

The background of the slide is a blurred photograph of a laboratory setting. It features several pieces of glassware, including a large Erlenmeyer flask in the center, a graduated cylinder to its right, and a beaker to its left. The glassware is filled with a clear liquid. The overall color palette is light blue and white, giving it a clean, scientific appearance.

Medivir

November 2013
AASLD Investor Event
4 November

Maris Hartmanis, President and CEO
Charlotte Edenius, EVP Development
Bertil Samuelsson, CSA
Rein Piir, EVP Corporate Affairs & IR

Strategic overview

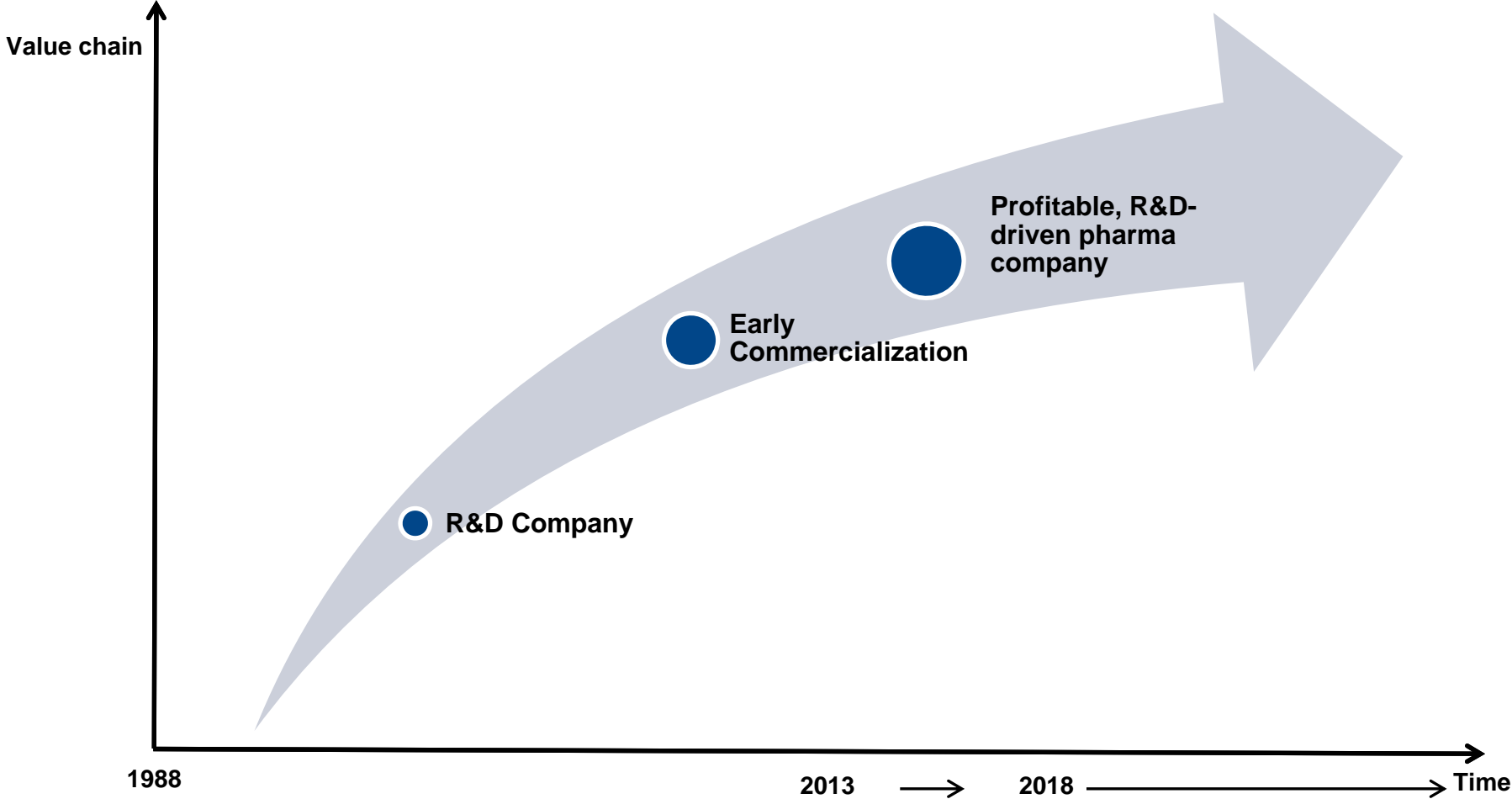
Maris Hartmanis, CEO

Medivir is well positioned for the future

- Discovery and research based pharmaceutical company with 16 marketed Rx pharmaceuticals in the Nordics
- World leading expertise in polymerase and protease drug targets
- Solid financial position and on the way to profitability
- Extensive collaboration and partnership track record with major global pharma companies
- Two in-house products developed from early research to commercialization
- Six projects currently in the R&D portfolio
- 130 employees, 90 of which are in R&D, from 16 nations

Recent milestones have generated significant momentum for Medivir

Medivir is rapidly evolving



We are on a journey to transform Medivir into a pharma company with long-term sustainable profit and growth

