Agenix Limited

AGX-1009 – a next generation prodrug for HBV with proven efficacy

Market update

March 2012

Forward looking statements

- This presentation includes forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Agenix to be materially different from the statements in this presentation.
- Actual results could differ materially depending on factors such as the availability of resources, the results of clinical studies, the timing and affect of regulatory actions, the strength of competition, and the effectiveness of patent protection.

Capital and shareholder snapshot

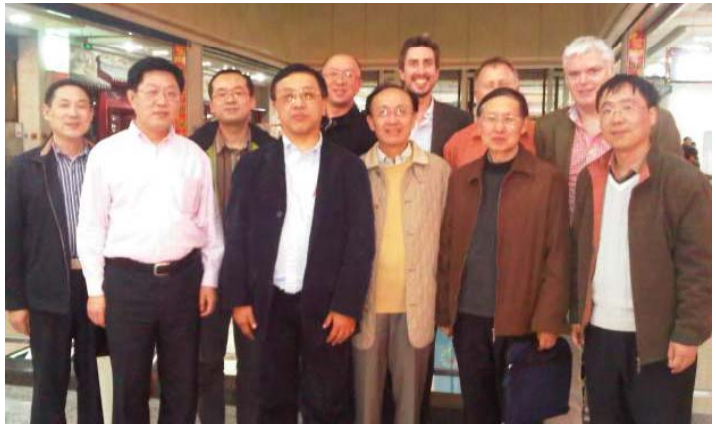
ASX:	AGX
Market cap:	$8.3 million
Shares on issue:	756,331,581
Shareholders:	3,660
Cash @ 31 Dec :	$0.6 million
Share price @ 8 Mar:	0.011 cents
Listed options:	6,444,993
Unlisted options:	700,000

Top shareholders:	**68%**
• Annmac	19.19%
• Directors/Management	14.17 %
• OKS AGX Inc	5.51%
• Pacific Super	4.71%
• Sino Sky Holdings	4.15%

- Recovery and placement revenues transformed financial position
- Listed on ASX in 1987 – one of Australia's oldest biotechnology companies
- Supportive shareholder base
- Subject to capital raising efforts, funded beyond 2012 by equity and grants
- No debt.

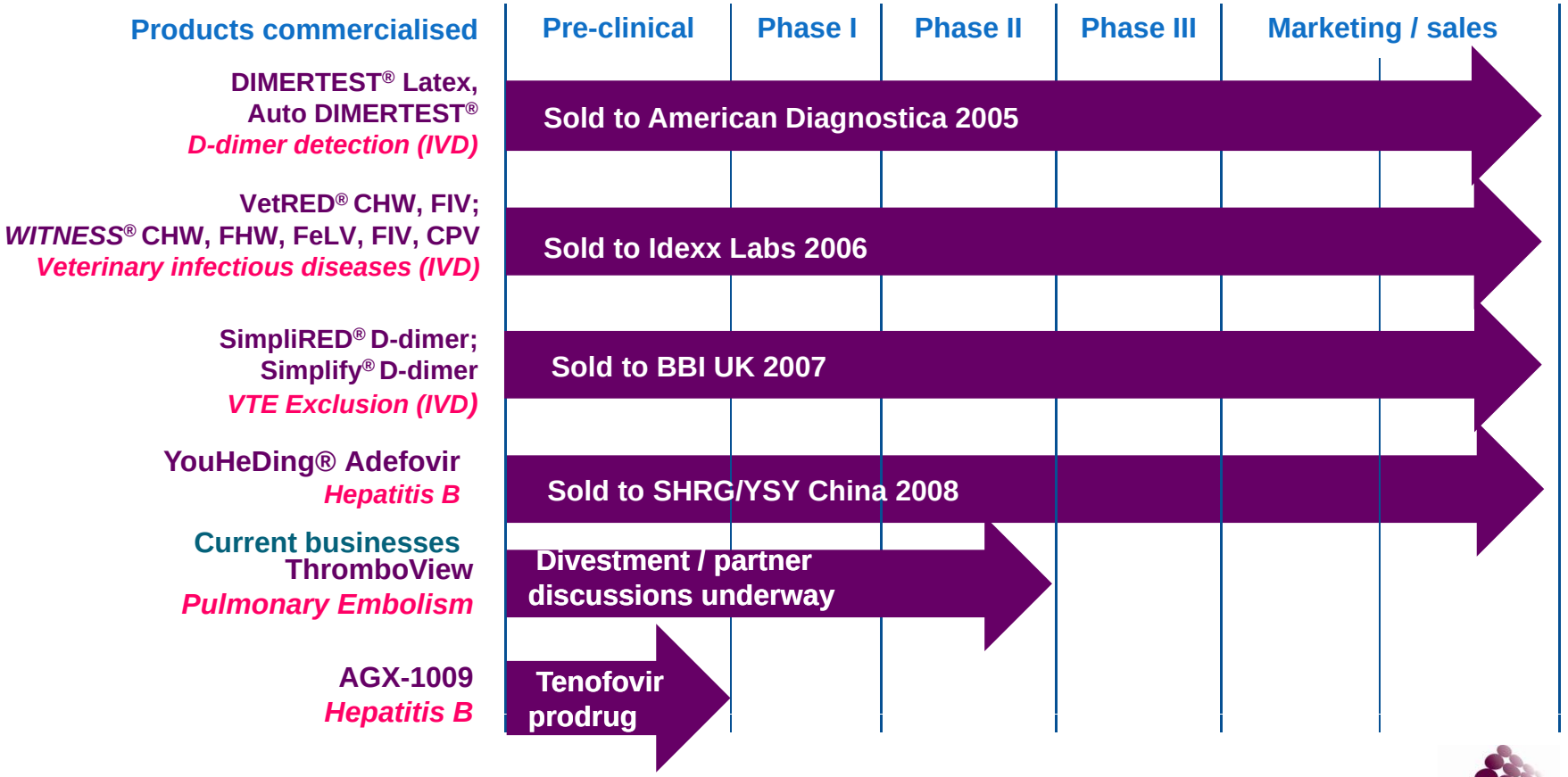
International experienced management team

- Our people are Agenix's core asset and strength
- Agenix today is a well managed company
- Proven technical and China skills of directors, management and team are driving our business forward to create long term shareholder value.



