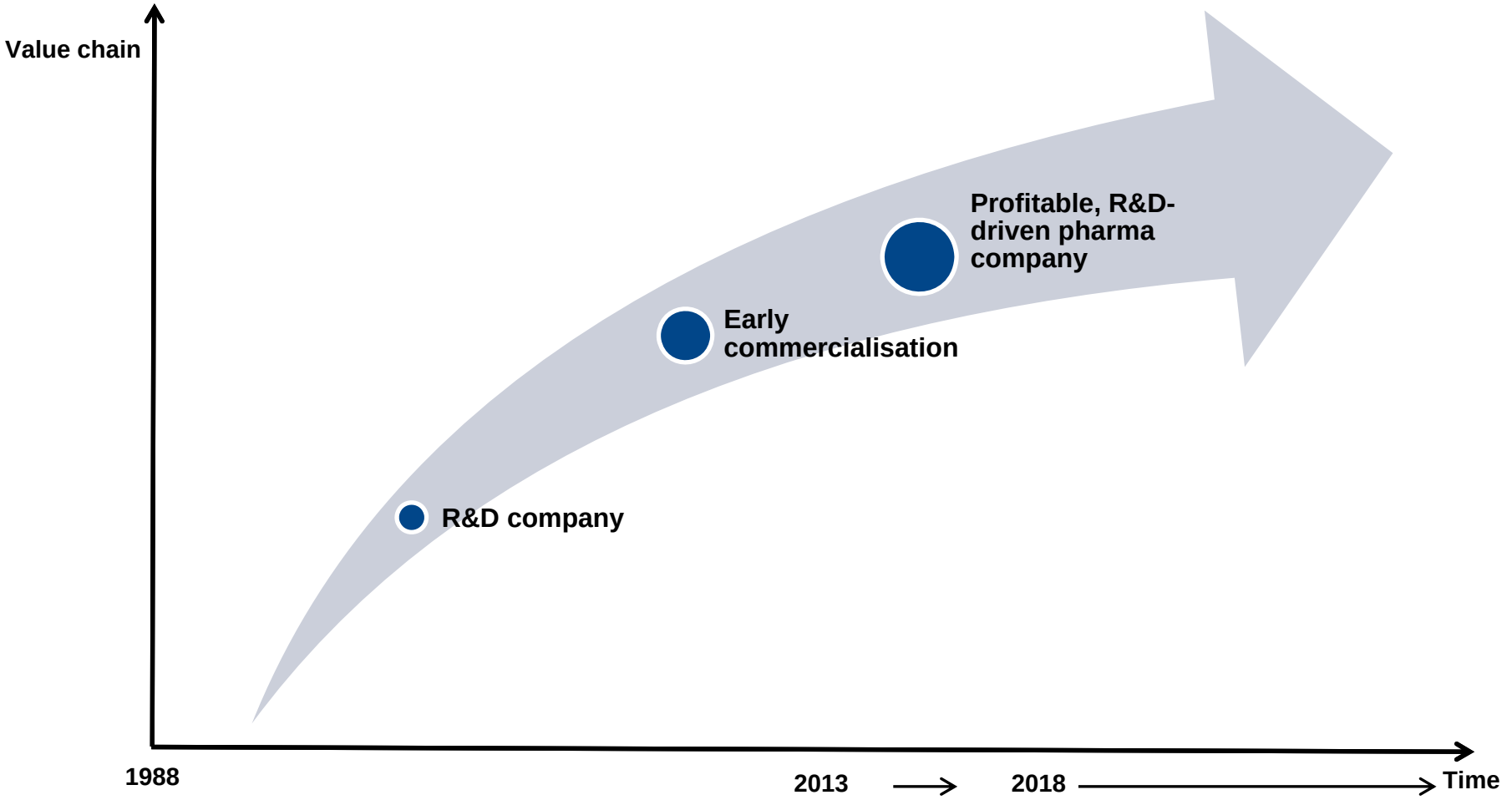
Medivir

A collaborative and agile pharmaceutical company with an R&D focus on infectious diseases and a leading position in hepatitis C

Redeye 28 November 2013

Rein Piir, EVP Corporate Affairs & IR

The transformation of Medivir



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

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

A pharmaceutical company, innovation and R&D driven with own marketing presence in the Nordic's

Recent highlights

- ✓ MIV-247 selected as Candidate Drug in our cathepsin S program. Now in pre-clinical development for the treatment of neuropathic pain.
- ✓ Phase I data on MIV-711 presented in our cathepsin K program. Different potential partnership structures under evaluation.
- ✓ Evaluation of our future discovery research strategy ongoing

- ✓ ADASUVE, a new Rx pharmaceutical was added to our Nordic portfolio

- ✓ Simeprevir has been approved in Japan, Canada and USA
- ✓ The approvals in Japan and USA triggered a milestone payment of €15m to Medivir
- ✓ Our partner Janssen acquired an NS5A replication complex inhibitor. Simeprevir will be evaluated with JNJ-56914845 in upcoming interferon-free trials
- ✓ Many new all oral interferon free trials with simeprevir to start ion the near future

Recent milestones have generated significant momentum for Medivir

We are committed to delivering sustainable shareholder value

Structure	Focus	Profitability
• Maintain financial discipline • Efficiently deploy resources • Maximize leverage • Identify new opportunities	• Key pipeline programs • Retain strategic products, partner others • Commercial targets • Geography	• Own products portfolio • Simeprevir revenue • Opportunistic product additions • Responsible R&D investment

We are excited to continue our momentum by achieving key R&D, commercial, and financial milestones