Our R&D pipeline is the engine of Medivir

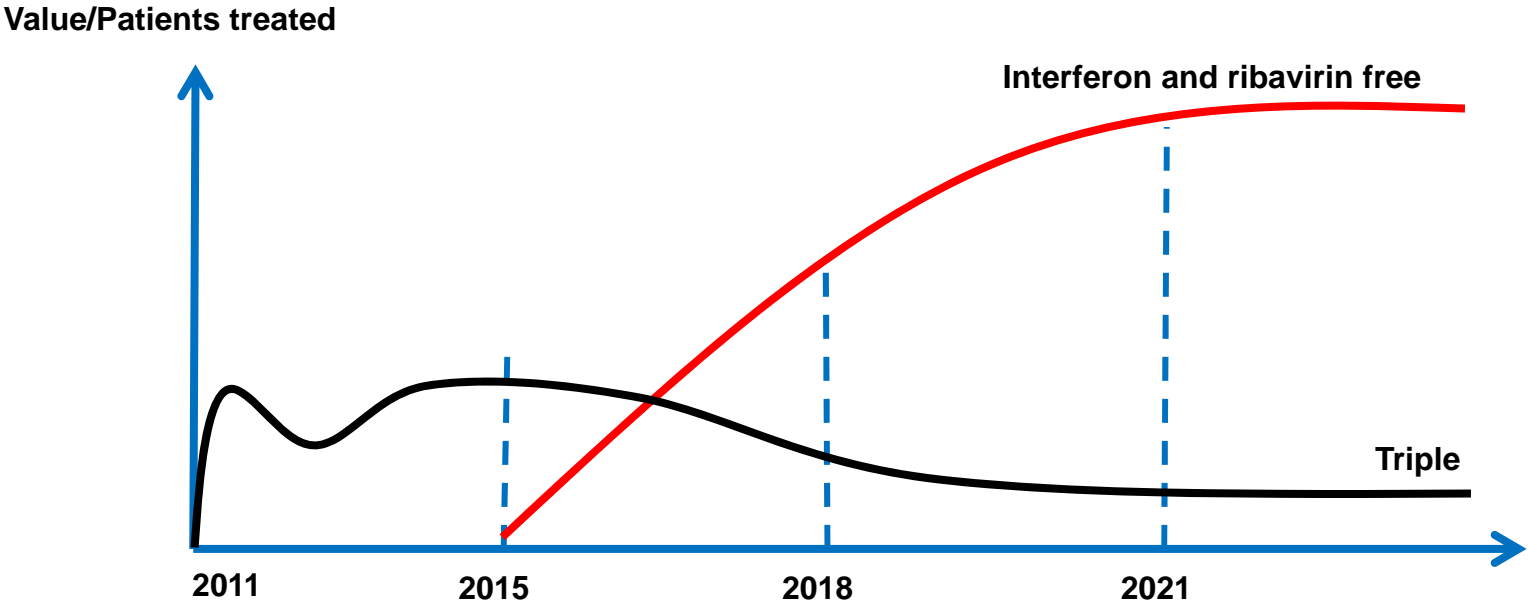
Field	Project	Partner	Preclinical phase		Clinical phase				Market	
			Re- search	Deve- lopment	Phase I	Phase IIa	Phase IIb	Phase III		
Anivirals										
Labial herpes	Xerclear (Zovido, Zovirax Duo)	GlaxoSmithKline (GSK)	[Green bar spanning Re-search, Deve-lopment, Phase I, Phase IIa, Phase IIb, Phase III]							
Hepatitis C	Simeprevir (TMC435), NS3 protease inhibitor	Janssen Pharmaceuticals	[Green bar spanning Re-search, Deve-lopment, Phase I, Phase IIa, Phase IIb, Phase III]							Approved in Japan
Hepatitis C	NS5B nucleotide-based polymerase inhibitor	Janssen Pharmaceuticals	[Green bar spanning Re-search, Deve-lopment]							
Hepatitis C	NS5B nucleotide-based polymerase inhibitor	Unpartnered	[Green bar spanning Re-search]							
HIV	Protease inhibitor	Janssen Pharmaceuticals	[Green bar spanning Re-search]							

Other indications

Bone related disorders	Cathepsin K inhibitor	Unpartnered	[Blue bar spanning Re-search, Deve-lopment, Phase I]				Phase I data		
Neuropathic pain	Cathepsin S inhibitor	Unpartnered	[Blue bar spanning Re-search, Deve-lopment]		CD nominated				

Simeprevir will play a central role in the transformation of the company

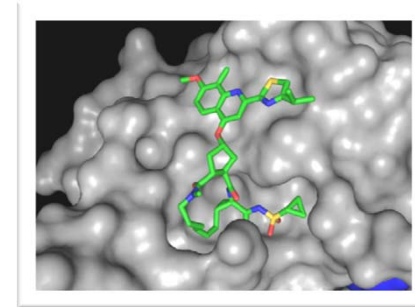
We are committed to advancing the treatment of hepatitis C



Simeprevir update

Charlotte Edenius, EVP Development

Simeprevir: a next generation HCV protease inhibitor



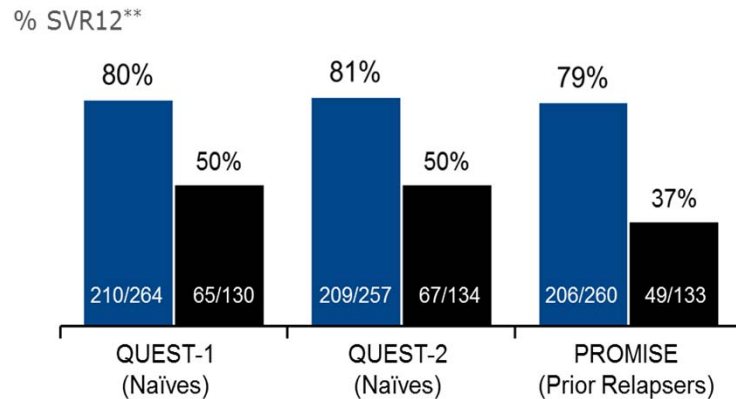
- Approved in Japan with a broad label
- Under review in US and EU
 - Unanimous recommendation for approval at Oct. 24 FDA AdCom
- Activities underway to expand commercial opportunity of triple regimen
- An important cornerstone in coming IFN free treatment options
 - currently studied in a large number of IFN and ribavirin free combinations

Simeprevir – High cure rates in broad patient populations and a favorable safety profile

Simeprevir - pivotal phase III studies highlight differentiated profile

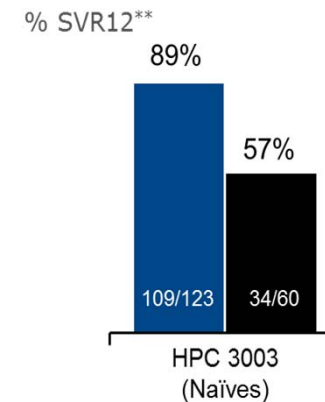
Global

- ~80% overall cure rates
- 83-91% SVR12 with 24 weeks treatment (up to 91% of the patients)



Japan

- 89-92% overall cure rates in naive patients
- 96-100% SVR12 in prior relapsers



Simeprevir showed robust overall efficacy in all studies with overall comparable adverse event profile to IFN/ribavirin

