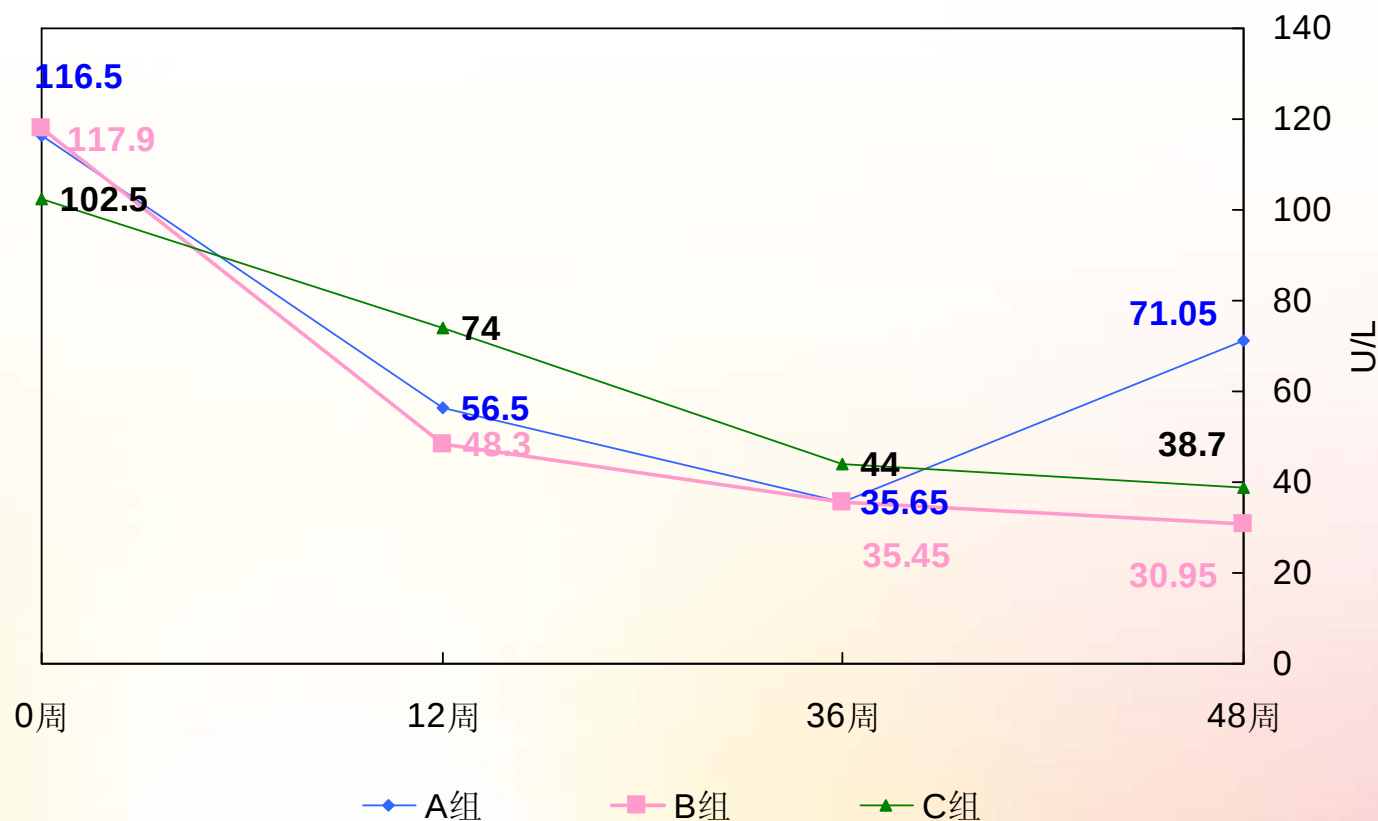
Secondary Efficacy Endpoints

- Mean change in ALT
- ALT normalization
- HBeAg seroconversion
- Overall





Mean change in ALT