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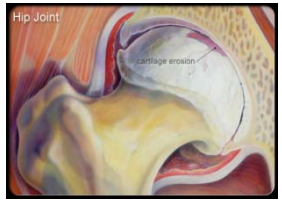
Our R&D pipeline is the engine of Medivir

Field	Project	Partner	Preclinical phase: Re-search	Preclinical phase: Deve-lopment	Clinical phase: Phase I	Clinical phase: Phase IIa	Clinical phase: Phase IIb	Clinical phase: Phase III	Market
Antivirals									
Labial herpes	Xerclear (Zoviduo, Zovirax Duo)	GlaxoSmithKline (GSK)							
Hepatitis C	Simeprevir (TMC435), NS3 protease inhibitor	Janssen Pharmaceuticals				Approved in			
Hepatitis C	NS5B nucleotide-based polymerase inhibitor	Janssen Pharmaceuticals							
Hepatitis C	NS5B nucleotide-based polymerase inhibitor	Unpartnered							
HIV	Protease inhibitor	Janssen Pharmaceuticals							
Other indications									
Bone related disorders	Cathepsin K inhibitor	Unpartnered					Phase I data		
Neuropathic pain	Cathepsin S inhibitor	Unpartnered					CD nominated		

MIV-711 - A cathepsin K inhibitor for osteoarthritis (OA) and other bone related disorders

Mechanism of action

- Cathepsin K degrades collagen in both bone and cartilage
- Pathological processes in both cartilage and bone occur in OA
- Genetic, animal and human data shows that cathepsin K inhibition improves bone quality



Phase I study recently finished

- Placebo controlled, double-blind study in healthy subjects
- Ascending single and multiple (7 - 28 days) once daily dosing
- Included biomarkers for bone and cartilage turnover
- Multiple dose data recently presented*
- Partnering activities initiated aiming for partnership for further clinical development

Our clinical data support further development of MIV-711 for osteoarthritis and other bone related disorders

* American Society for Bone and Mineral Research, Baltimore, 4 -7 Oct 2013

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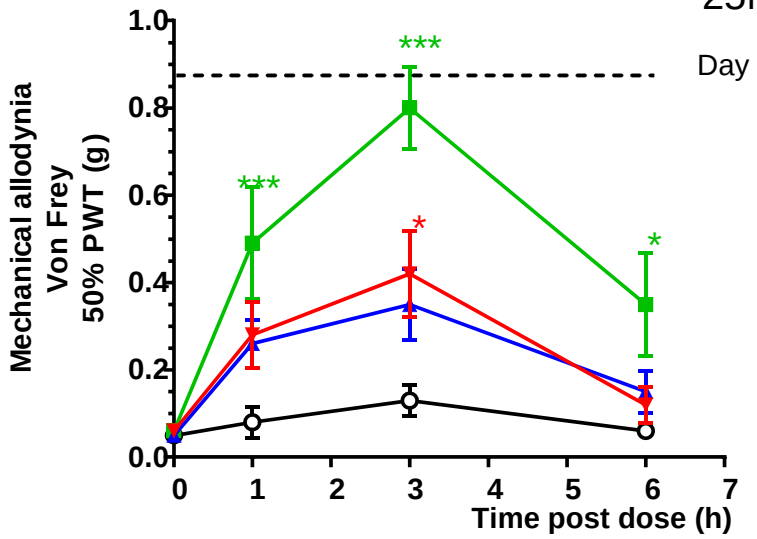
Cathepsin S inhibitor to address unmet needs in treatment of neuropathic pain (NP)

Neuropathic pain

- Associated with a lesion or disease affecting the somatosensory system
- e.g. diabetic neuropathic pain, post-herpetic neuralgia & neuropathic lower back pain
- Inhibition of Cat S prevents inflammatory damage to the sensory system in the spinal cord by blocking fractalkine release



Big market with high medical need

- Current treatments incl. anticonvulsants and antidepressants
  - Pain persists in 75% patients with at best a 50% reduction in overall pain
  - Significant side effects e.g. dizziness, somnolence
- 25M people in the 7 MM suffer from NP

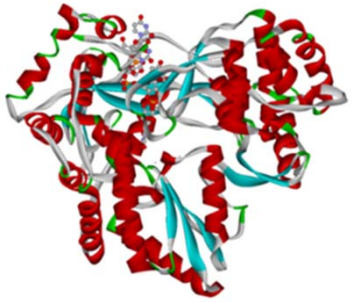
Day 10 contralateral

Vehicles alone
MV-CATSI (50):Gabapentin (146)
MV-CATSI (50)
Gabapentin (146)

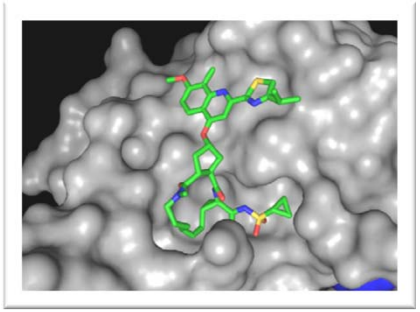
(µmol/kg)

Wholly owned HCV nucleotide program is an important strategic asset

- Medivir has leveraged nucleoside experience to pursue high value nucleotide compounds
- Current Medivir effort focused on novel uridine-based series
- Medivir's compounds are structurally distinct from existing nucleoside starting points
- Initial protide series features include:
  - EC50 values <100nM
  - High in vitro selectivity indices
  - Attractive early pharmacokinetic profile



Simeprevir: a next generation HCV protease inhibitor



- Approved in Japan, Canada and USA with a broad label
- Under review in EU
- 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