Additional phase III studies of simeprevir triple therapy to enhance commercial profile

12 week treatment duration

- **12 weeks full stop triple combination study**, open-label, single-arm study in treatment naïve GT1 patients
 - Recruitment ongoing

Regional expansion - China

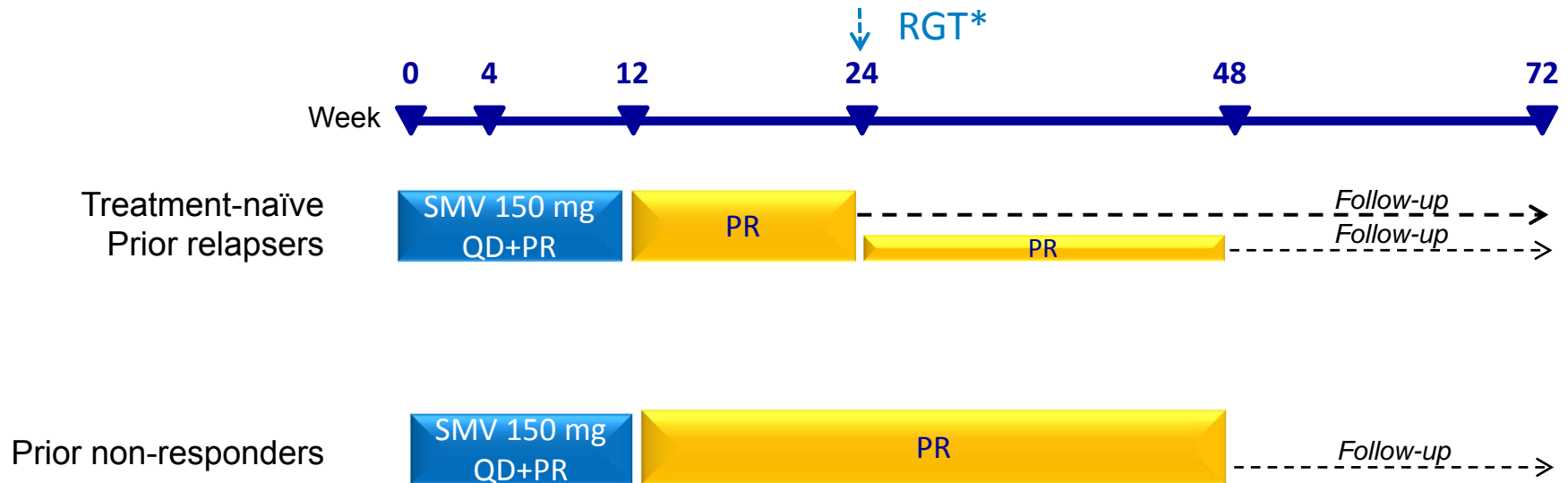
- A pivotal study of Efficacy, Safety & Tolerability and Pharmacokinetics in treatment naïve GT1 HCV patients (*fully enrolled; n=444*)

Patient population expansion

- **Genotype 4 HCV infected patients**
 - Interim results presented at EACS, Brussels, Oct 2013
- **HIV/HCV co-infected patients**
 - Primary SVR12 results at EACS, Brussels, Oct 2013

