



POLHEPREVIR

Targeted HCV therapy for Genotype 1

## Synergistic Solutions

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# Overview

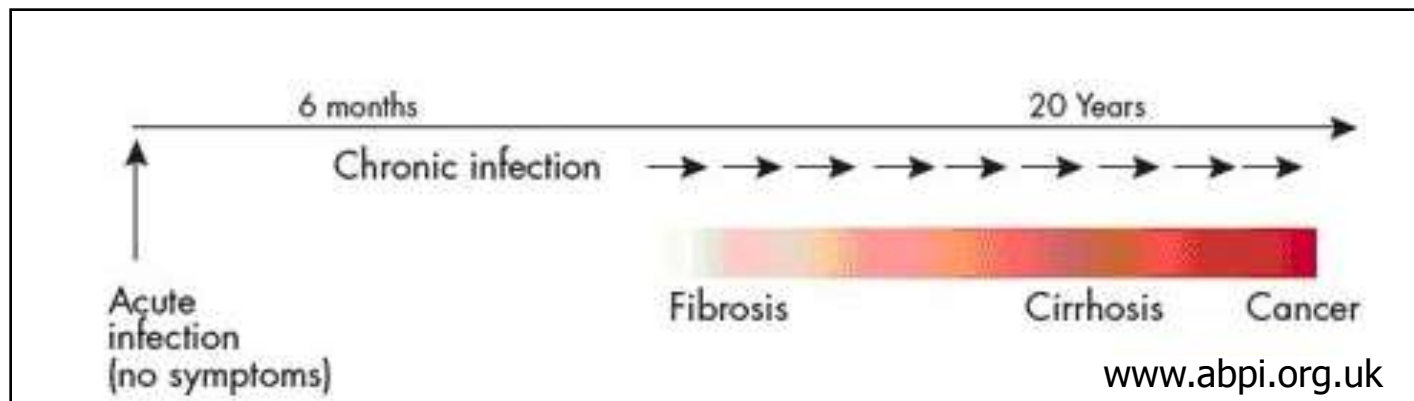
- I. Hepatitis C Epidemiology
- II. Benefits of POLHEPREVIR
- III. Market Potential
- IV. Recommended Strategy

“The worldwide antiviral market is estimated to grow from \$18 billion to as much as \$25 billion by 2011”

*The World Market for Anti-Infectives 2007*

# Hepatitis C Epidemiology

- Blood-borne Viral Infection
- Major Cause of Liver Disease
- 4 million infected in U.S.
  - Genotype 1: 3 million
  - Genotypes 2 and 3: 1 million
- 30,000 new infections/year
- 2 million unresponsive to current treatments
- Delayed treatment results in costly complications and adverse outcomes



