

A background image of laboratory glassware, including a beaker and a graduated cylinder, with a blue tint. The text is overlaid on this image.

Medivir

January 2014

Maris Hartmanis, President and CEO
Charlotte Edenius, EVP Development
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*Medivir is a collaborative and agile pharmaceutical company
with an R&D focus on infectious diseases and a
leading position in hepatitis C.*

Short facts about Medivir's business

Ownership and market cap

- Public Swedish company listed on NASDAQ OMX Stockholm since 1996
- Market cap of approximately 2.9 BSEK (450MUSD)

Business description

- Discovery and Researched based pharmaceutical company, with marketing and sales of 16 Rx products in the Nordic market
- Core competence in drug development based on two enzyme classes – polymerases and protease
- Solid financial position and on the way to sustainable profitability

Overall track record

- Two own products developed from the bench to commercialization
- Extensive partnering and collaboration track record with big pharma

Overview of company operations

Activities range from early research to the marketing and sale of prescription drugs

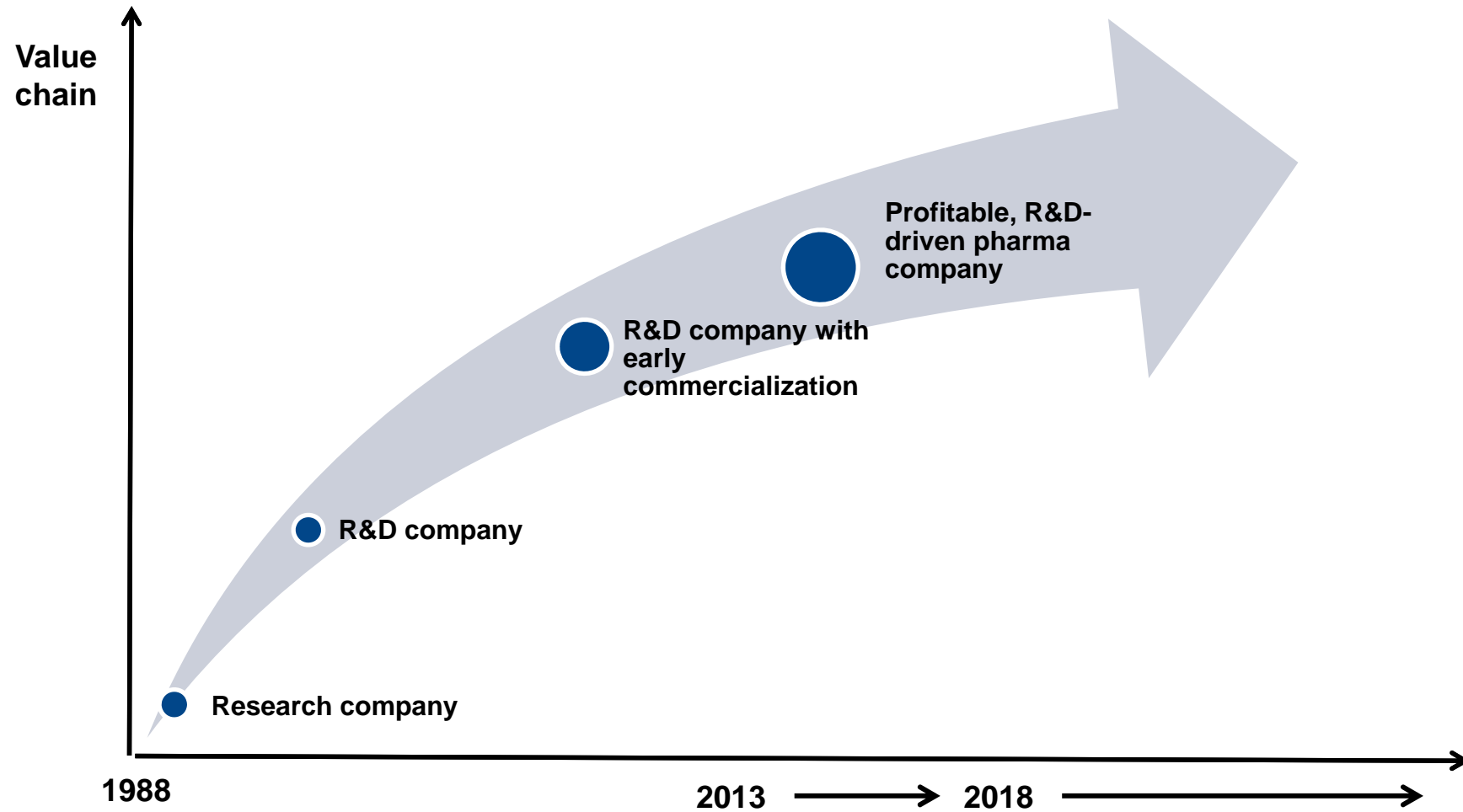
R&D Operations

- In-house focus on discovery and early development
- Late stage development conducted through collaboration/partnerships with big pharma
- Focus on proteases and polymerases give opportunities in anti-virals, infectious disease and oncology
- Proven track record – latest achievement flagship product simeprevir against hepatitis C

Commercial Operations

- Marketing and sales of high profitability commercial portfolio consisting of mature products
- Nordic organisation in place
- On-going activities to add new products to portfolio – focus is specialist/hospital products
- Preparations for Nordic market launch of retained rights for simeprevir

Medivir – towards sustainable profitability



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

We are committed to delivering sustainable shareholder value

Structure & Focus

- Maintain financial discipline
- Efficiently deploy resources
- Maximize leverage
- Identify new opportunities

R&D

- Key pipeline programs
- Retain strategic products, partner others
- Commercial targets
- Responsible R&D investment

Commercial