RESTORE: HCV genotype 4 infected patients

Interim analysis

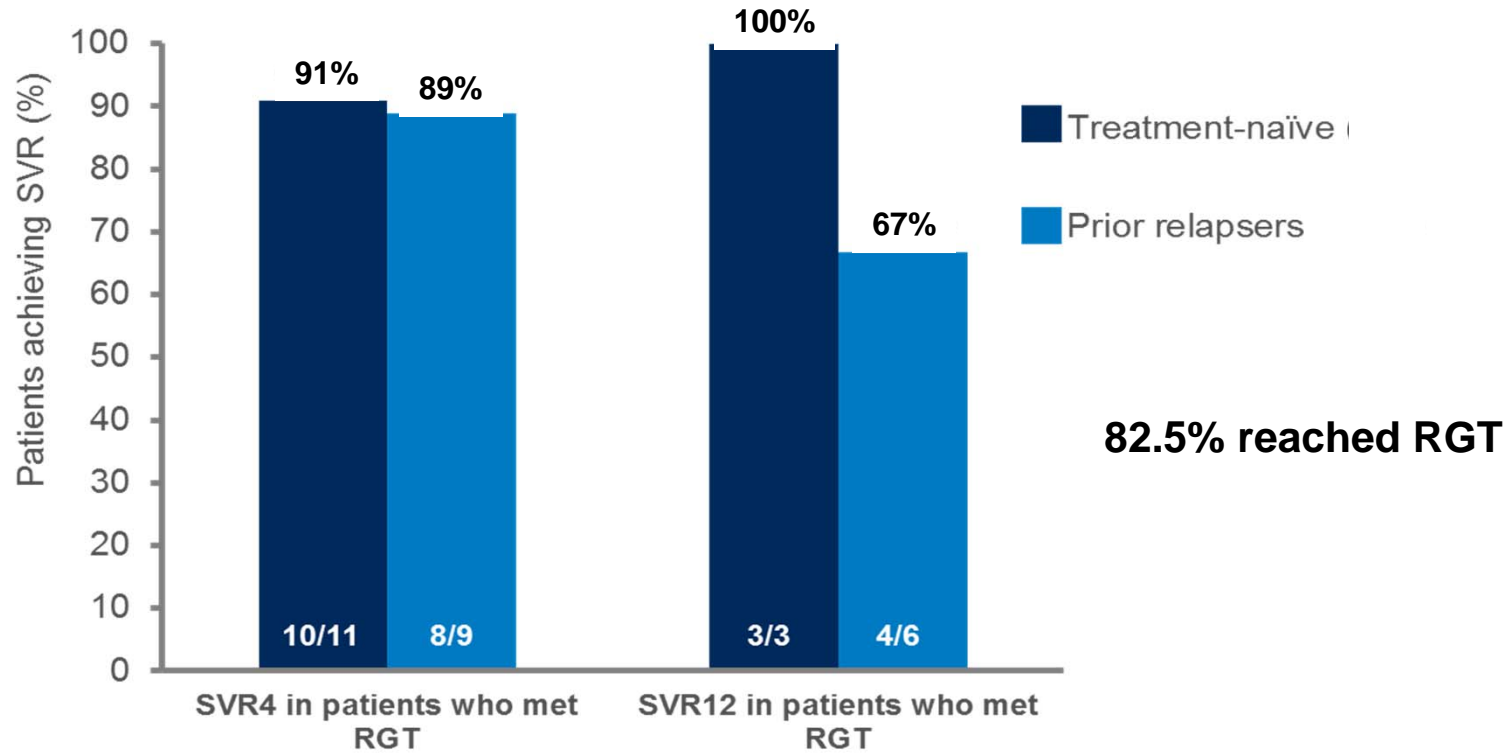


At time of interim analysis SVR could only be assessed in patients who met RGT and reached study visit W28 (SVR4) and W36 (SVR12)

HCV genotype 4 accounts for approximately 20% of all cases of chronic HCV worldwide¹

HCV genotype 4 infected patients

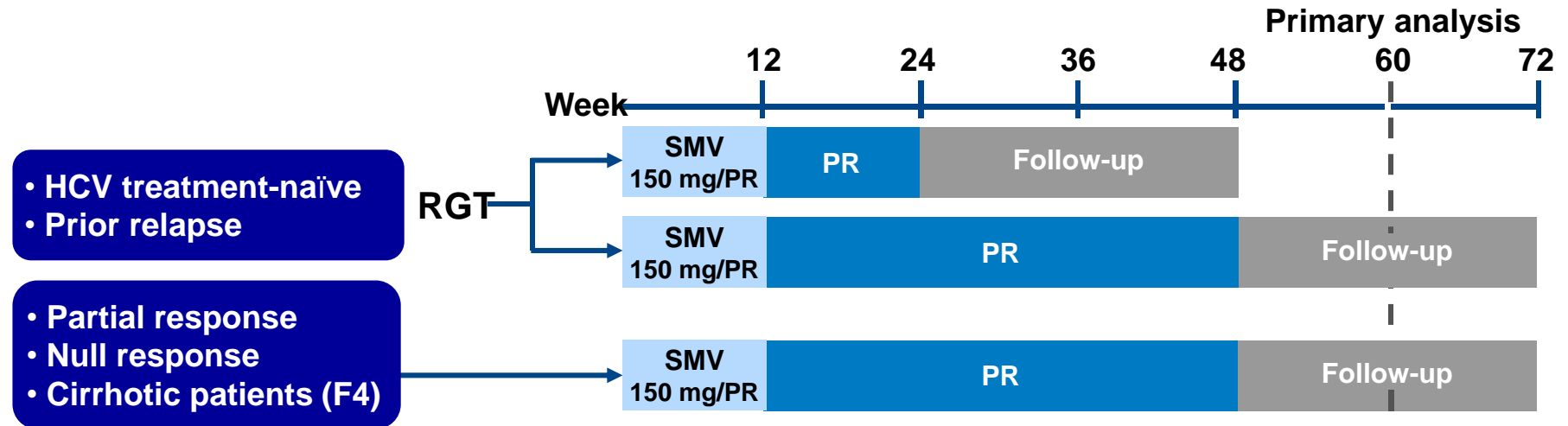
Results & conclusions from interim analysis



The interim analysis suggests good efficacy and safety of simeprevir also in patients with HCV genotype 4 infection