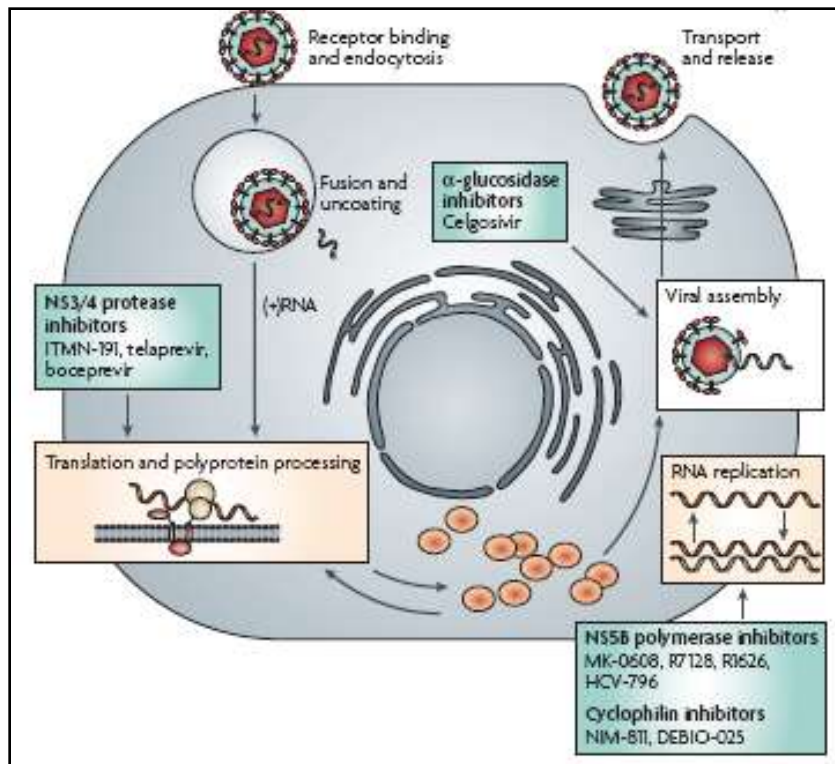
# Complications with Current Therapy

## Peg-IFN $\alpha$ + Ribavirin for 48 weeks

- 50% of total patients do not respond
- Genotype 1 does not respond well
- Development of resistance
- Serious Side Effects:  
Anemia, Depression, Nausea, Injection-site Reaction and Inflammation
- Low Patient Compliance

# POLHEPREVIR

## Targeted HCV therapy for Genotype 1



- Polymerase Inhibitor
- Phase II trial completed
- Combination with Peg-IFN $\alpha$  and Ribavirin
- 24 Week Treatment
- Increased SVR
- Diagnostic Test

# The **POLHEPREVIR** Advantage

Drug Class	Drug Product		POLHEPREVIR Provides		
	Drug	Pharmaceutical Manufacturer	Decrease Peg-IFN	Initial Entrant	Lower Toxicity
Protease Inhibitors	Telaprevir	Vertex/Tibotec Therapeutics	✓		
	Boceprevir	Schering Plough	✓		
	ACH-806	Gilead/Achillon	✓	✓	
	BI-201335	Boehringer Ingelheim	✓	✓	
Polymerase Inhibitors	VCH-759	ViroChem Pharma		✓	
	R-1626	Roche		✓	
	HCV-796	Wyeth		✓	✓
	Valopicitabine	Novartis		✓	✓

POLHEPREVIR

# Benefits

Payer

Physician

Patient

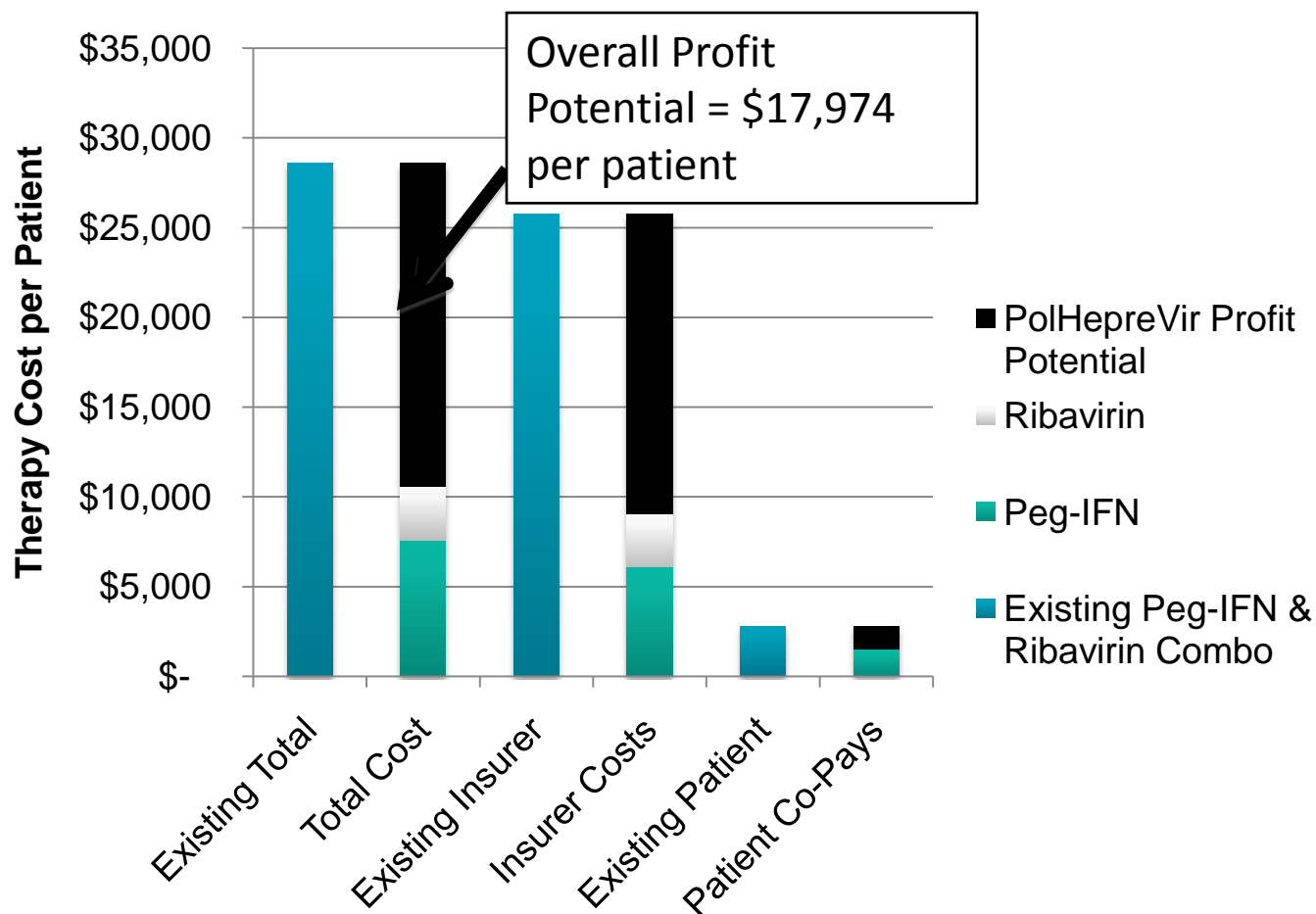
Cost-Effective  
Shorter Treatment Course  
Reduced Indirect Cost  
Diagnostic Test