A successful history of commercialisation

Since 1987 Agenix has taken ~ 20 animal and human products across 4 technology platforms to successful commercialisation and/or strategic sale and exit



Operations

Melbourne, Australia

Shanghai, China

Strategy to create long term value

1. Complete transformation to a company based on capital:
    - human capital (experience, creativity, networks, core competencies)
    - relationship capital (ASX listed since 1987, partners, consultants, suppliers, customers, hospitals, universities, alumni, scientific advisory board, goodwill)
    - intellectual capital (patents, copyright, trade marks, licensing)
    - organisational capital (research methodologies, reference material, research results)
    - monetary capital (raisings, recoveries)

2. Partnering our capital with China infrastructure and technical skills

3. Driving business by reference to technical, clinical and commercial value inflection points and realistic milestones

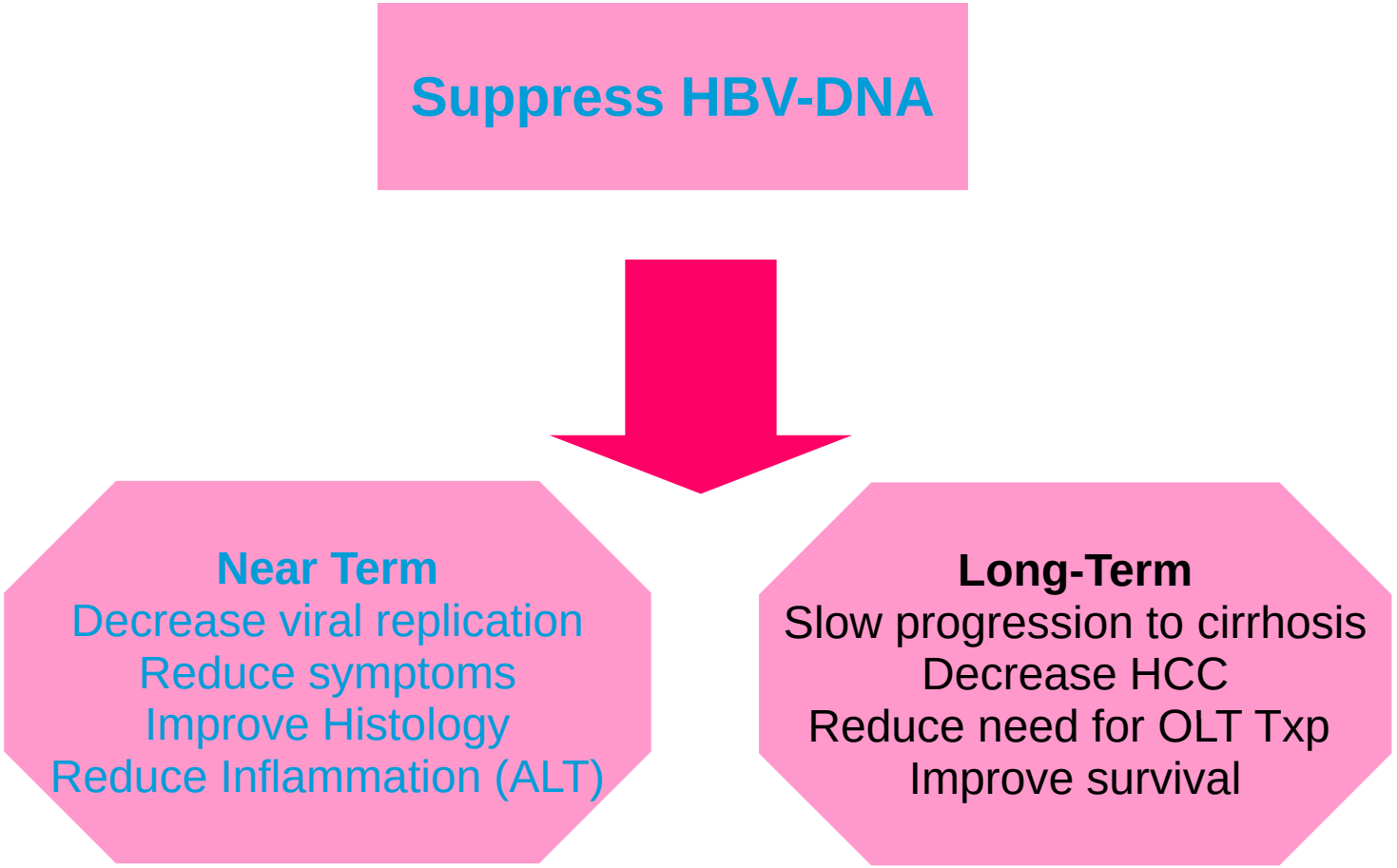
4. Competent execution of basics like good corporate governance, mitigating risk and communicating milestones and results.