HCV/HIV co-infected patients

Study design



- N=106
- Primary endpoints: SVR12, safety and tolerability

In the US 25 % of HIV patients are coinfectd with HCV

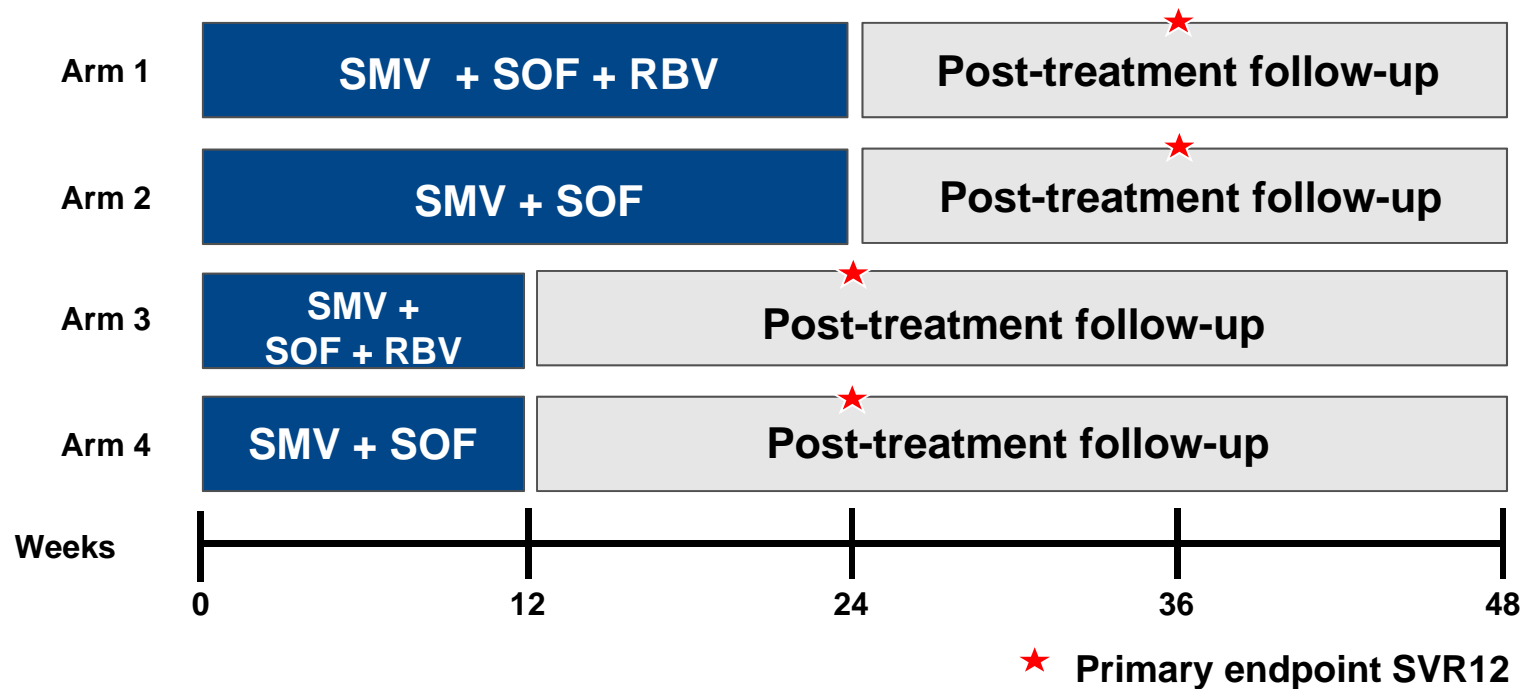
HCV/HIV co-infected patients

Results & conclusions

- SMV QD + PR for 12 weeks led to high rates of SVR12 regardless of prior HCV treatment response
 - **Treatment-naïve** **79%**
 - **Prior relapsers** **87%**
 - **Prior partial responders** **70%**
 - **Prior null responders** **57%**
- SVR12 rates were high, regardless of baseline METAVIR fibrosis score
 - **64% SVR12 in F3-4 patients**
- **87% SVR12 with 24 weeks** therapy (89% of eligible patients)
- Well tolerated with a safety profile similar to that observed in mono-infected patients

Simeprevir was safe and efficacious in a broad population of HCV-HIV co-infected patients

COSMOS study was the first in a series of collaborative studies for DAA combinations



- Cohort 1: n=80, nulls, F0-F2 - *SVR12 data available*
- Cohort 2: n=87, naives and nulls, F3-F4 - *SVR4 data available*
- SMV 150 mg QD + SOF 400 mg QD +/- RBV

COSMOS study

– results from 12 weeks treatment arms

	Cohort 1 Null responders (METAVIR F0-F2)		Cohort 2 Null responder and treatment naïve (METAVIR F3 or F4)	
	SMV / SOF+ RBV (n=27)	SMV / SOF (n=14)	SMV / SOF + RBV (n=27)	SMV / SOF (n=14)
SVR4	96 (26/27)	93 (13/14)	96 (26/27*)	100 (14/14**)
SVR12	96 (26/27)	93 (13/14)	-	-
SVR4/12 (GT1a Q80K positive)	89 (8/9)	83 (5/6)	88 (7/8)	100 (3/3)

*null responders 93 (14/15) ** null responders 100 (7/7)

High efficacy in hardest to cure HCV patients also without ribavirin



COSMOS Study

12 weeks treatment with SMV + SOF ± RBV:

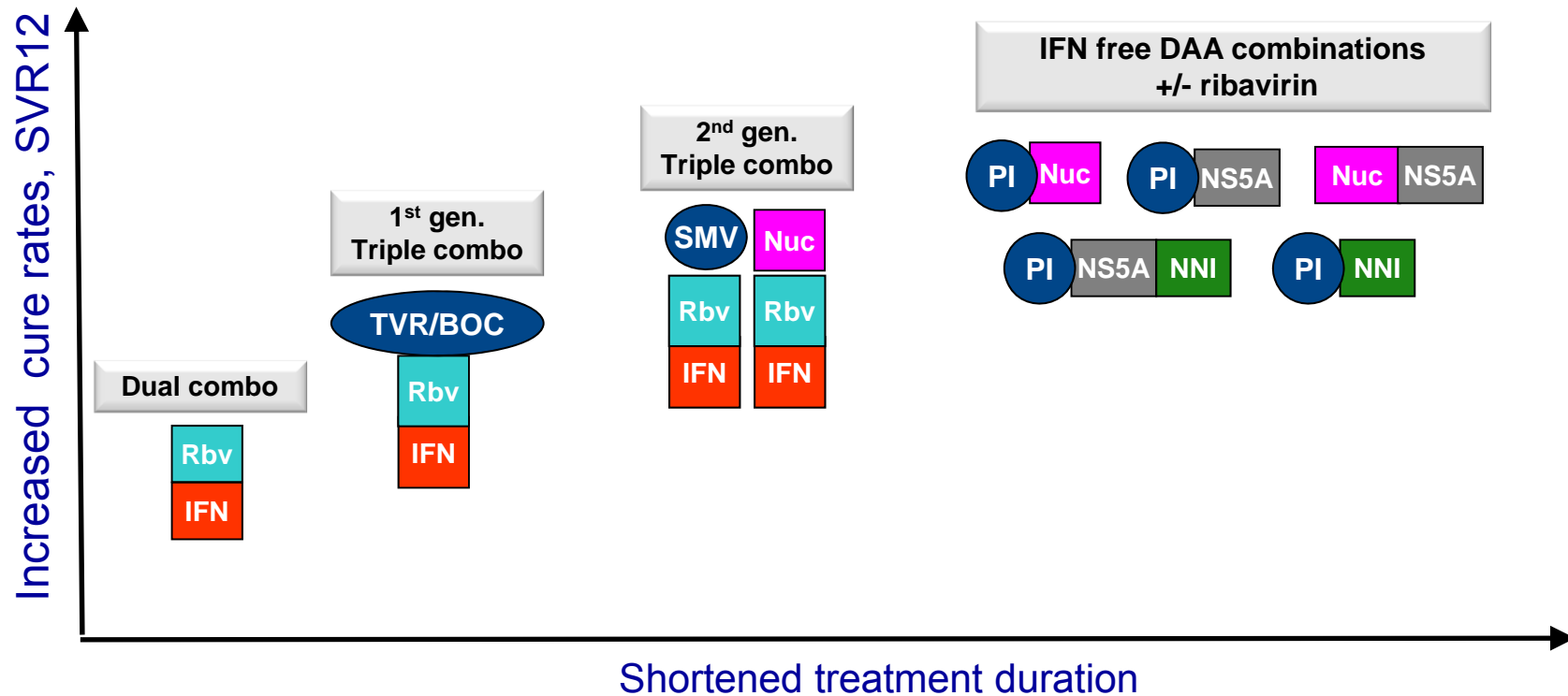
- High SVR12 rates (93-96%) in HCV GT 1 null responder patients with METAVIR F0-F2
- High SVR4 rates (96-100%) in naïve and null responder patients with METAVIR F3-F4
- No benefit from adding ribavirin to SMV and SOF in this difficult to treat groups of hepatitis C patients
- SMV + SOF ± RBV was generally well tolerated
 - Anemia and bilirubin increases were predominantly limited to the RBV-containing treatment arms