- Own products portfolio
- Simeprevir revenue
- Opportunistic product additions
- Geography

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

Financial Summary

Market Capitalization: SEK 2,900M \$450M USD

Cash (as of September 30): SEK 340M \$52M USD

Debt (as of September 30): SEK 42M \$6M USD

Revenues own products: SEK 180M \$28M USD

Burn rate: SEK 230M \$35M USD

Shares Outstanding:

Class B:	30,600,027
Class A:	660,000
Options:	404,374
Fully Diluted:	31,664,401

Simeprevir – enabler and value driver

A potent protease inhibitor for the treatment of hepatitis C

Short- and mid-term perspective

New standard treatment option for patients with hepatitis C – “triple combination”

In-house generated antiviral agent

Simplified and shorter treatment in combination with ribavirin and interferon

Efficient and safe profile with a high cure rate

Market approval and launch in Japan, USA and Canada in Q4 2013

On-going registration application in 2013 Europe (EMA)

Long-term perspective

Improved treatment quality for patients – “interferon free treatment”

Exclusion of interferon and ribavirin

Achieved by combining several antivirals with different mechanisms

Will expand long-term market potential

Simeprevir part in several on-going combination trials

Contributes to better treatment by its superior mechanistic profile

Development in partnership with Janssen Pharmaceuticals

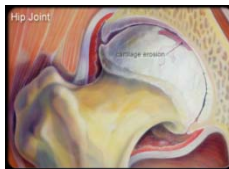
The pipeline is Medivir's value driver

Field	Project	Partner	Preclinical phase		Clinical phase				Market	
			Re- search	Deve- lopment	Phase I	Phase IIa	Phase IIb	Phase III		
Antivirals										
Labial herpes	Xerclear (Zovido, Zovirax Duo)	GlaxoSmithKline (GSK)								
Hepatitis C	Simeprevir (TMC435), NS3 protease inhibitor	Janssen Pharmaceuticals								
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								
Neuropathic pain	Cathepsin S inhibitor	Unpartnered								

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

Mechanism of action

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



MIV-711 - Phase I finished

- Placebo controlled, double-blind study in healthy subjects
- Ascending single and multiple once daily dosing (up to 28 days)
- Biomarkers for bone (CTX-I) and cartilage (CTX-II) turnover measured
- In process for partnership for further clinical development