AGX-1009 – path to market in China

- Four products are the most widely used for HBV in China: Lamivudine, Adefovir, Entecavir lose efficacy over time and Interferon is very expensive

1. IMS Health

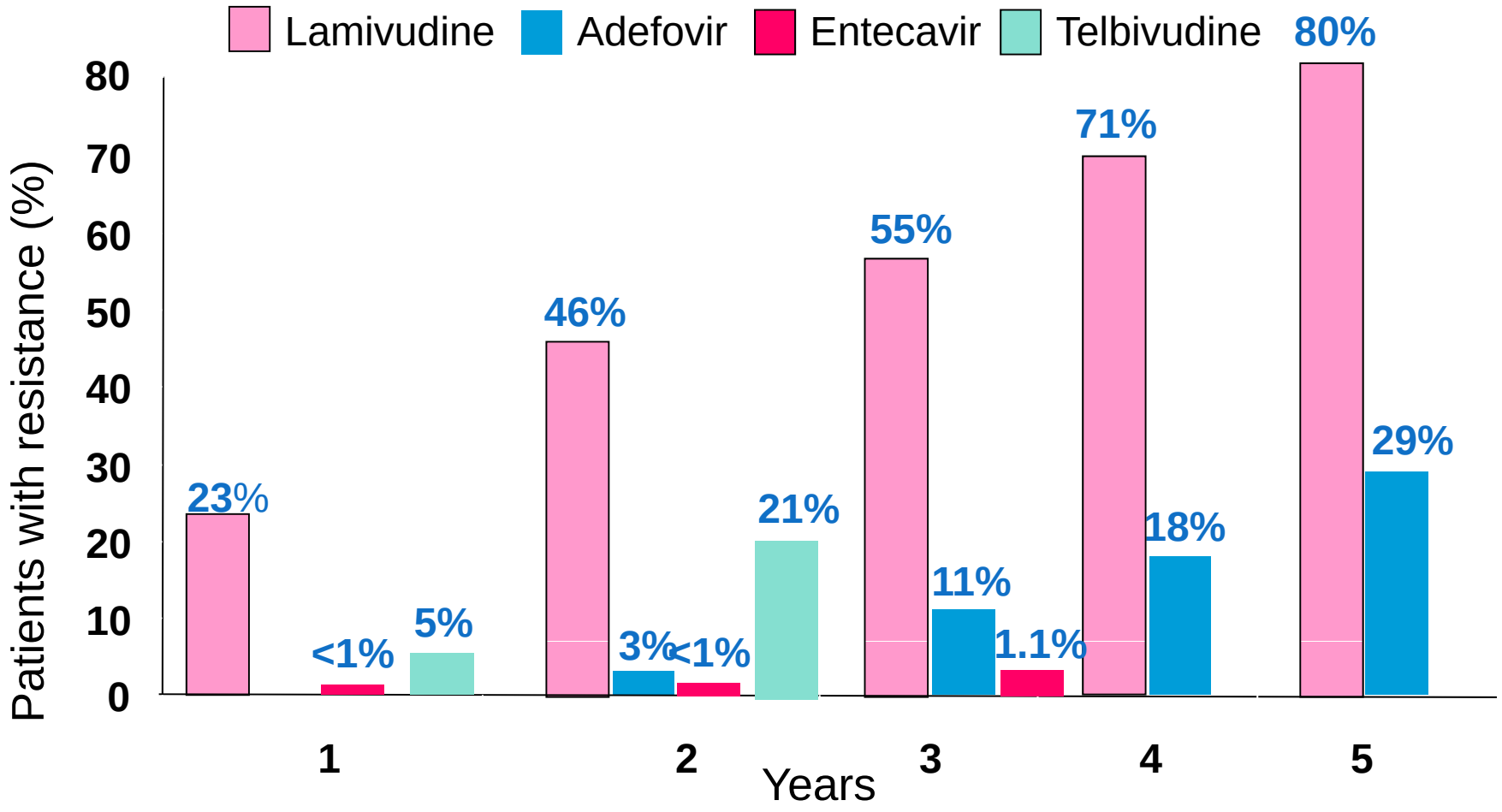
Clinical goals of HBV treatment



TCM therapies sidelined by SFDA

Traditional Chinese Medicines Used in the Treatment of Hepatitis B Virus	
Chinese Name	**Scientific and Common Names/Sources**
Danshen	Radix salviae miltiorrhizae, danshen root
Chishao	Radix paeoniae sinjian-gensis, Xinjiang peony root
Zhidahuang	—
Huangbai	Cortex phellodendri, amur corktree bark
Danggui	Radix angelicae sinensis, Chinese angelica
Shenghuangshi	Radix astragali, milkvetch root
Wuweizi	Fructus schisandrae Chinensis, Chinese magnoliavine fruit
Nuzhenzi	Fructus ligustri lucidi, glossy privet fruit
Kushen	Radix Sophorae Flavescentis, lightyellow sophora root, oxymatrine (*sophora alopecuraides*)
Yinchen	Herba artemisiae scopariae, capillary wormwood herb
Fuling	Poria, Indian bread
Zhizi	Fructus gardeniae, Cape Jasmine fruit
Gancao	Radix glycyrrhizae, licorice root
Fufangbielinganpian	—
Huzhang	Rhizoma polygoni cuspidati, giant knotweed rhizome
Baijiangcao	Herba patriniae, whiteflower patrinia herb
Source: Decision Resources, Inc.	