High efficacy in hardest to cure HCV patients also without ribavirin

HCV market overview

Rein Piir, EVP Corporate Affairs & IR

We are in the late stages of the evolution to all oral, interferon-free treatment

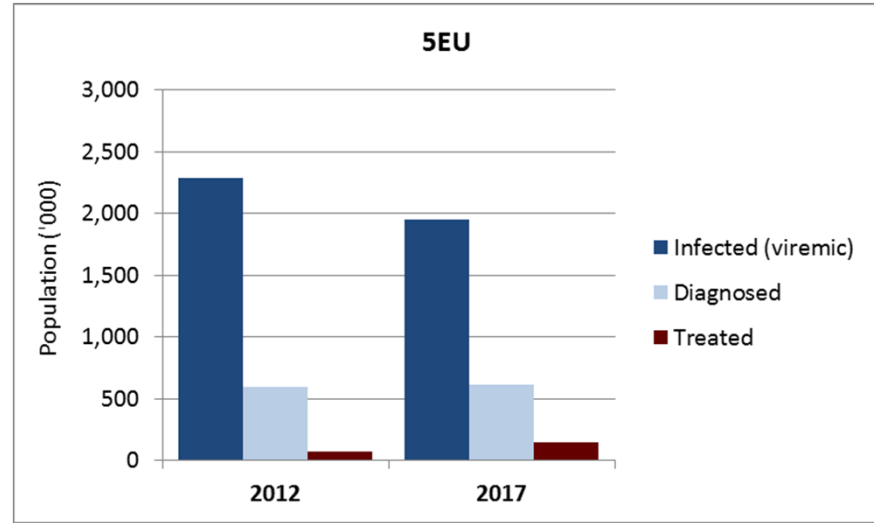
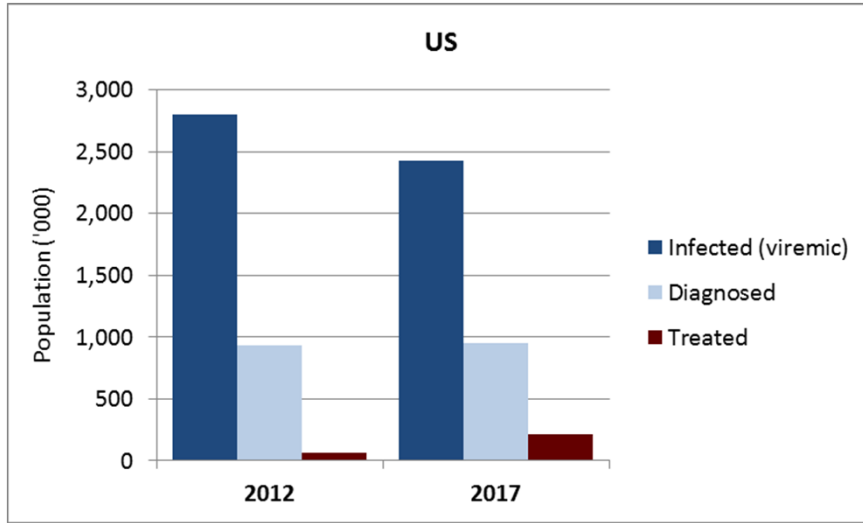


Different combinations of direct acting antivirals (DAAs) have shown good efficacy in various patient populations

Data driven approach to exploring different interferon free simeprevir combinations (with or w/o ribavirin)

Simeprevir given in combination with:	Investigational compound	Study information
Nucleotide	Sofosbuvir	COSMOS : Cohort A: nulls ; Cohort B: nulls + naives (F3&4)
	VX-135	DDI finished, Next step to start Phase II
NS5A inhibitor	Daclatasvir	Naives and nulls, F0-F4
	Samatasvir	HELIX-1: Phase II on-going (Gt1b and 4)
NS5A inhibitor + NNI	TMC647055 + Samatasvir	HELIX-2 to start YE-13
	TMC647055 + GSK2336805	Phase II, in planning phase
+ NNI	TMC647055	Naives/relapser and nulls

Hepatitis C dynamics can provide long-term market growth through increases in treatment and diagnosis rates



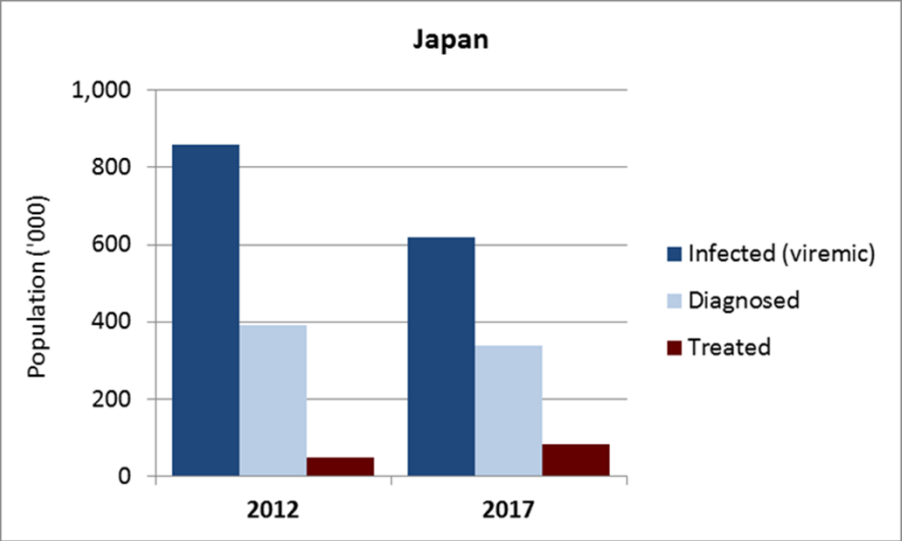
Source: Decision Resources (July, 2013)