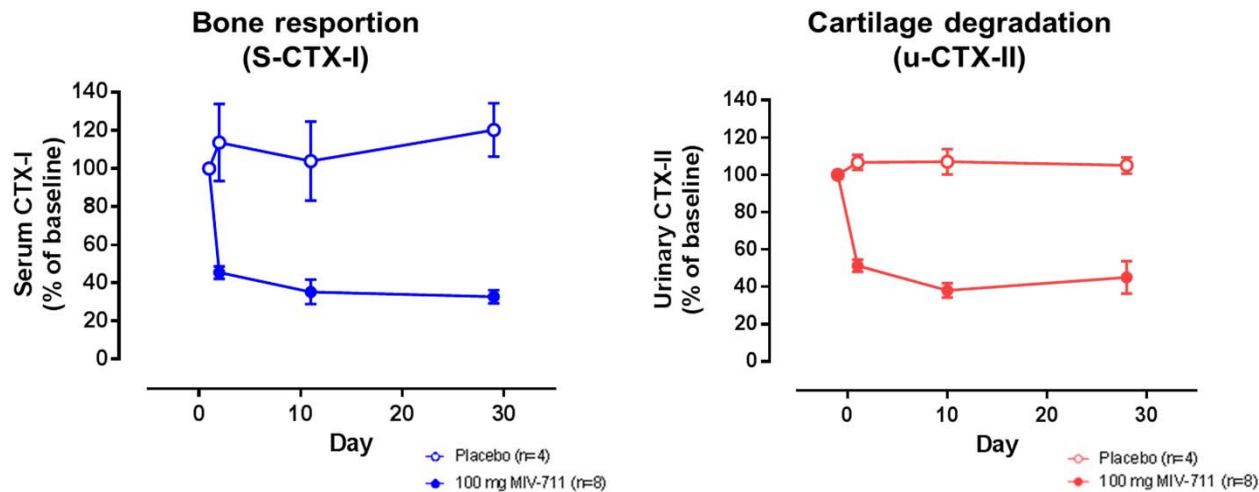
MIV-711 is a potent and selective cathepsin K inhibitor that is efficacious in preclinical models of osteoarthritis

MIV-711 in preclinical OA models

In preclinical osteoarthritis models once daily MIV-711:

- ✓ attenuated joint pathology in dogs paralleled by decreased urinary CTX-I and CTX-II levels and

In the clinical study once daily MIV-711 in healthy postmenopausal women:

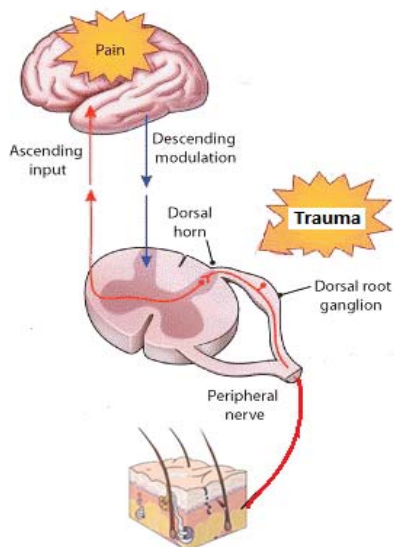


Preclinical models of OA and clinical biomarker data support MIV-711 as a disease modifying treatment for human disease

Cathepsin S inhibitor for chronic pain including neuropathic pain

Chronic and neuropathic pain

- Associated with a lesion or disease affecting the somatosensory system
- Includes e.g. diabetic neuropathic pain, post-herpetic neuralgia, neuropathic lower back pain, cancer and HIV related pain,