Development of resistance to Nucleos(t)ides in naïve patients



Gish RG, Locarnini S. Clin Liver Dis 2007;11:761–795

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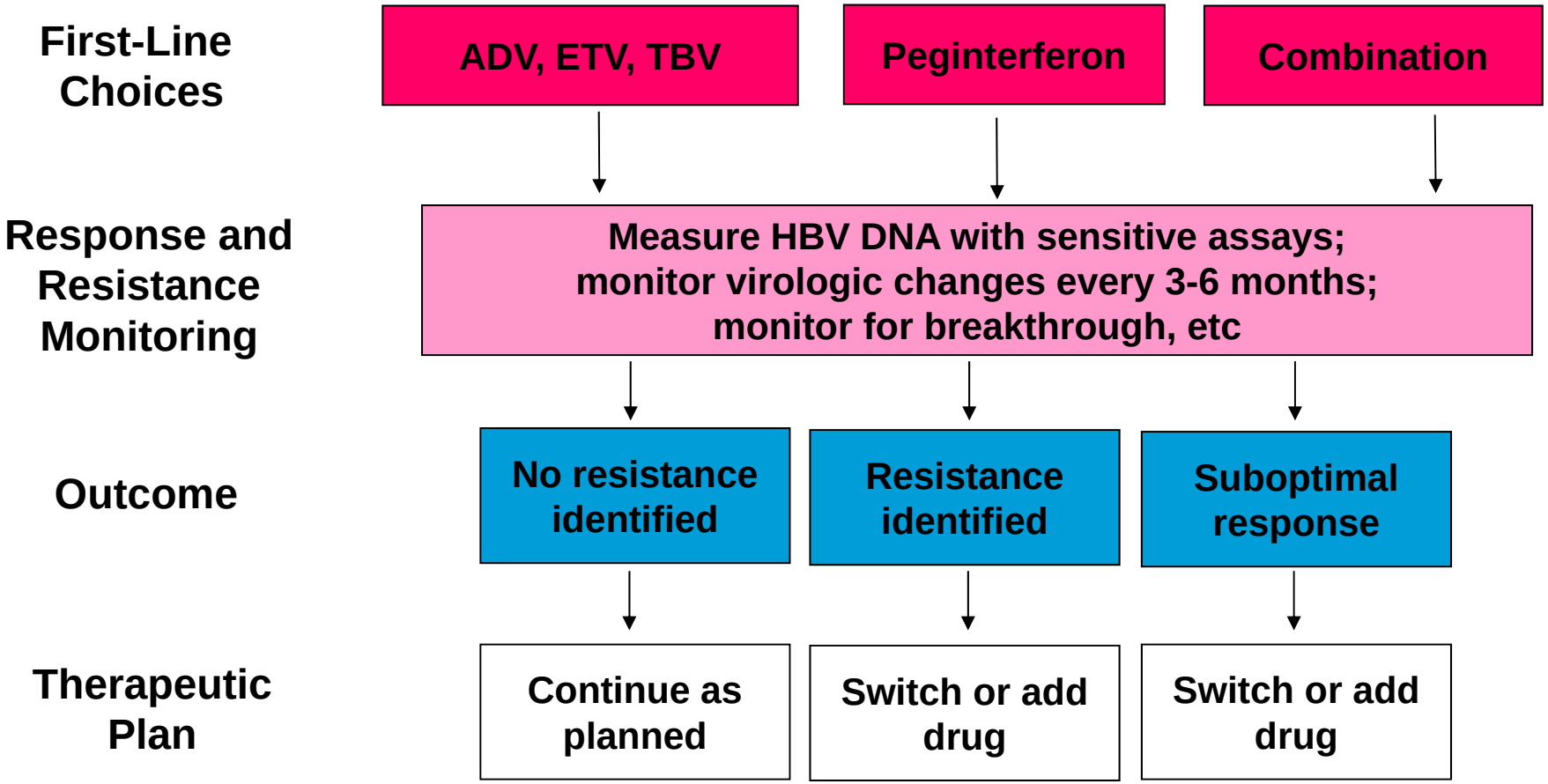
Resistance management algorithm for treatment of naïve patients