Shorter Treatment Course  
Improved Quality of Treatment  
Improved Outcomes

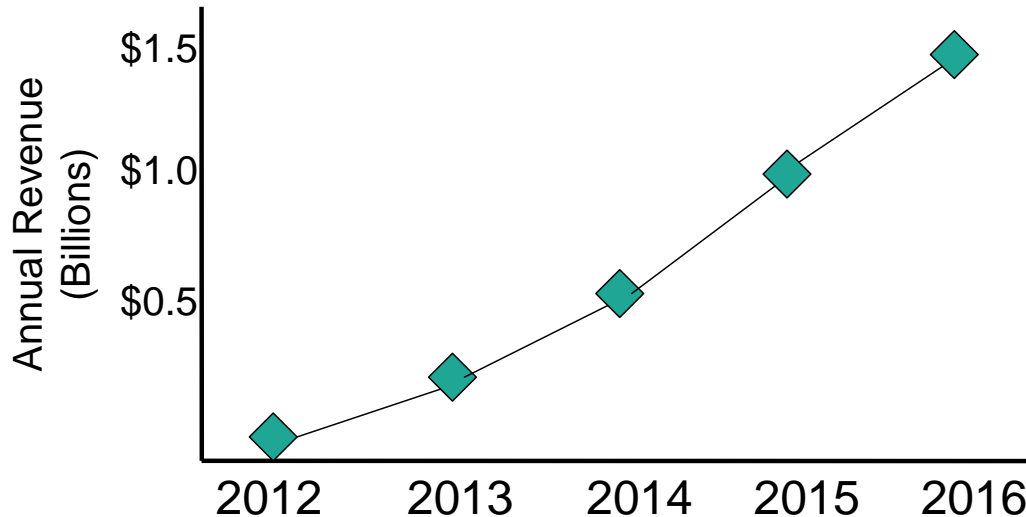
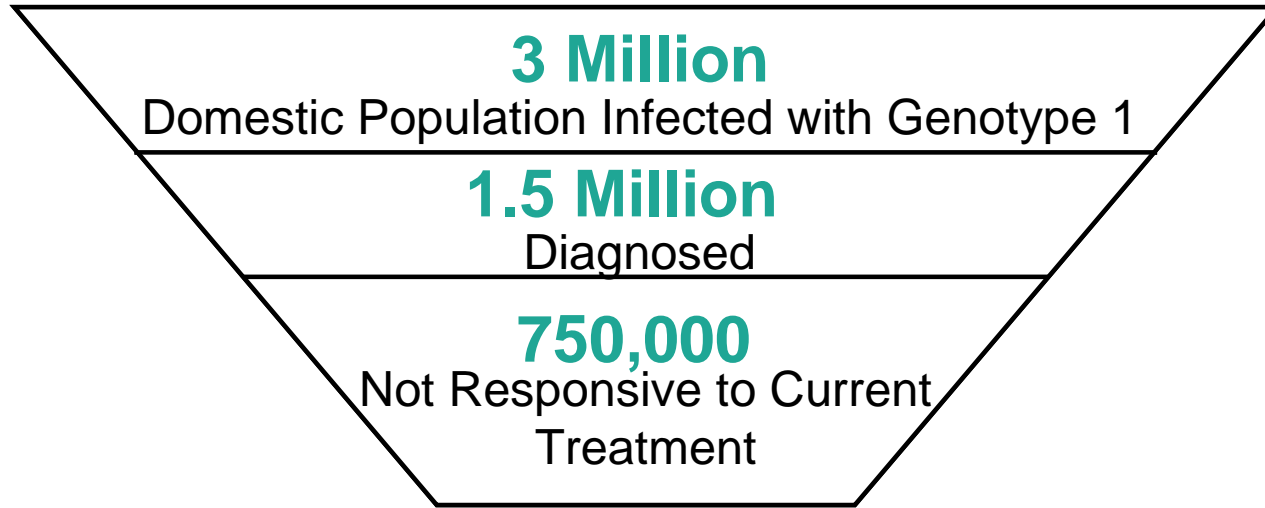
Relapser Treatment  
Non-responder Treatment  
Patient Compliance