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 naive GT1 HCV patients *(fully enrolled; n=444)*

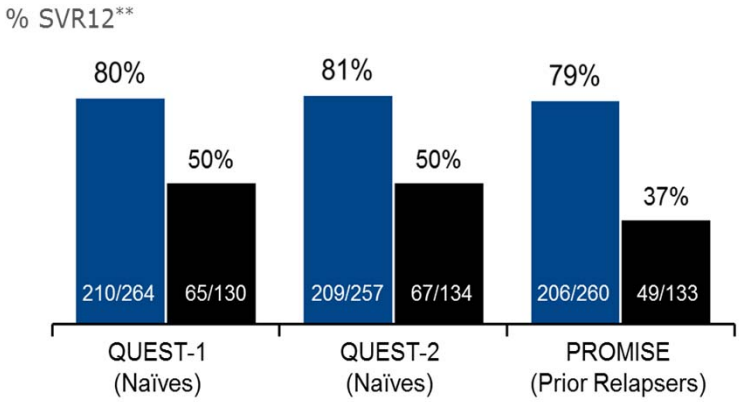
Patient population expansion

- **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

Simeprevir - pivotal phase III studies highlight differentiated profile

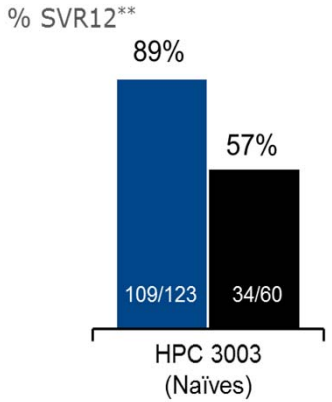
Global

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



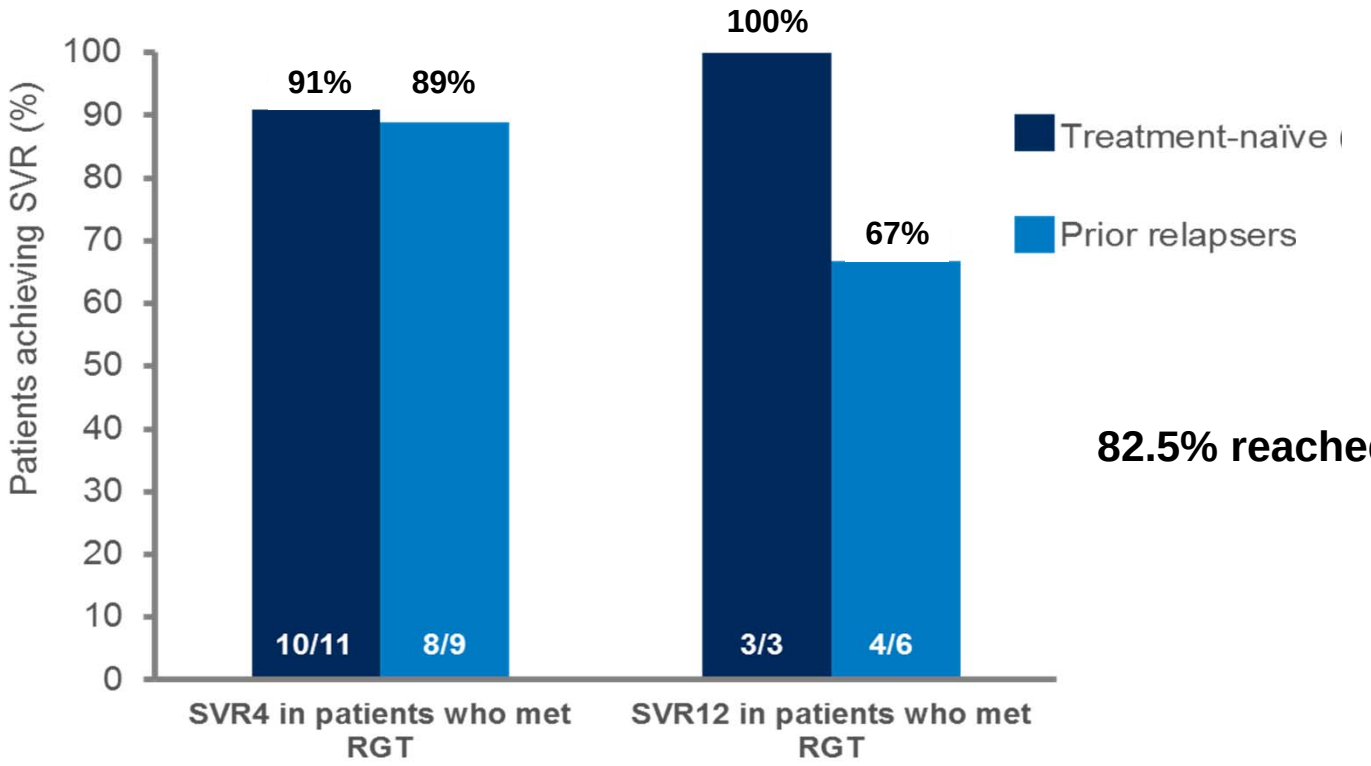
Japan

- 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

HCV genotype 4 infected patients
Results & conclusions from interim analysis



82.5% reached RGT

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

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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