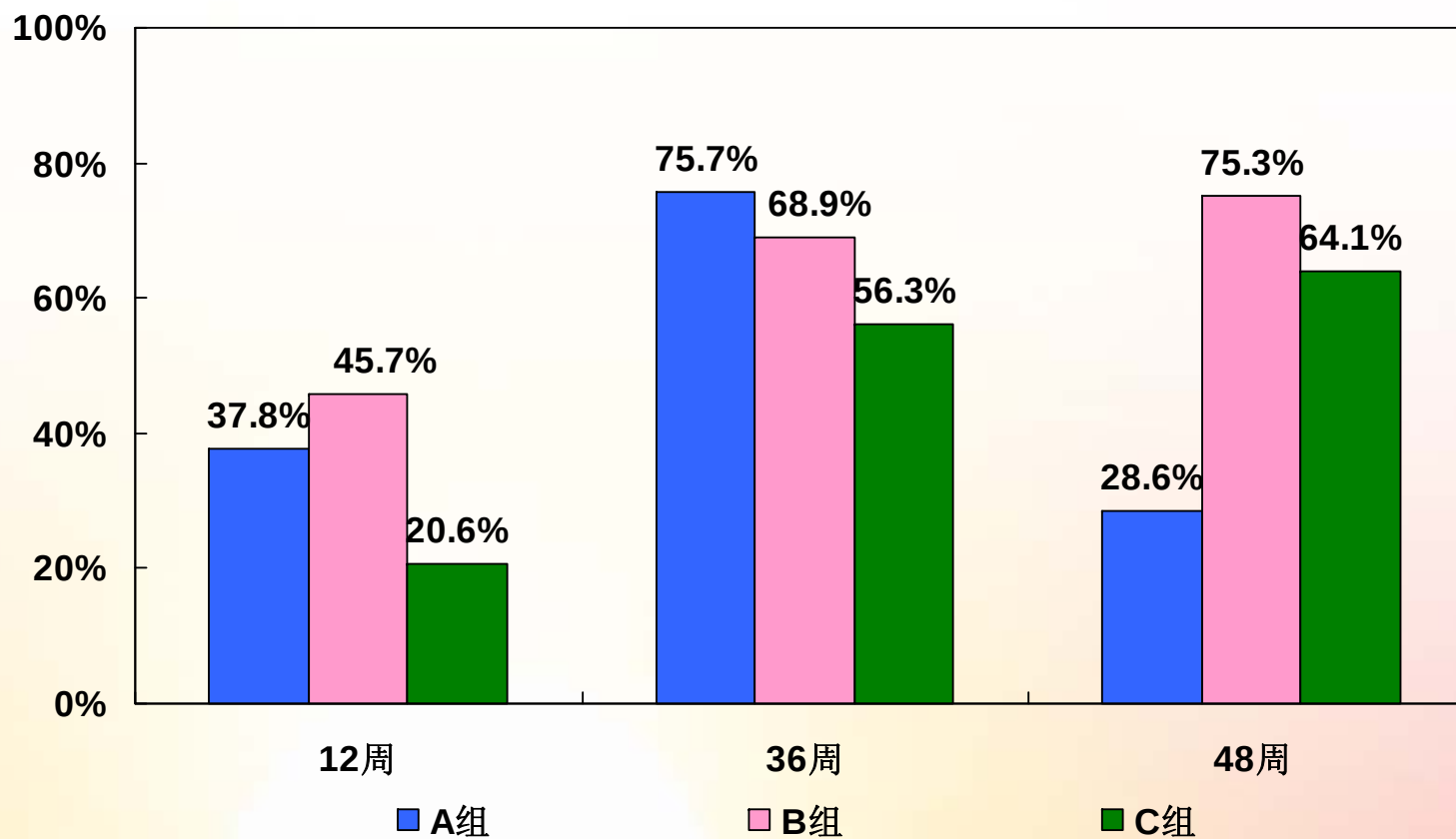
治疗组在48时 (B组)

- ALT中位数水平显著下降至31.0U/L





ALT normalization



治疗组在48周时 (B组)

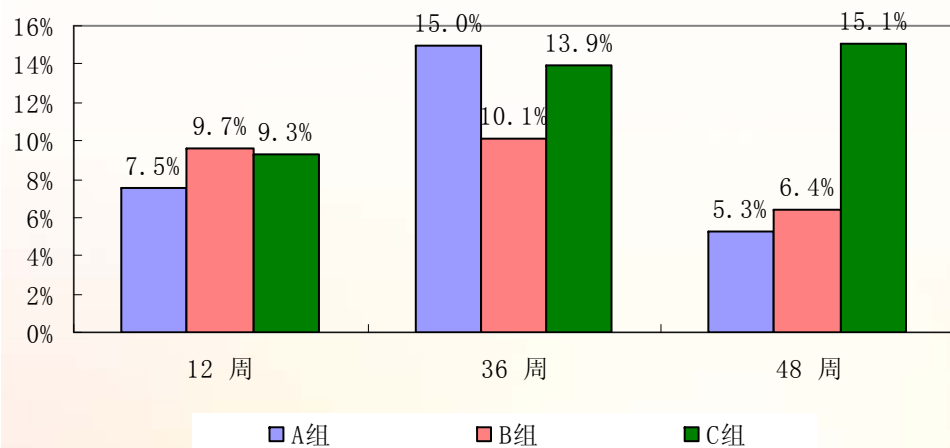
- ALT 复常率为 75.25% ($P < 0.01$).