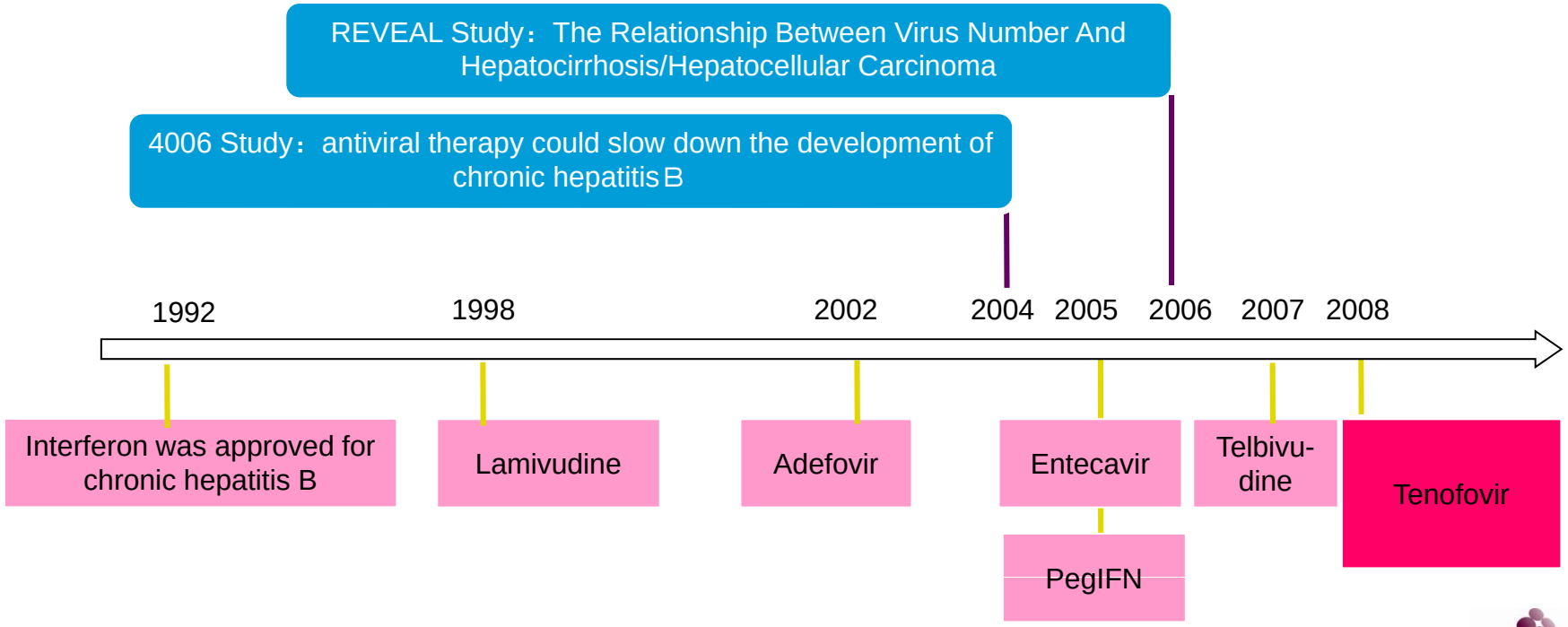


Lok ASF, McMahon BJ. *Hepatology*. 2007;45:507-539.

AGX-1009 – proof of concept

AGX-1009 is a next generation Nucleotide analog reverse-transcriptase inhibitor (NtARTIs or NtRTI) patented tenofovir 'prodrug' with the same proven active compound as Gilead's FDA-approved Viread but activated by a different molecular sidechain.

Tenofovir DF (Viread) is FDA approved in USA for HIV (2001) and HBV (2008). It is not approved in China but may achieve SFDA approval and be distributed by GSK in 2014.

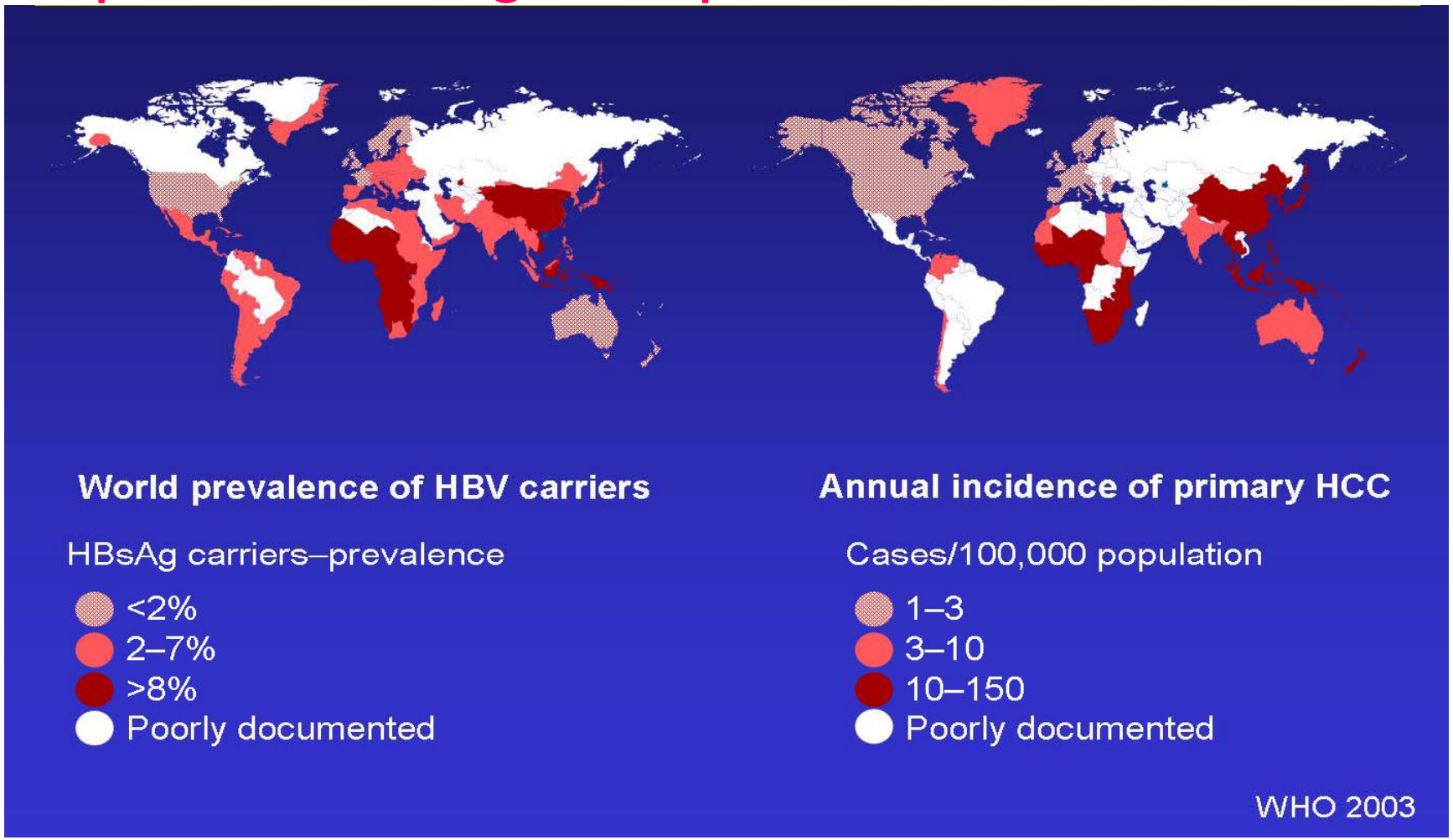


AGX-1009 – path to market in China

- Market currently worth US $460 million (estimated to be US $1.3 billion in 2019)[1]