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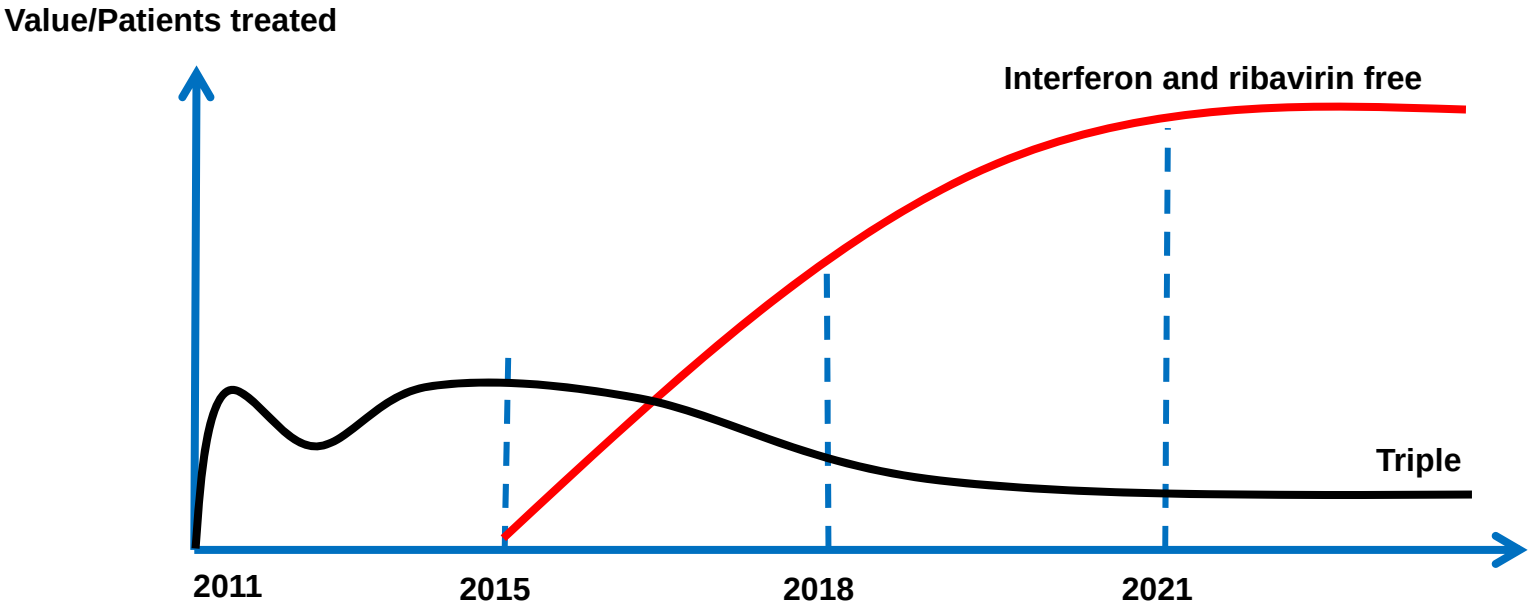
Simeprevir

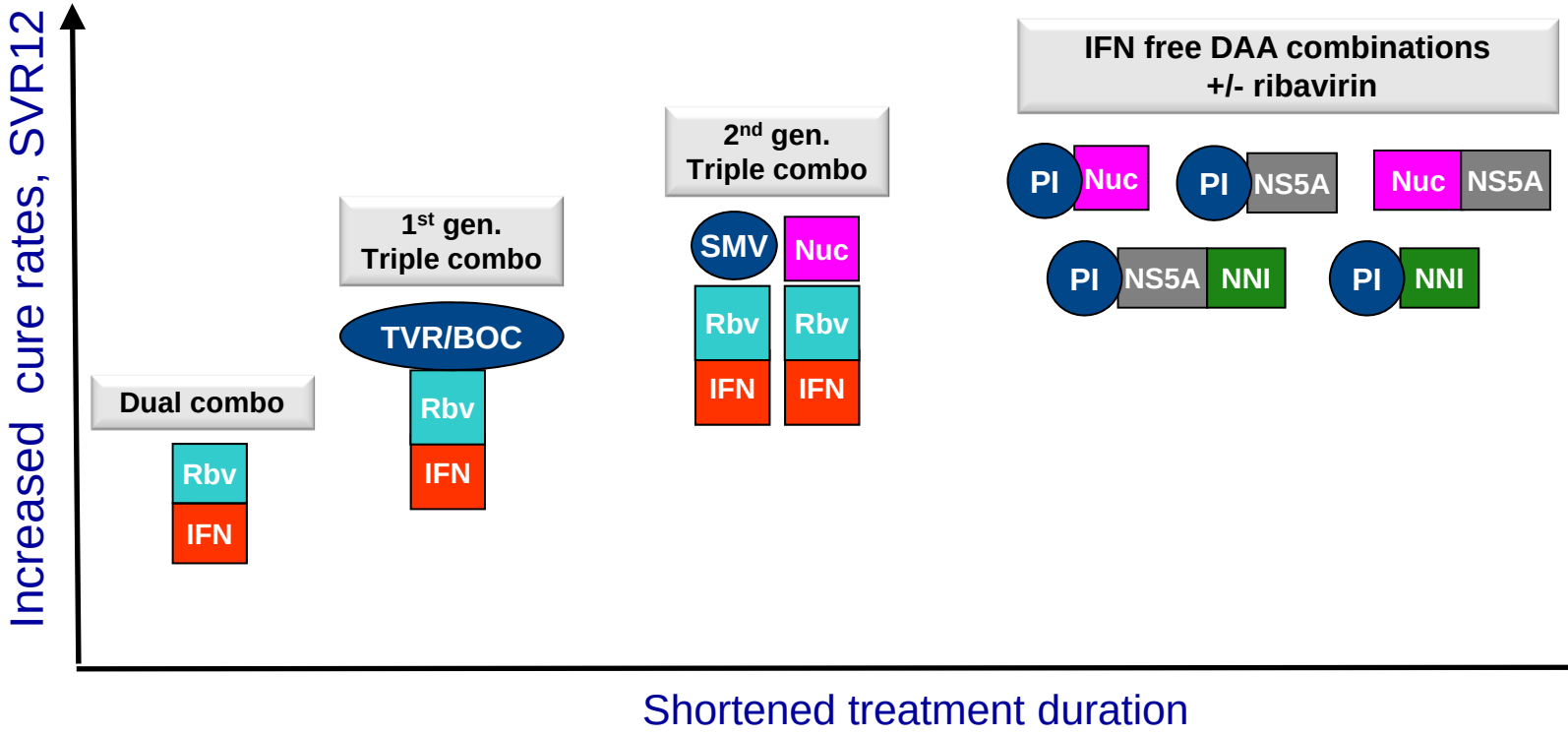
- All oral interferon-free combination update