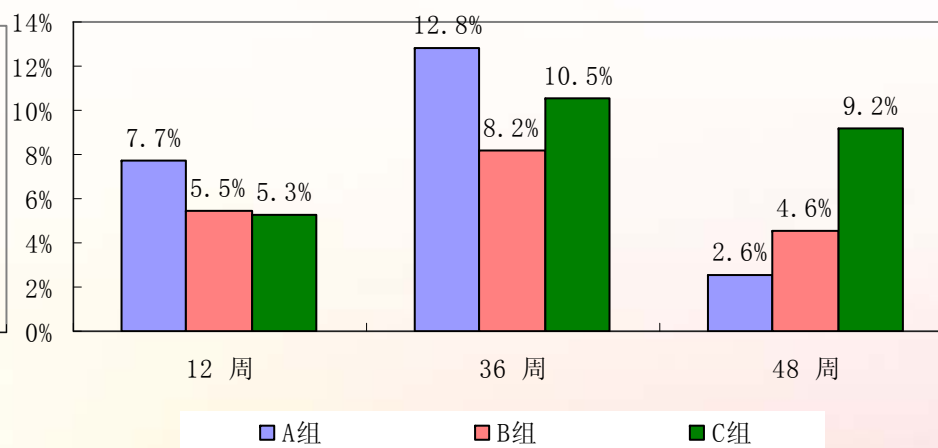


HBeAg seroconversion

HBeAg 阴转率



HBeAg血清转换率



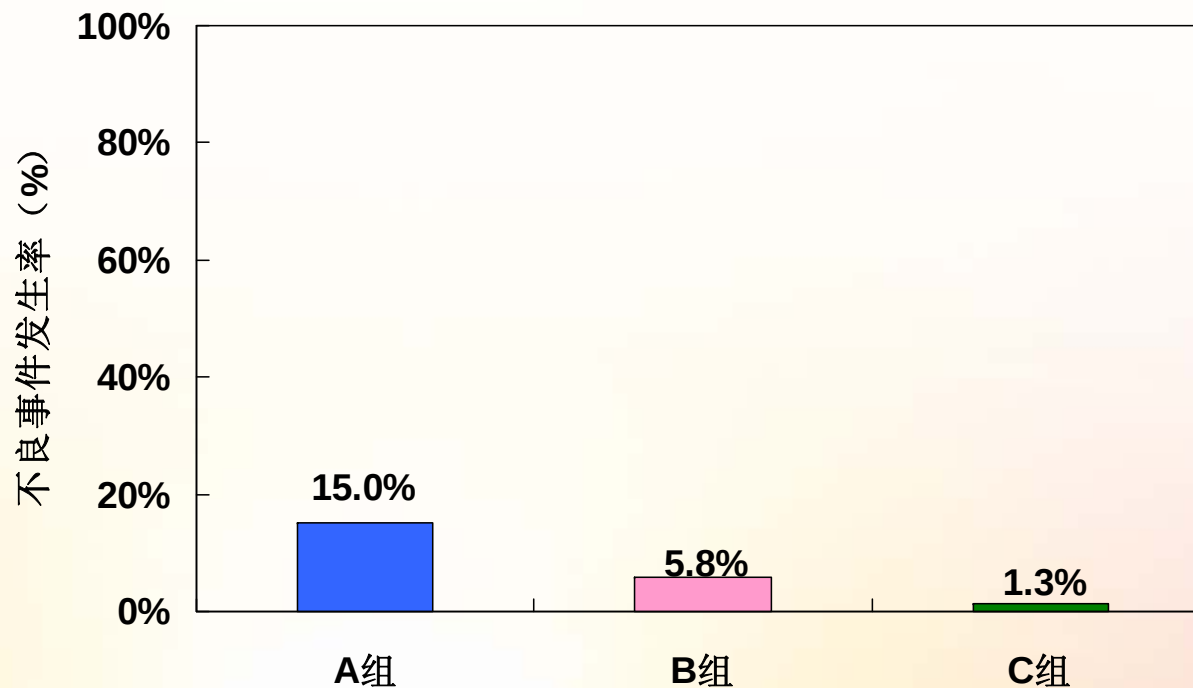
治疗组在 48周时 (B组)

- HBeAg阴转率为 6.42%
- 血清转换率4.55%





Overall



不良反应发生率低，无证据表明存在肾脏安全性问题
A组不良事件发生率高主要与最后12周中停用优贺丁有关





Summary

■ Proprietary synthetic process

- ADV crystallization with absolute ethanol
- impurity of raw ADV $\leq 1.6\%$
- New 5-step synthesis process
- Improved harvest rate (raw material) with catalysts including bromide and/or iodine (15% vs. 5-8%)
- **New pattern of drug crystal**

■ Clinically proven Adefovir Dipivoxil

- Strong inhibition of HBV DNA showing a $>2\log$ drop
- Effectiveness to inhibit HBV-DNA ($P < 0.01$) at week 48 is 85%
- % HBV-DNA turn-negative ($P < 0.01$) at week 48 is 35%
- ALT levels dropped $>50\%$