Genotype	US (%)	5EU (%)
1a	54	15
1b	20	55
2	16	9
3	7	14
4	1	6
5&6	2	1

Source: Datamonitor (2011)

Japanese HCV market has similar dynamics to US/EU but is larger and more concentrated than many realize

Hepatitis C Patient Population in Japan



Source: Decision Resources (July, 2013)

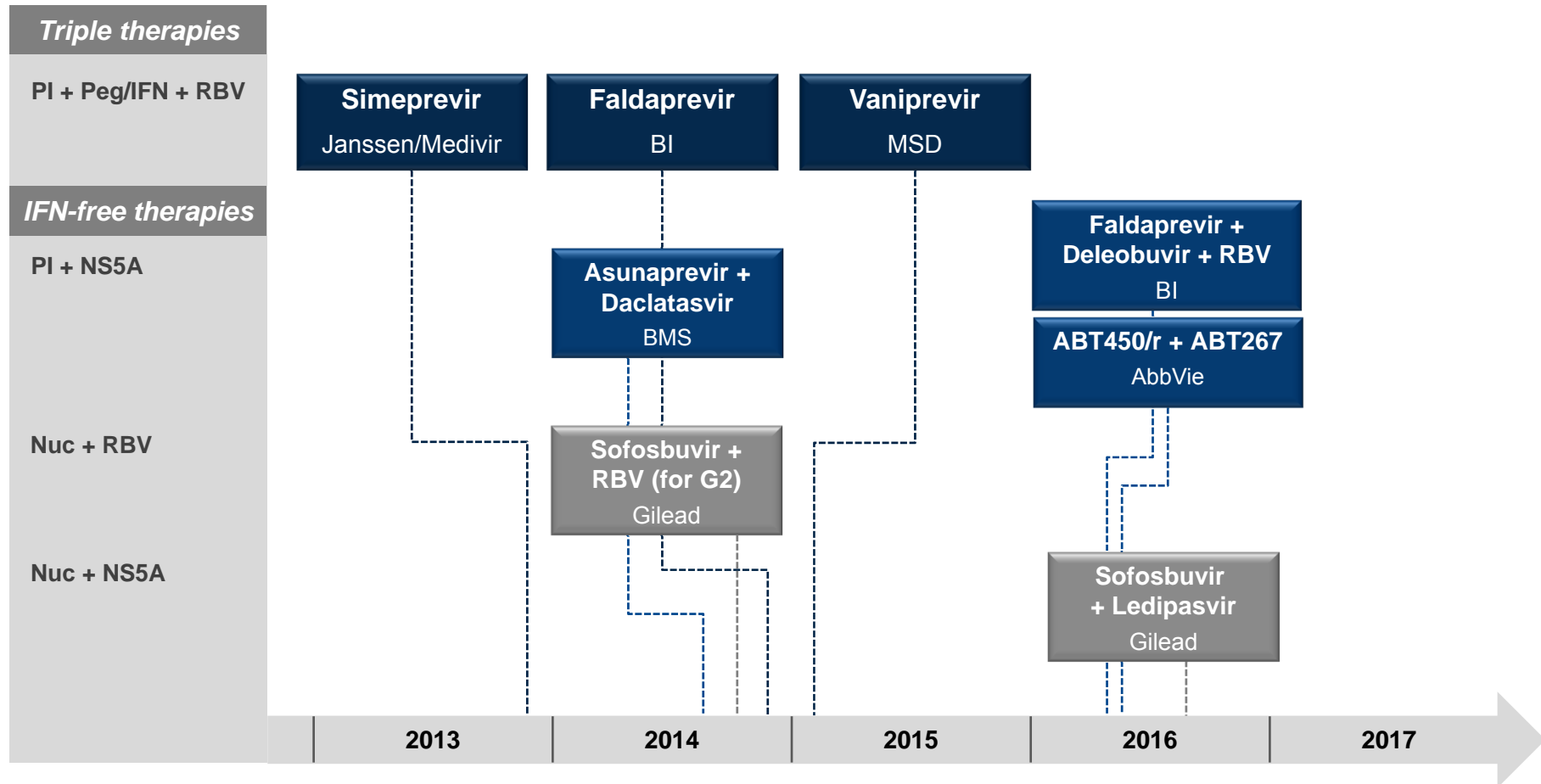
Genotype distribution in Japan

Genotype	JP (%)
1a	3
1b	66
2	30
3	1
4	0
5&6	0

Source: Datamonitor (2011)

Known pricing data from Japan	
<ul style="list-style-type: none"> ▪ Telaprevir price lower than US and EU 	Approx. \$13,000
<ul style="list-style-type: none"> ▪ Potential for price premium <ul style="list-style-type: none"> ○ Approximately 30% premium possible for the same mechanism ○ Higher levels can only be negotiated for new mechanisms 	

Simeprevir has a head start on the competition in Japan



Summary of Japanese HCV market dynamics

- Large prevalence (1.5-2 M) of HCV infection, >500 K diagnosed, with ~50-60 K patients treated annually
- Competition at less advanced stage than in US/EU
- With the majority of patients infected with genotype 1b virus, Japan is an ideal market for a DAA combo treatment containing an HCV PI, NS5A or nucleotide
- Pricing of TPV (~13 K USD) plus IFN/RBV substantially lower than EU/US; higher prices can be negotiated for improved regimens or new mechanisms, i.e. IFN-free combos

Simeprevir is well positioned to be a leading HCV therapy in the Japanese market

www.medivir.com

Ticker: MVIR
Exchange: OMX / NASDAQ

**For more information please contact
Rein Piir, EVP Corporate Affairs & IR
(rein.piid@medivir.com)**

High cure rates even in difficult-to-cure sub-groups of treatment-naive and treatment-experienced patients

QUEST-1 and 2

	Cure rate (SVR12) %		Week 4 response (RVR) %	SVR12 in those who achieved RVR %
	SMV + PR	PBO + PR	SMV + PR	SMV + PR
<i>All patients</i>	80*	50	78	90
METAVIR F4	60*	34	67	75
IL28B TT	61*	21	69	77
HCV GT 1a overall	75*	47	72	87
HCV GT 1a with Q80K	58*	47**	63	79