Simeprevir will play a central role in the transformation of Medivir

We are committed to advancing the treatment of hepatitis C



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

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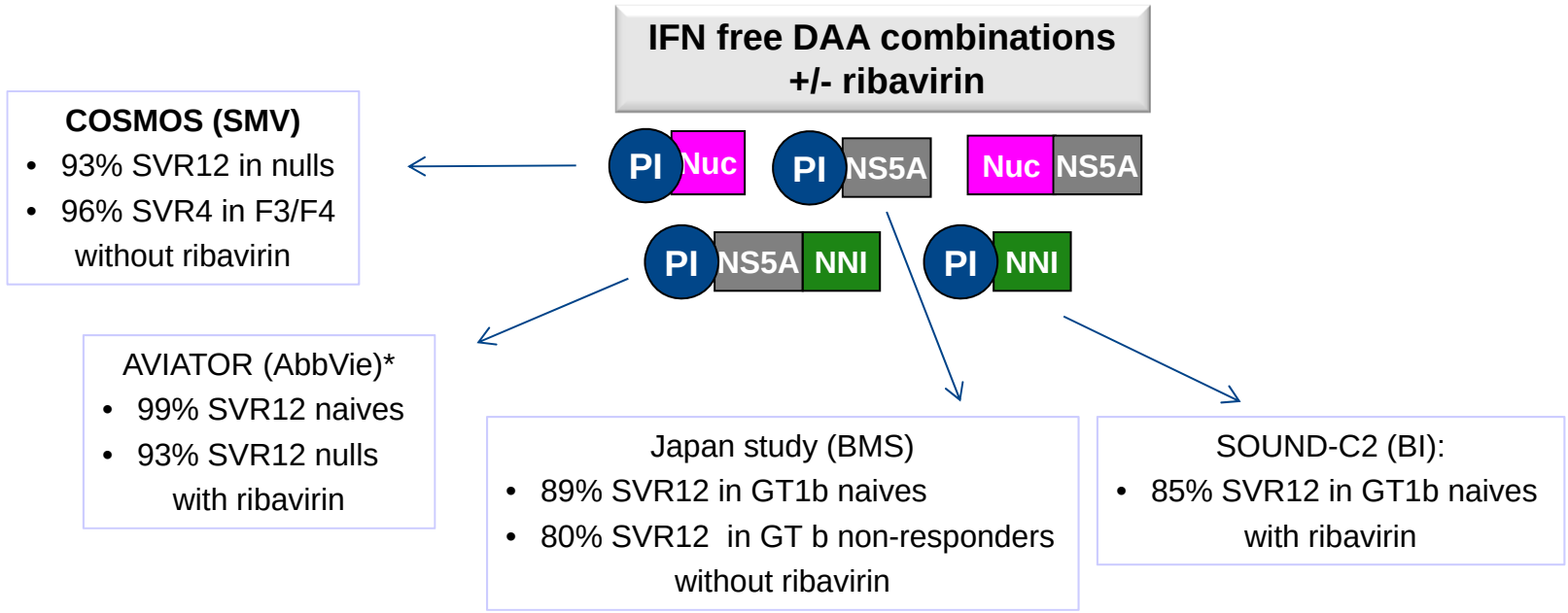
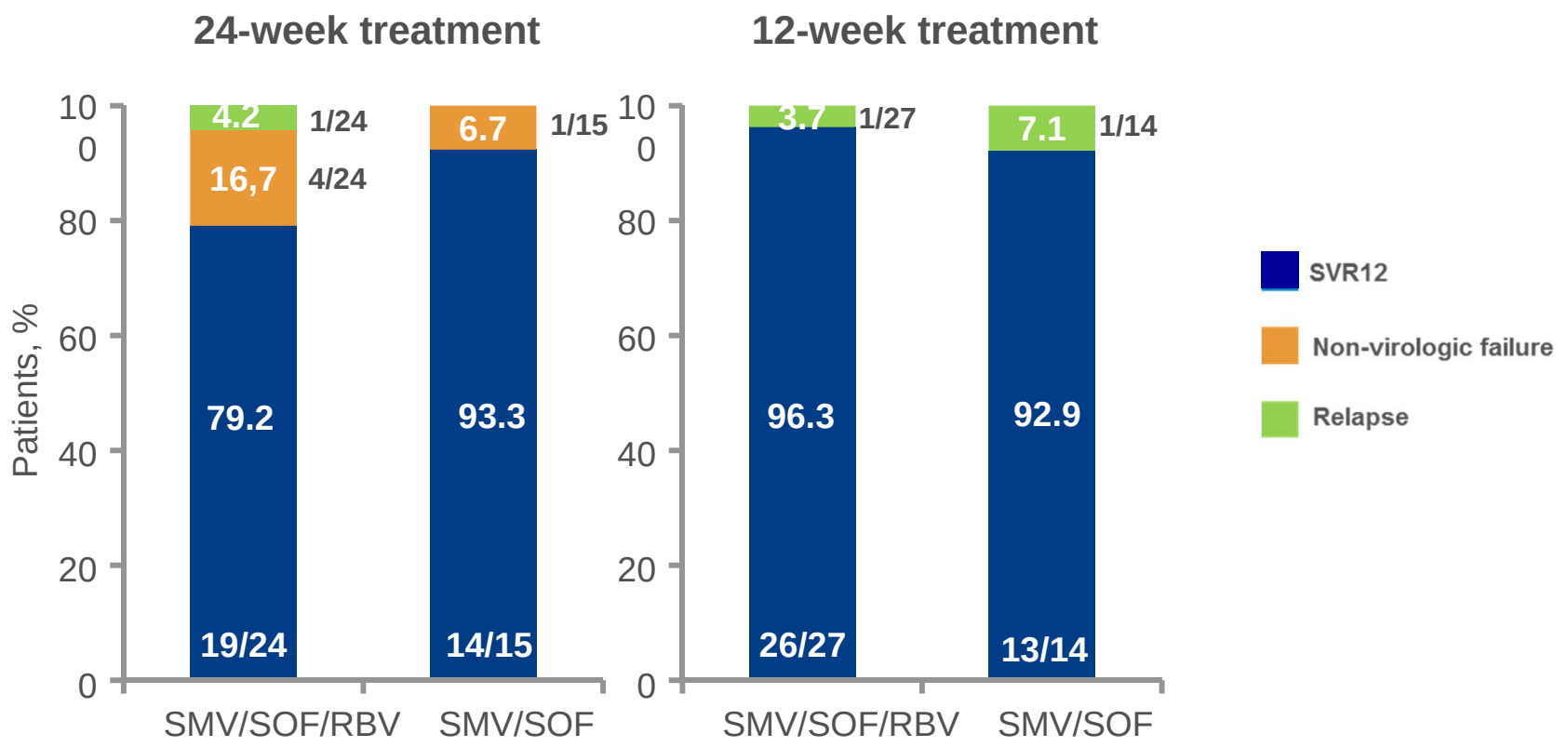
SVR12; Sustained Virologic Response 12 weeks (cure rate)
IFN: Peginterferon; Rbv: ribavirin; Nuc: nucleotide; NS5A; NS5A inhibitor;
NNI: non-nucleotide inhibitor; TVR: telaprevir; BOC: boceprevir