优贺丁™ Marketing





- Market and Product Overview
- Key Issues
- Marketing Objectives
- Positioning Statement
- Key Marketing Strategies
- Key Tactical Programs
- Implementation Timeline
- 5 Year Sales





The anti-viral therapeutic drug market

- The anti-viral therapeutic drug market (wholesale value) is estimated at **RMB 2.7 Billion**.
- The anti-viral therapeutic drug market increased 7.2 % * in year 2006. **Nucleotide analogues** are driving market growth: **44.0% vs 2005**
- Heptodin, Hepsera, Baraclude, DaiDing are major competitors, with 24.3%, 4.9%, 3.9% and 6.0% market share respectively in 2006*.

**Source: IMS 16 cities, 2006 Q2 MAT*





Hepatitis B in China

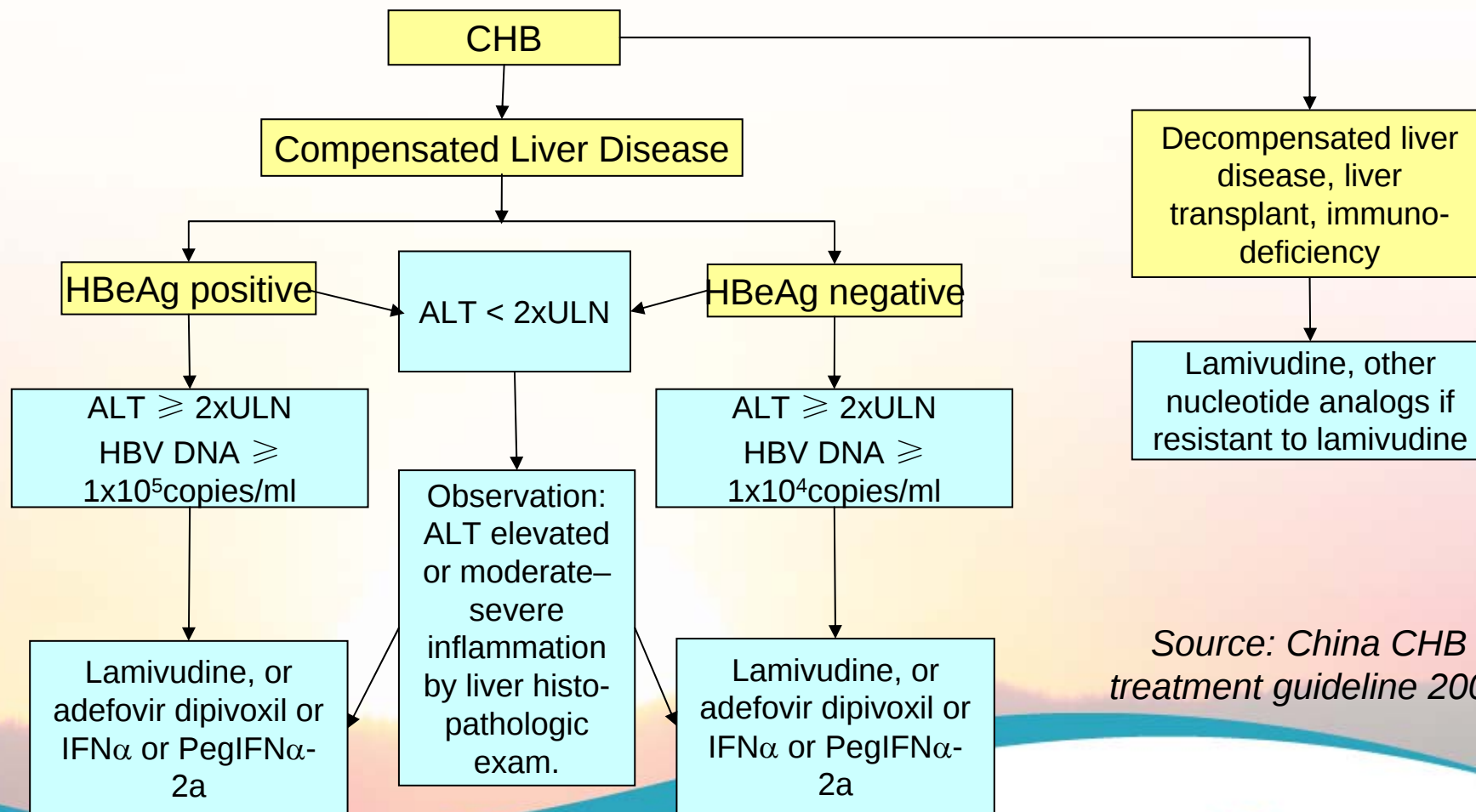
- China has 130M HBV carriers
 - HBsAg positive prevalence: 9.09% of total population
- And 30M patients with Chronic Hepatitis B
- There are 2-3M new patients diagnosed annually