1. IMS Health

Hepatitis B – A global problem



Hepatitis B in mainland China

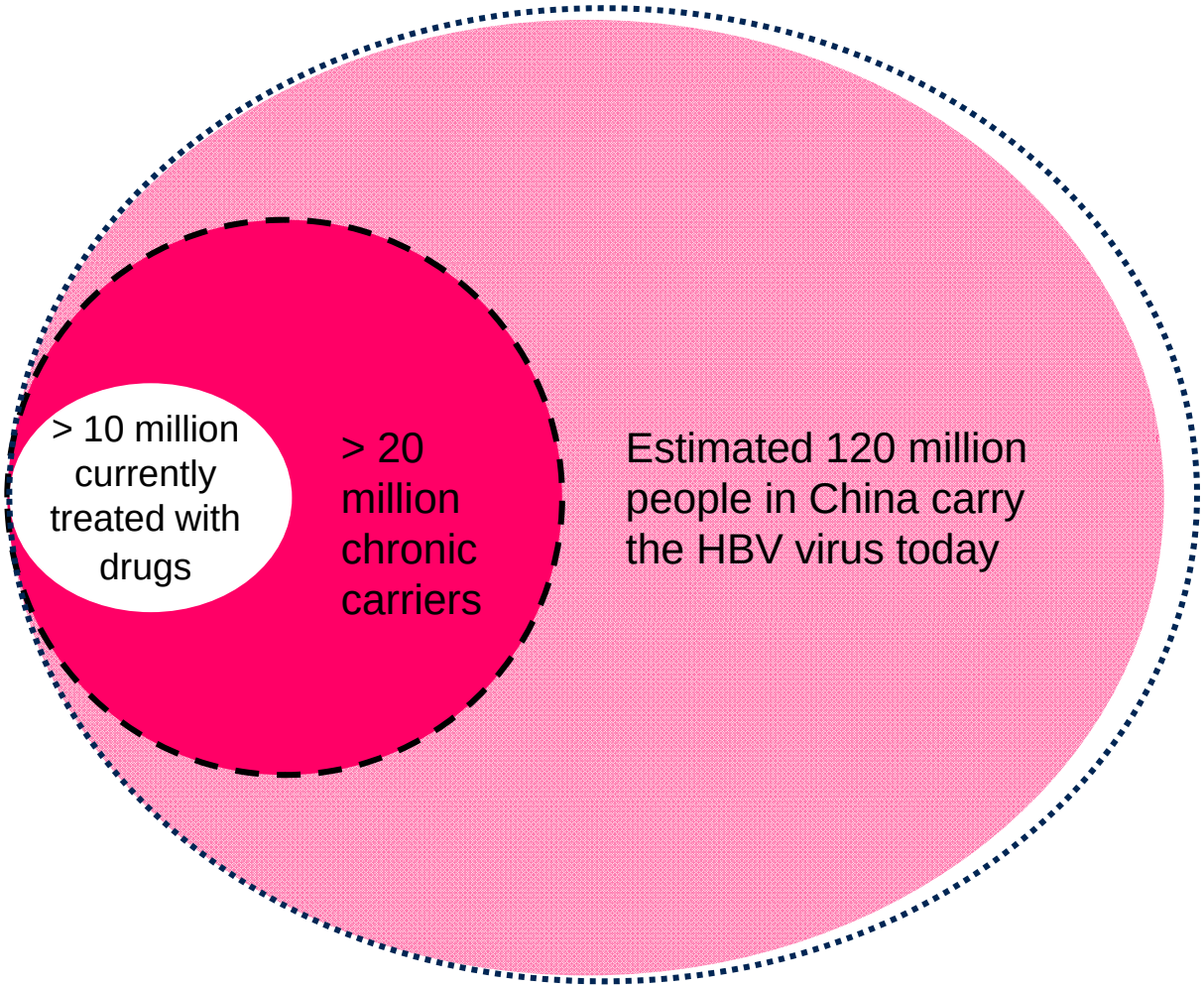
Major unmet medical problem

Significant cost to medical system

Burden to millions of Chinese

Government priority to address

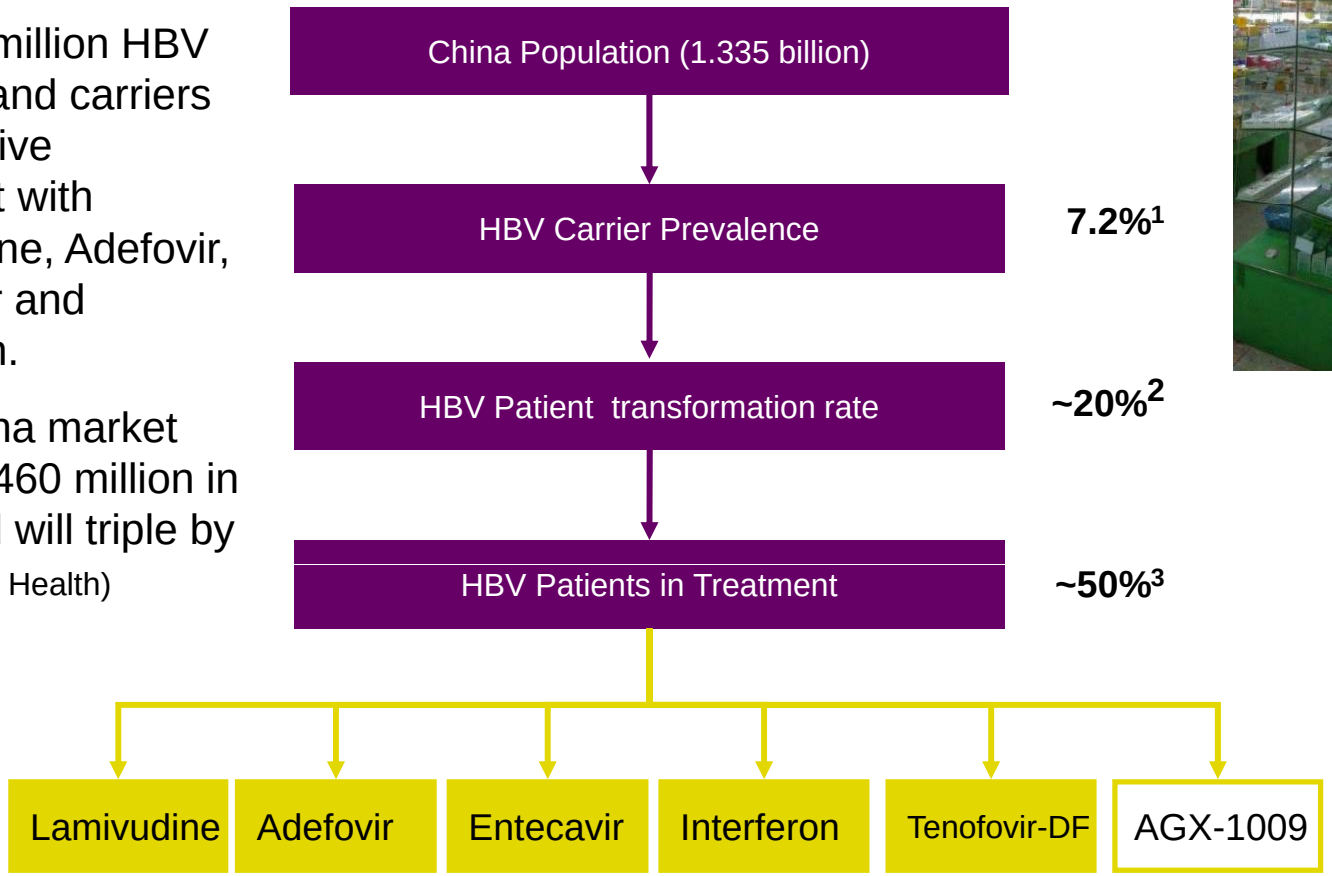