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



* = AbbVie recent results from the SAPPHIRE-I study (Phase 3) achieved SVR-12 between 95-98% in naive patients

Cohort 1: Prior null responders (METAVIR F0-F2) SVR12
ITT population



High efficacy in prior null responder HCV patients also without ribavirin

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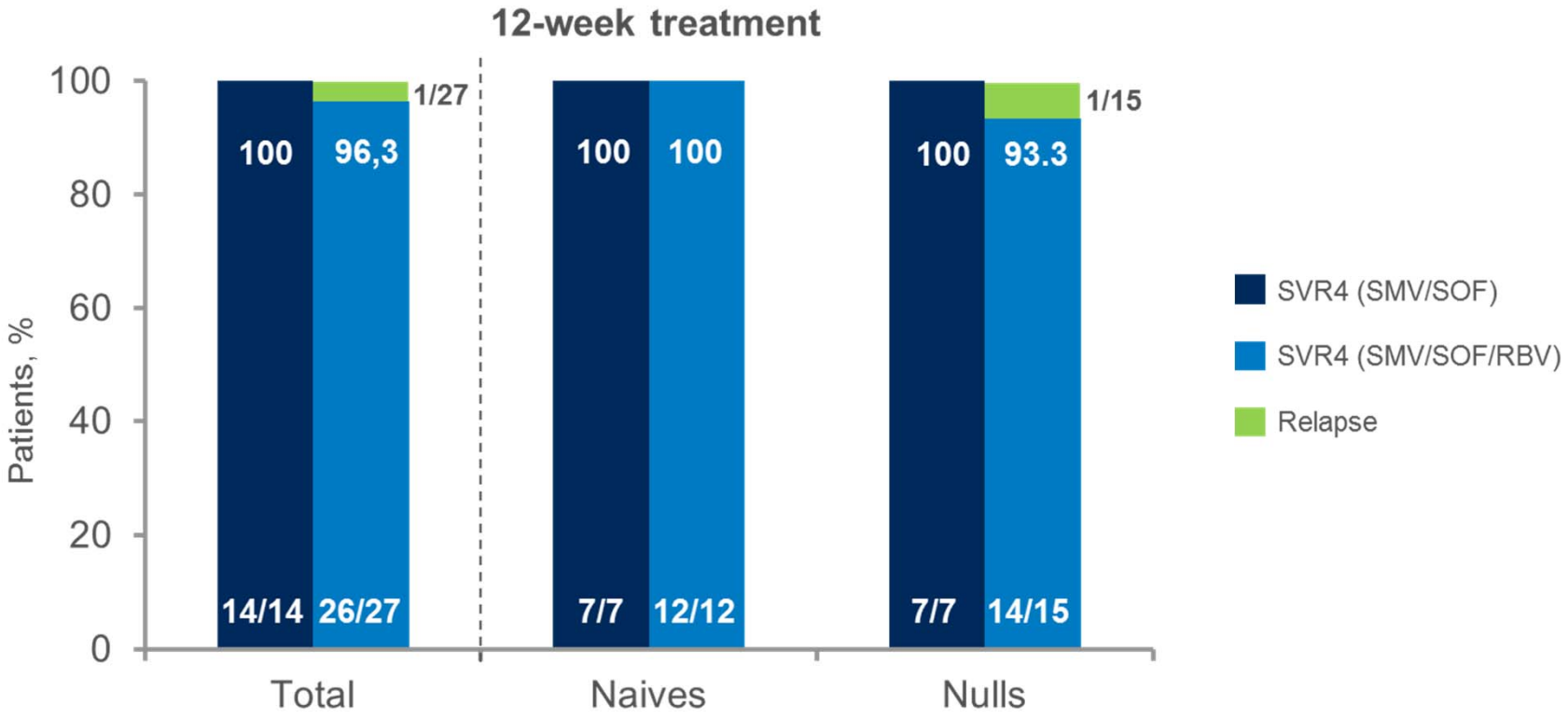
ITT, intent-to-treat
SMV: simeprevir; SOF: sofosbuvir; RBV: ribavirin
Sustained Virological Response 12 weeks (SVR12) after end of treatment.