Source: Chinese Journal of Hepatic Disease





Treatment Guideline (China)



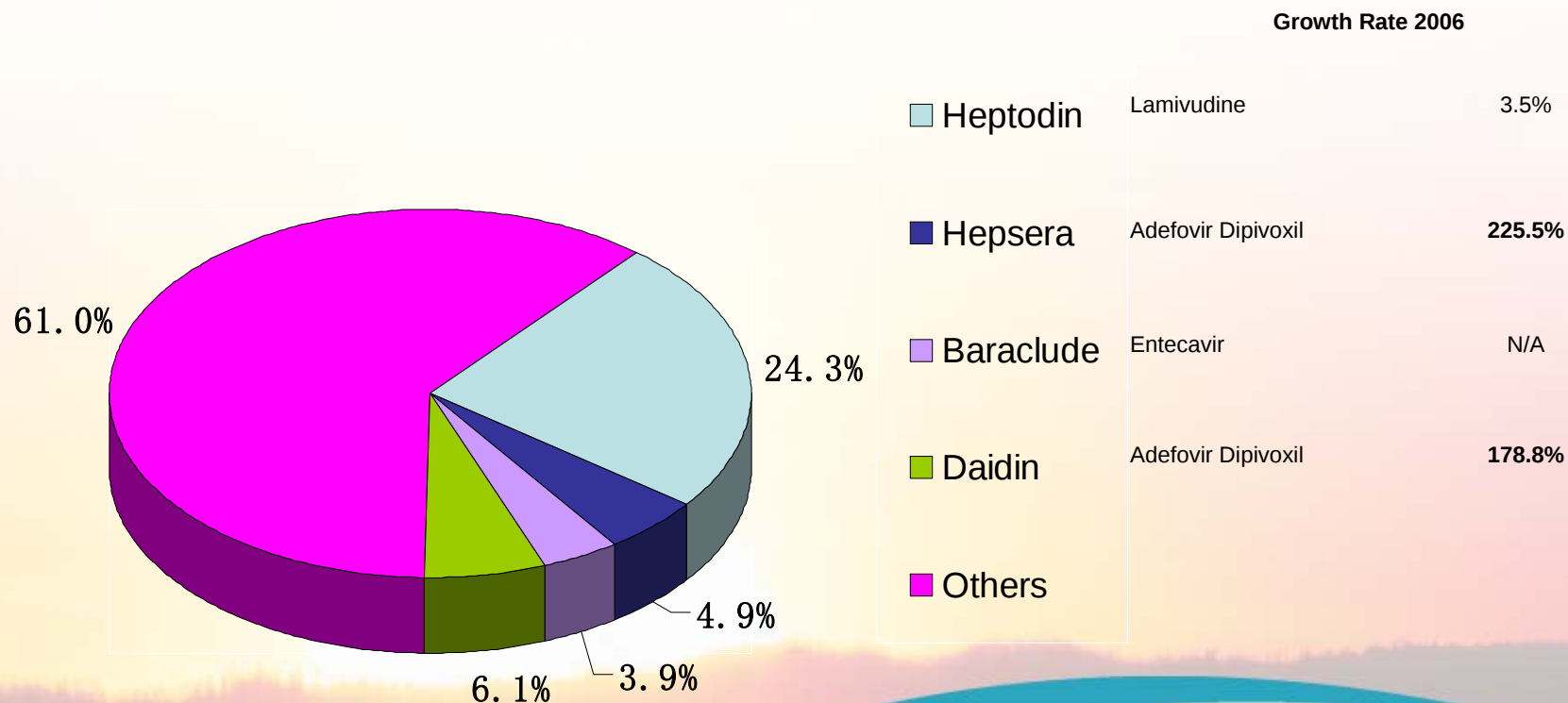
Source: China CHB treatment guideline 2006





Market Size

2006 Total segment Market Growth Rate*: +7.2%



*Source: IMS06Q2, 16cities.





Market Analysis 1

Hepsera (Adefovir dipivoxil) – GSK

- Launched in September 2005
- Estimated total hospital sales of RMB 130 mil, 4.9% of J05B market, increased 225.5% in 2006
- Key marketing strategies and tactics:
 - Co-promotion with Heptodin sales team
 - First line treatment for CHB and patients with Heptodin resistance
 - Advertisement in medical journals and at medical congresses to further enhance brand awareness.
 - Direct-To-Consumer (DTC) campaign
- Key messages:
 - Long term treatment with low incidence of resistance
 - Improves key liver functions
 - First line treatment for CHB

Source:NRDL:N,RDL(BJ/SH/GZ):NSource:IMS06Q2,16cities.