Early treatment response (undetectable HCV RNA at Week 4) predicts high cure rates

PROMISE

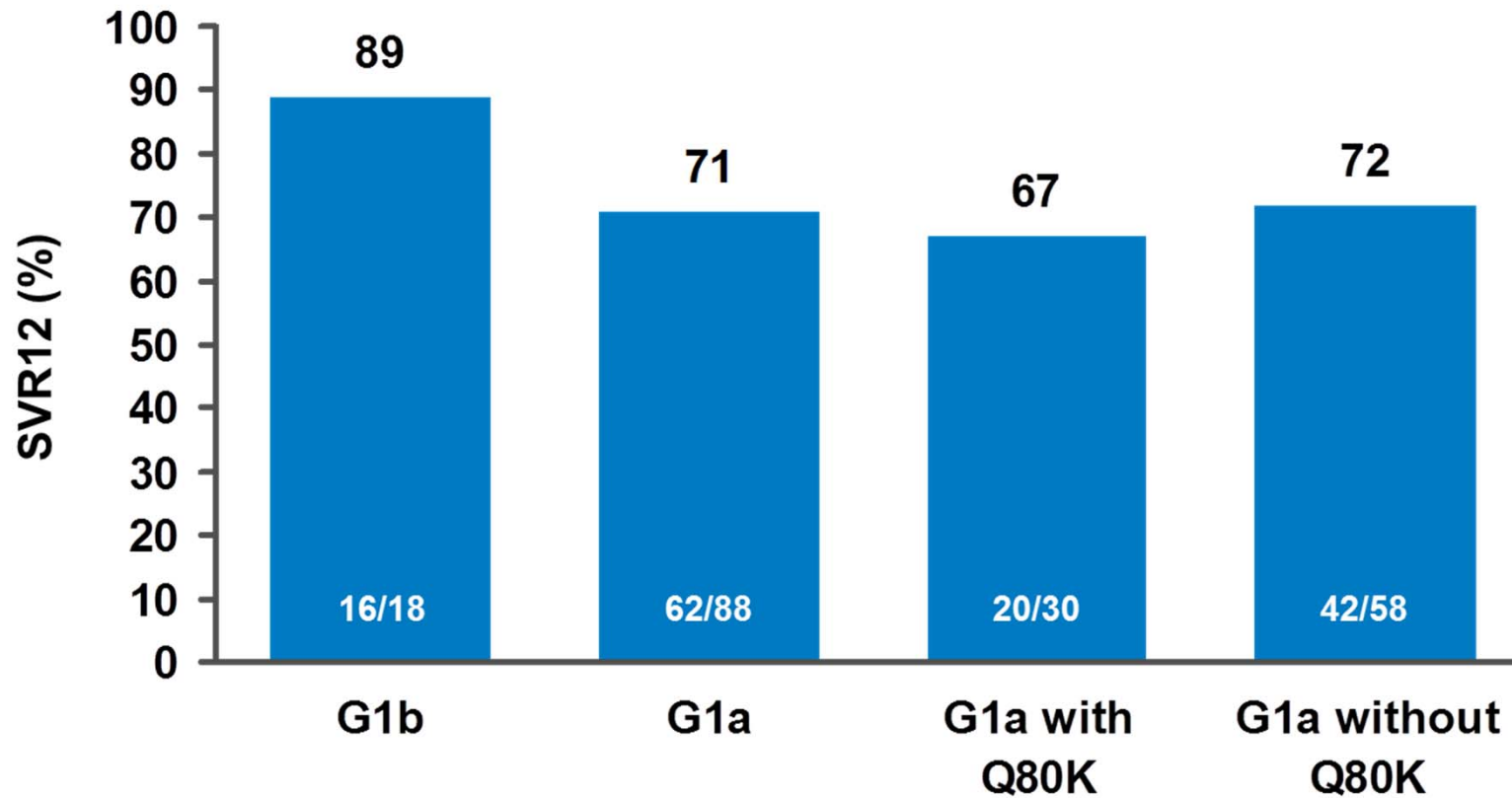
	Cure rate (SVR12) %	
	SMV + PR	PBO + PR
<i>All patients</i>	79*	37
METAVIR F4	74*	26
IL28B TT	65*	19
HCV GT 1a overall	70*	28
HCV GT 1a with Q80K	47*	28**

Strong clinical benefit across sub-populations of prior relapsers



*p<0.05 for all comparisons SMV vs PBO; ** pooled placebo, includes all GT1a patients
SMV: simeprevir; PR; Peginterferon/ribavirin; RVR: Rapid Virologic Response

C212: SVR12 by HCV-1 G1 subtype and baseline NS3 Q80K polymorphism



Simeprevir triple therapy has comparable AEs and discontinuation rates to IFN/ribavirin

Patients, %	QUEST-1 ¹		QUEST-2 ²		PROMISE ³	
	SMV + PR (N=264)	PBO + PR (N=130)	SMV + PR (N=257)	PBO + PR (N=134)	SMV + PR (N=260)	PBO + PR (N=133)
Grade 3 or 4 AE	23	29	26	24	20	21
Serious AE	3	4	2	2	1	2
AE leading to discontinuation of SMV	3	3	2	1	0	0
Most common AEs⁴						
Fatigue	40	38	35	39	32	42
Headache	31	37	37	34	32	36
Rash (any type)	27	25	24	11	18	14
Pruritus	21	11	19	15	24	16
Pyrexia			30	36		
Influenza-like illness			26	26	30	20
Other AEs of interest						
Increased bilirubin	9	4			6	2
Photosensitivity	3	1	4	1	4	0
Anemia	16	11	14	16	11	6
Neutropenia	19	11			15	16

Overall incidence of adverse events was similar to placebo control



¹Jacobson I *et al.* EASL 2013; ²Manns M *et al.* EASL 2013; ³Lawitz *et al* DDW 2013; SMV: simeprevir; PR: PEG-interferon + ribavirin; PBO: placebo

⁴≥25% in SMV arm in either study

Phase II data of various PI based combinations have shown promising results