US$1.3 billion market in 2019



Hepatitis B Market opportunity in China

Over 10 million HBV patients and carriers who receive treatment with Lamivudine, Adefovir, Entecavir and Interferon.

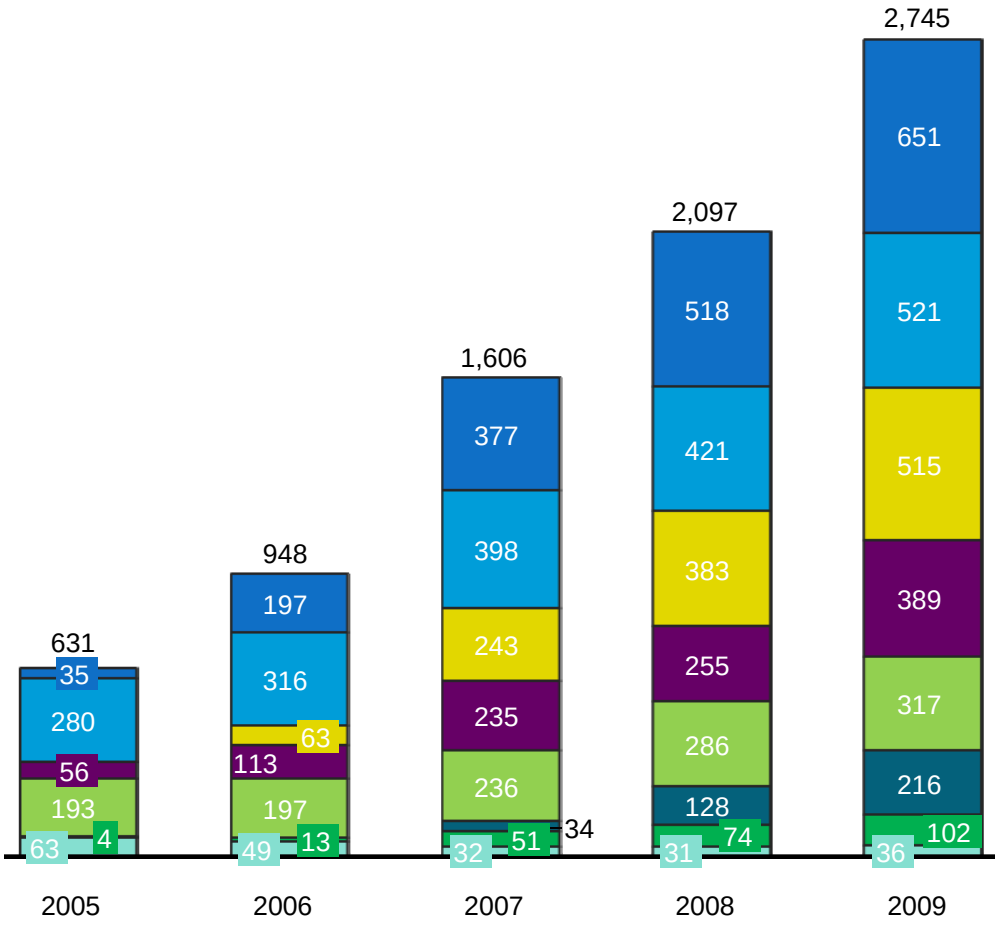
HBV China market worth A$460 million in 2009 and will triple by 2019 (IMS Health)