Market Analysis 2

Heptodin (Lamivudine) – GSK

- Launched in 1999
- Estimated total hospital sales of RMB 649 mil, 24.3% of J05B market, increased 3.5% in 2006
- Key marketing strategies and tactics:
 - Advertisement in medical journals and at medical congresses to further enhance brand awareness.
 - DTC campaign
- Key messages:
 - First nucleotide analogue to enter the market

Source:NRDL:N,RDL(BJ/SH/GZ):NSource:IMS06Q2,16cities.





Market Analysis 3

Baraclude (Entecavir) – BMS

- Launched in November 2005
- Estimated total hospital sales of RMB 103 mil, 3.9% of J05B market
- Key marketing strategies and tactics:
 - Current promotion focus on first line cities (estimated 30 cities)
 - First line treatment on CHB and patients with Heptodin resistance
 - Advertisement in medical journals and medical congresses to further enhance brand awareness.
- Key messages:
 - Better inhibits HBV replication vs. Heptodin
 - Similar safety and tolerability profile as Heptodin

Source: NRDL: N, RDL (BJ/SH/GZ): N Source: IMS06Q2, 16 cities.





Market Analysis 4

DaiDing (Adefovir dipivoxil) – TJT

- Launched in mid 2005
- Estimated total hospital sales of RMB 163 mil, 6.1% of J05B market, increased 178.8% in 2006
- Key marketing strategies and tactics:
 - Focus on first line cities
 - Lower price: RMB 16 Yuan / Tablet (daily treatment)

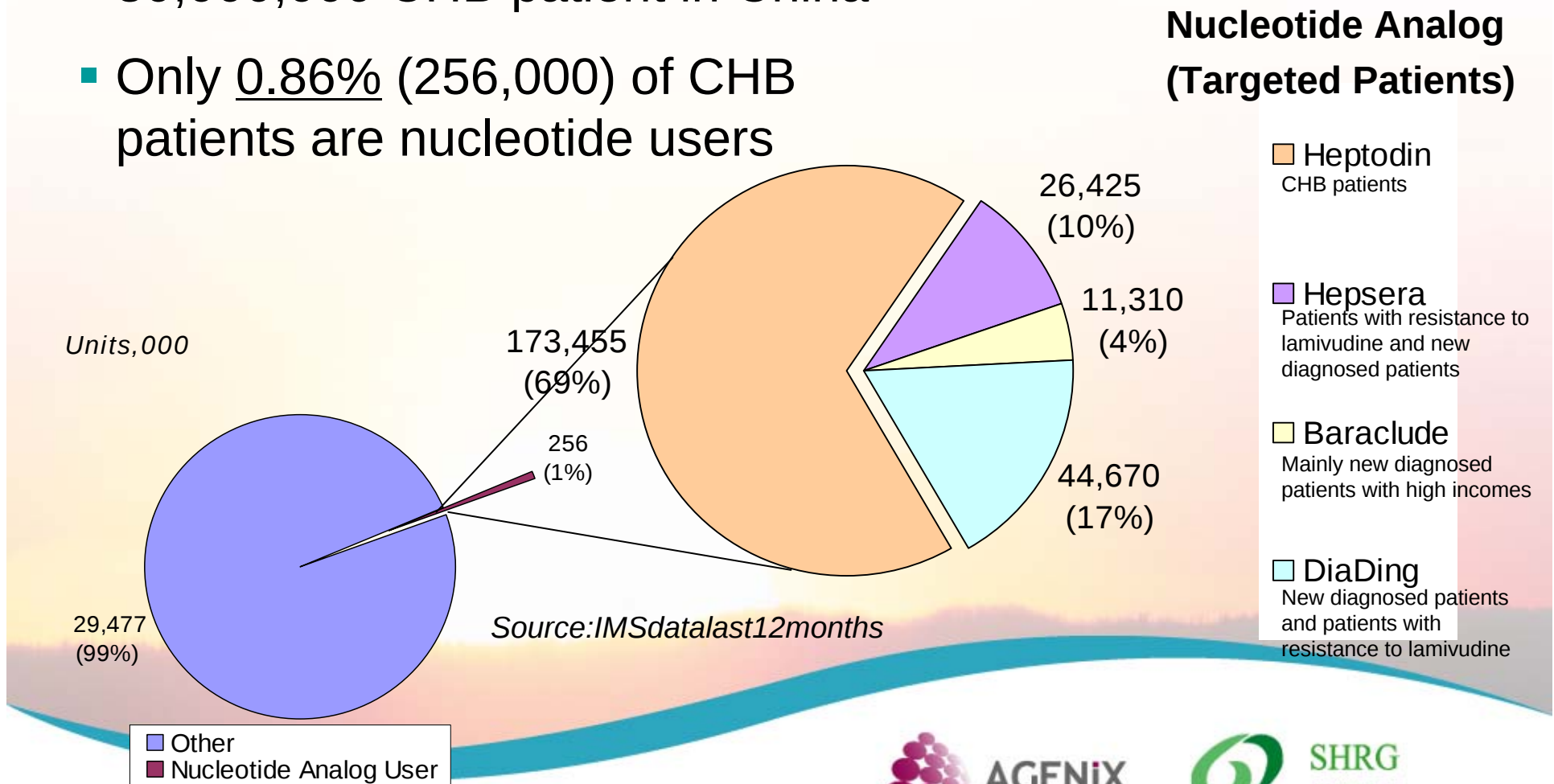
Source: NRDL: N, RDL (BJ/SH/GZ): N Source: IMS06Q2, 16 cities.