Cohort 2: Naïve and prior null responders (METAVIR F3-F4) SVR4* interim analysis, ITT population



**SVR4 data was only available for 12-week arms at time of interim analysis cut-off*

High efficacy in hardest to cure HCV patients also without ribavirin

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ITT, intent-to-treat
SMV: simeprevir; SOF: sofosbuvir; RBV: ribavirin
Sustained Virological Response 4 weeks (SVR4) after end of treatment.

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

Simeprevir given in combination with a:	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 before YE-13
	TMC647055 + **JNJ-56914845**	Phase II, in planning phase
+ NNI	TMC647055	Naives/relapser and nulls

NNI: non-nucleoside poymerase inhibitor

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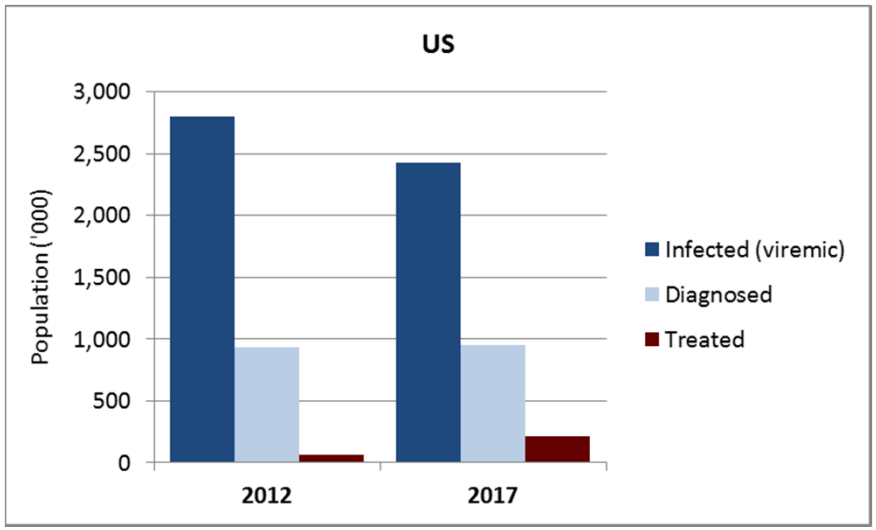
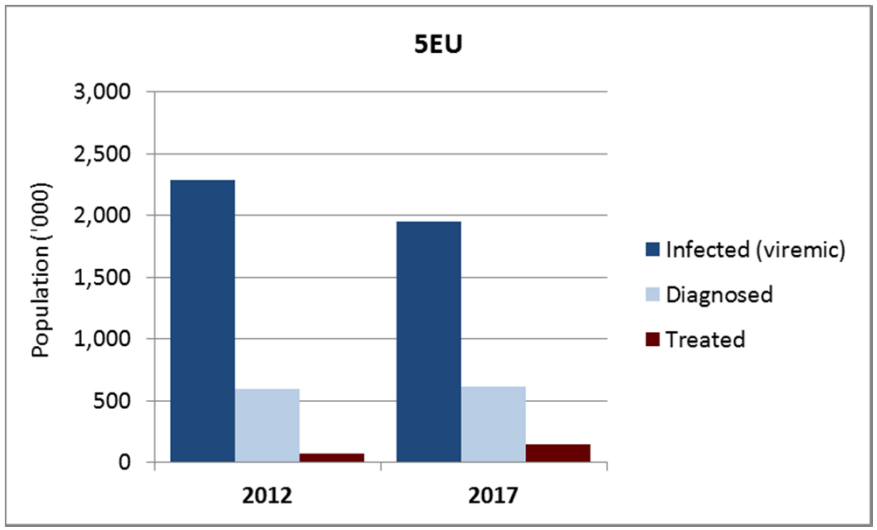
Hepatitis C dynamics can provide long-term market growth through increases in treatment and diagnosis rates