1 MOH Statistics, 2008
2 Ibid
3 IMS Health

Hepatitis B Current market in China

Million , RMB



SOURCE: IMS HEALTH

AGX-1009 – proven active substance

- AGX-1009 is a patented tenofovir ‘prodrug’ with the same active compound as Gilead’s FDA-approved tenofovir ‘prodrug’ Viread

1. IMS Health

AGX-1009 – a next generation therapy

- Virus resistance develops that make the HBV (and HIV) virus less susceptible to NRTIs and NNRTIs so that patients on Lamivudine, Adefovir and Telbivudine must after 3 years or so change to a next generation NtARTI or NtRTI drug like tenofovir.

AGX-1009 – path to market in China

- AGX-1009 pre-clinical work being conducted by the Institute of Pharmacology and Toxicology (IPT) of the Chinese Academy of Military Medicine Sciences, Beijing (AMMS) demonstrates good inhibitory efficacy on virus replication
- Demonstrated manufacturing in pre-clinical batches to 99.63% purity
- P450 toxicity test passed - significant de-risking point
- State Food & Drug Administration CTA filing set for third quarter of 2012 (clinical trial approval expected early 2013)
- Potential commencement of combination trials / partnerships
- Working with the best in China: IMB, IPT, AMMS.

1. IMS Health

Intellectual Property protection

- Patent registered in China for AGX-1009 Tenofovir prodrug compound to 2026
- PCT applications for synthesis methods
- Future PCT patent applications for drug fixed-combination formulations

Intellectual Property protection

The patent protection of tenofovir in China

- There are more than 30 patent applications related to Tenofovir in China, which cover new compounds, synthesis methods, and drug combinations. Among these applications, 12 highly relevant applications, which include all TFV patents from Gilead Science, were carefully reviewed to evaluate the patent protection scope in this area.

The strength of patent protection of AGX-1009 in China

- the strength of patent protection of AGX-1009 is medium strong, especially for the compound protection.

The potential legal risks for AGX-1009 as an antivirus drug in China market are low

SIPO* approved the patent application of AGX-1009 after it authorised five tenofovir related patents to Gilead, which indicates that Gilead's patents have little impact on AGX-1009 at compound level.

* SIPO: State Intellectual Property Office of the P.R.C.

A strategic approach to reduce our risks

Issue	Strategy
Clinical results	• AGX-1009 based on an established and proven existing compound • Significantly lower risk profile to a new drug compound
Clinical recruitment	• Working with strategic partners who are the experts in China • Minimum errors in data and regulatory submissions in China • Government priority to expedite new drugs like AGX-1009
Intellectual property	• AGX-1009 protected by compound patent in China until 2026 • Protected by method of manufacture patent applications in all key global markets • Continue to build and will aggressively defend
Capital needs	• Continue to develop strong supportive shareholder base • Close control of costs and programs
Sentiment	• Lead drug candidate based on a successful proven compound • Proven strategic partners in China • Positioned to benefit from significant unmet needs in China • Well managed company with strong management team

Value inflection points – near term

AGX-1009

- Data available from pre-clinical studies of tenofovir prodrug AGX-1009
- Announcements regarding proof of confidence
- SFDA CTA filing expected mid-2012
- Announcements regarding distribution and clinical partnerships
- Potential licensing deals in key geographies
- Potential clinical trial approval in 2013
- Potential commencement of combination trials
- Progress of patent applications

AGX-1009 – path to market in China

Stage	Content		Average Timeline (months)
Pre-Clinical & CMC	Pharmacokinetics	Chemistry, Manufacture & Control (CMC)	CTA filing mid 2012
	Pharmacology		
	Toxicity		
Phase I	Clinical Trial Application (CTA)		6 - 9
	Phase I Study		8 -12
Phase II/III	Clinical Trial Application (CTA)		8 -10
	Phase II/III Study likely if Phase I Study Data as expected		32 -36
NDA/Production applications	NDA Filing		12 -15
	Manufacture Licensing		6 -12

Significant Near Term Value Inflection Points

Our partners in China on the AGX-1009 project are world leaders

- **Our partners include experienced State Food and Drug Administration (SFDA) hands and Hepatitis B experts**:
  - (acquisition of AGX-1009 patents and MoU of Cooperation) Institute of Medicinal Biotechnology (IMB), Chinese Academy of Medical Sciences (CAMS), Beijing
  - (pre-clinical partner) Institute of Pharmacology and Toxicology (IPT), Chinese Academy of Military Medical Sciences (AMMS), Beijing
  - (pre-clinical partner) Institute of Radiation Medicine (IRM), AMMS, Beijing
  - (pre-clinical drug manufacturing partner) Beijing Honghui Meditech

Conclusion and proposals

Conclusion

- Based on market assessment, patent review, risk assessment on pre-clinical and clinical development path, we think the overall development and regulatory risk is relatively low for AGX-1009 with a positive NPV
- P450 inhibition study was successfully conducted and has significantly de-risked the program
- Using reputable organisations as CROs to ensure appropriate preparation of documents and materials to avoid costly regulatory delays

Proposal

- Full partnership available or take a position in Agenix Limited by share placement
- Distribution rights available
- Will consider licensing/divestment of program for access to technology fees, milestones and royalties

Thank you

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