Market Analysis by Population

- 30,000,000 CHB patient in China
- Only 0.86% (256,000) of CHB patients are nucleotide users



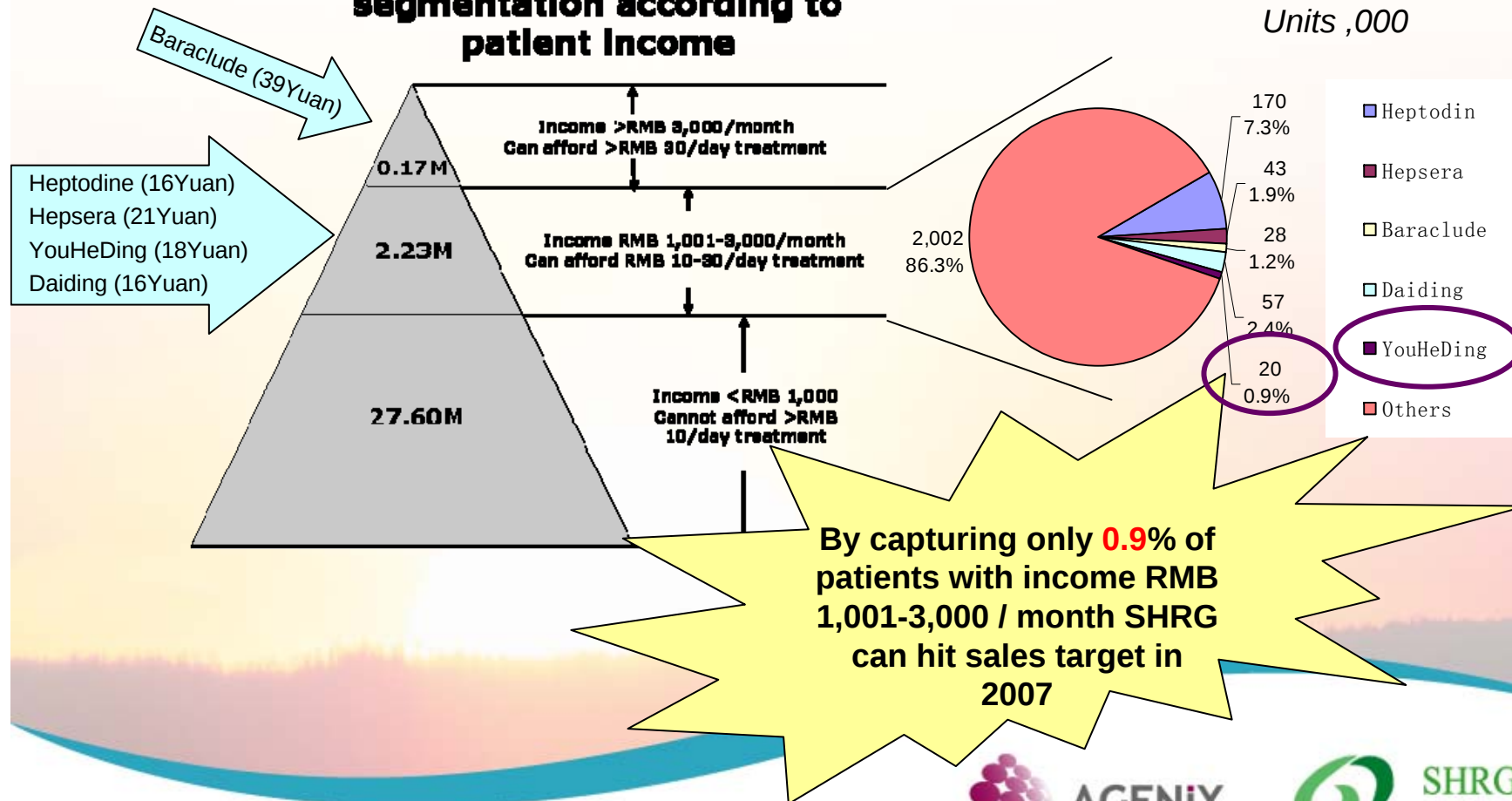


Market Analysis by Income

Brand (Daily Cost)