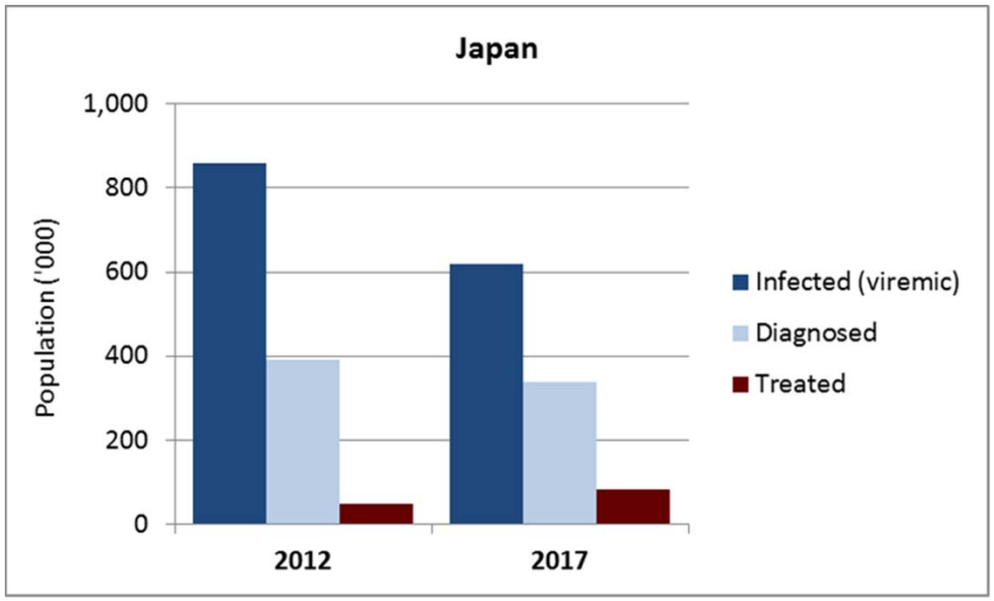
Source: Decision Resources (July, 2013)

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)

Hepatitis C market in Japan has similar dynamics to US and EU but also some important differences

Hepatitis C Patient Population in Japan



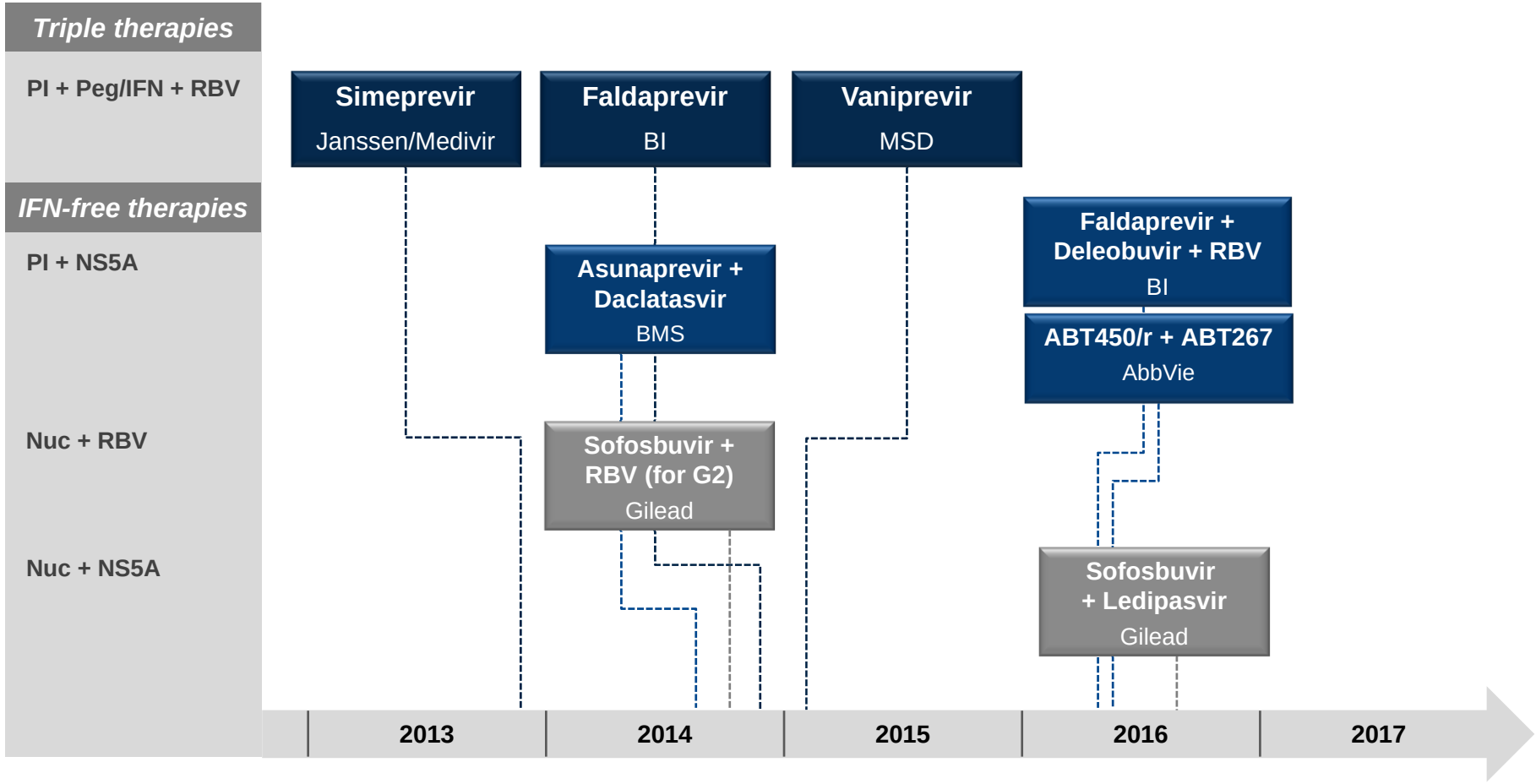
Source: Decision Resources (July, 2013)

Genotype distribution in Japan

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

Source: Datamonitor (2011)

Simeprevir has a head start on the competition in Japan



www.medivir.com

Ticker: MVIR
Exchange: OMX / NASDAQ

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