# Market Pricing Potential

Utilizing a 20% reduction in Peg-IFN coupled with 50% shorter treatment schedule, market pricing potential is significant.



# Opportunity for Profit and Market Share



Potential Revenue over lifetime of patent = \$3 billion

# Messaging the Market

## **Payers**

**Insurers, State, & Federal  
Providers of Access to Care**

**GOAL:** Placement on formulary

### **Message:**

Cost-effective  
Decreased Treatment Time

### **Mechanism:**

Direct Communication Strategy  
Relationship Development  
Strategic Pricing Opportunities

## **Physicians**

**Infectious Disease  
Specialists,  
Gastroenterologists, and  
Hepatologists**

**GOAL:** Patient Prescription

### **Message:**

Higher Patient Compliance  
Increased SVR

### **Mechanism:**

Targeted Physician Promotion  
Relationship Development  
Medical Journal Advertising

# Recommendations


- Proceed with Phase III trials
- Upon FDA approval pursue Genotype 1 population through prescribed marketing mechanisms
- Opportunities for revenue in excess of \$3 billion



# Potential Risks

Risk	Potential	Mitigation Strategy
Fails Phase III Trials	Low	None
Only approved for one subgroup (naïve, non-responders, or relapsers)	Medium	Market to physicians specializing in treatment group
Teleprevir and/or Boceprevir have significant advantages over PolHepreVir	Unknown	Identify specific subgroup with improved results
Patients develop resistance	High	Combination Therapies

# Worldwide Opportunities



WHO Region	Total Population (million)	Infection Rate	Infected Population (million)
Africa	602	5.3	31.9
Eastern Mediterranean	466	4.6	21.4
Europe	858	1.03	8.8
South-East Asia	1500	2.15	32.3
Western Pacific	1600	3.9	62.4

- After FDA approval, submit to EMEA's Human Medicine Board for approval
- Must hire marketing agency with EU expertise due to differences in marketing
- Possible collaborations to bring drug to market in the developing world

# Targeted Physician Breakdown

- 15,371 offices of hematology, gastroenterology, and infection disease
- 26,454 doctors
- Medical Journals
  - NEJM
  - Journal of Infectious Diseases,
  - American Journal of Gastroenterology
- 1 representative per 8 offices = 1900 reps.
- *Lipitor* – 2,400 representatives
- Less aggressive – 1000 reps.

# Projected Revenue Flow

Assigning a price of \$14,000 per 24 week treatment, leaves a margin of \$4000 between existing therapy pricing and PolHepreVir for the duration of the HD patent

	Market Penetration	<b>Annual Revenue</b>	Population Estimate
2012	0%	<b>\$-</b>	
2013	6%	<b>\$420,000,000</b>	500000
2014	13%	<b>\$587,860,000</b>	484500
2015	21%	<b>\$854,589,400</b>	436015
2016	34%	<b>\$1,139,073,871</b>	358951.85

Total Expected Revenue through Life of Patent = \$3,001,523,270



# HIV-HCV Co-Infected

- 33% of people with HIV also have HCV
- Many HIV treatments cause liver toxicity
- Some HIV drugs increase risk of anemia from ribavirin
- HCV therapy is less effective in people with less than 200 CD4 T cells
- IFN $\alpha$  decreases CD4 T cell levels