AntiHBV drugs market segmentation according to patient income

Patient Allocation 2007
Units ,000





YouHeDing Pricing

Profile	
Trade Name:	YouHeDing(优贺丁)
Dosage Form:	10mg/Tab
Packaging:	14 Tabs/bottle
Approved Indication:	Chronic Hepatitis B
Pricing:	RMB 249.06/bottle RMB 17.79/tablet
SFDA Registration Approval:	2nd half, 2007
Launch:	Q4 2007





YouHeDing vs. Others

Product	Main Ingredient	Company	Presentation	Wholesale Price	Average daily dose	DCT (Patient Price)	DCT Index (vs Agenix /SHRG Product)
				RMB		RMB	
YouHeDing	Adefovir dipivoxil	Agenix/ SHRG	Tablet (10mgx14/box)	about 219	10mg	about 18	100
Heptodin	Lamivudine	GSK	Tablet (10mgx14/box)	195	100mg	16	90
Hepsera	Adefovir dipivoxil	GSK	Tablet (10mgx14/box)	256	10mg	21	118
Baraclude	Entecavir	BMS	Tablet (0.5mgx7/box)	237	0.5mg	39	219
DaiDing	Adefovir dipivoxil	TJT	Tablet (10mgx14/box)	190	10mg	16	88





YouHeDing Position

Heptodin (lamivudine)	Resistance to YouHeDing is <i>significantly lower</i>
Hepsera (adefovir dipivoxil)	YouHeDing offers comparable efficacy and safety profile with very competitive pricing (<i>18% lower</i>)
DaiDing (adefovir dipivoxil)	YouHeDing is a <i>patented</i> product from Shanghai
Baraclude (entecavir)	YouHeDing has comparable efficacy / safety profile but much more affordable (<i>119% lower</i>)





Marketing Strategy 1

- To establish YouHeDing as the first choice for treatment of CHB and lamivudine resistant patient with gastroerologist and hepatologist against Heptodin, Hepsera, and DaiDing by:
 - Academic promotion
 - Market orientation meetings in main cities (Beijing, Shanghai, Guangzhou, Chongqing)
 - Emphasizing proven consistent efficacy and safety profile
 - Focusing on patented technology
 - A Shanghai-made patented product with lower and more affordable price
 - Develop and keep good relationship with KOLs
 - Youheding National Assistant Program
 - Quickly develop heavy prescribers
 - DTC campaign
 - Utilize strong governmental support and promotion





Marketing Strategy 2

To establish YouHeDing as an attractive product with sustained growth and significant potential to the sales team by:

- Quickly penetrate into 5 tier 1 regions (Northeast, North China, South China and Southwest China)
- Establish Patient Monitoring System (PMS)
- IP education
- Sales skill training
- Internal motivation (incentive) program
- Made-in-Shanghai promotion





Marketing Campaign 1

Core Marketing Strategy	Tactical Programs	Timing
Establish YouHeDing as the first choice for treatment of CHB to gastroenterologist and hepatologist	Clinical trial summary meeting in Australia	Q4
	Round table meeting in BJ, SH, GZ, CQ	Sep
	Market orientation meeting in BJ,SH,GZ,CQ	Q4
	Medical Journal advertising	Year round
	National and local congress sponsorship	Year round
	Advisory board meeting (YouHeDing National Assistant Program)	Sep/Apr
	Hospital seminars	Year round
	CME	Year round
	Sponsorship for hospital/Dept.	Year round
	Promotional material & Gimmicks	Year round
	Heavy prescriber activities: Three Gorge, 110 doctors + 10 staff)	May-08
	Local city symposium	Year round
	Patient education (PMS) (ZJ/JS/GD/SH/BJ)	Year round





Market Campaign 2

Core Mktg Strategy	Tactical Programs	Timing
To establish YouHeDing as a sustainable, attractive product with huge potential to sales team	Internal motivational program for Reps with good sales performance (Top 10 Reps who achieve 100% sales target to attend National Infectious Disease Congress in Haikou, 1 day product training, 1 day attend congress, 1day trip)	Dec
	Youheding Q&A quick review	Jul/Jan
	Visiting factory (100 HDAC members)	Nov
	Clinical trial IV + Sample	Year round
	Selling skill training	Dec/Mar
	HDAC activities (278 HDAC members, mainly physicians)	Jan





Market Projection

Quantitative

- To achieve RMB100 million in sales in fiscal year 2008.
 - November 2007, signed distribution agreement with Sinopharm(SH) for RMB50 million for year 2008
 - Own sales force is to complete with recruitment for 50 staff by year end 2007
- Achieve accumulated revenue near RMB1billion, net profit RMB300million for the first 5-year (end of 2007 – 2012).





Projected Returns

- 5-year accumulated revenue near 1 billion RMB

- Net profit near 300 million RMB