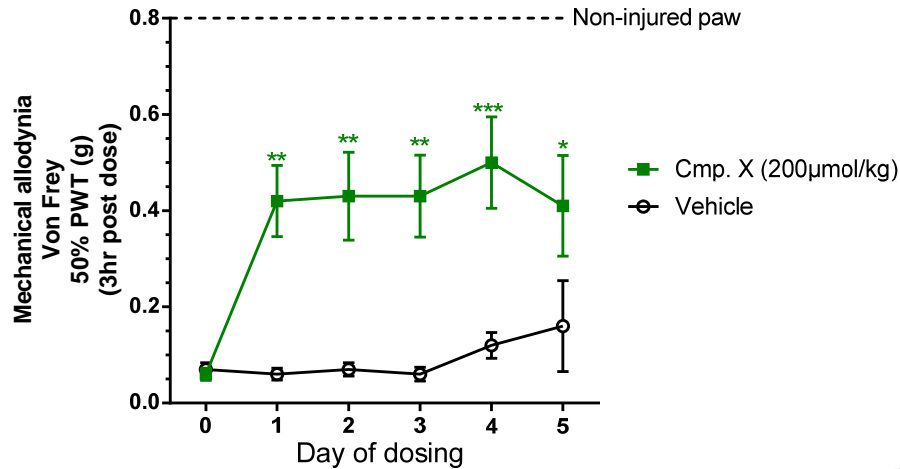
Medical need and market

- 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

Mechanism of action

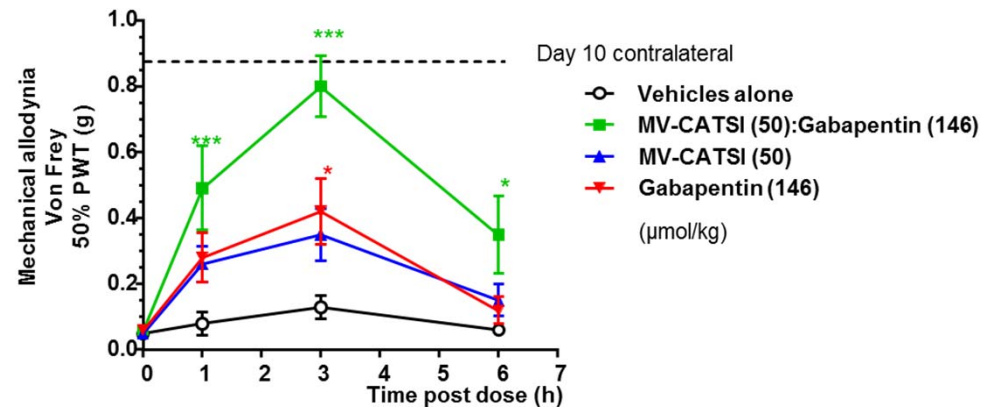
- Inhibition of Cathepsin S prevents inflammatory damage to the sensory nervous system by blocking fractalkine release
- A candidate drug has been selected for further development

Cathepsin S inhibitor – efficacious as monotherapy and additive with gabapentin in a model of neuropathic pain



Monotherapy:
Acute and sustained effects of cathepsin S inhibition in murine model of neuropathic pain

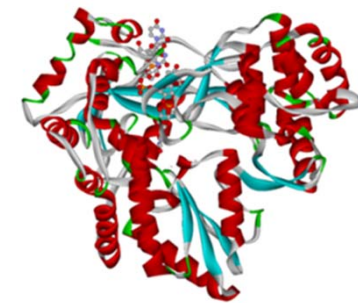
Combo therapy:
Additive effects of cathepsin S inhibitor and gabapentin in murine model of neuropathic pain



Candidate selected and up scaling on-going for IND preparatory package

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



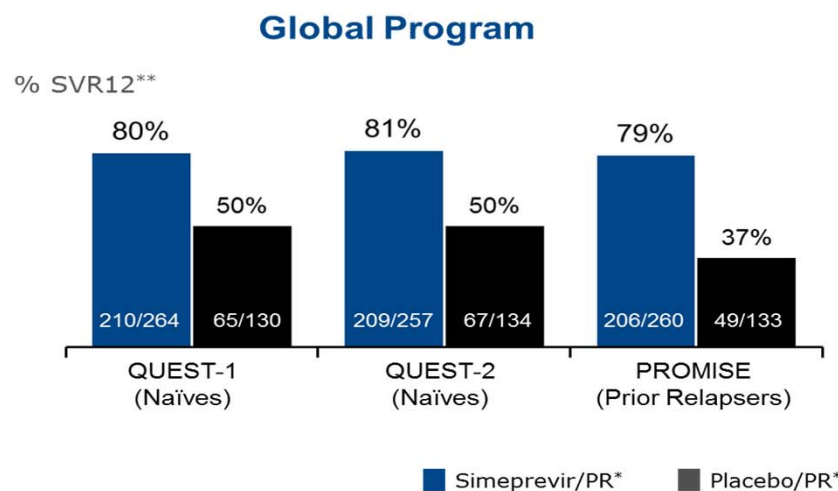


Simeprevir on the market:

- ✓ **Japan (Sovriad™)**
- ✓ **Canada (Galexos™)**
- ✓ **USA (OLYSIO™)**

Simeprevir (OLYSIO™) USPI

- Simeprevir (OLYSIO™) is a hepatitis C virus (HCV) NS3/4A protease inhibitor indicated for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen
 - OLYSIO™ efficacy has been established in combination with peginterferon alfa and ribavirin, in HCV genotype 1 (GT1) infected patients with compensated liver disease (including cirrhosis)



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 - results expected summer-14

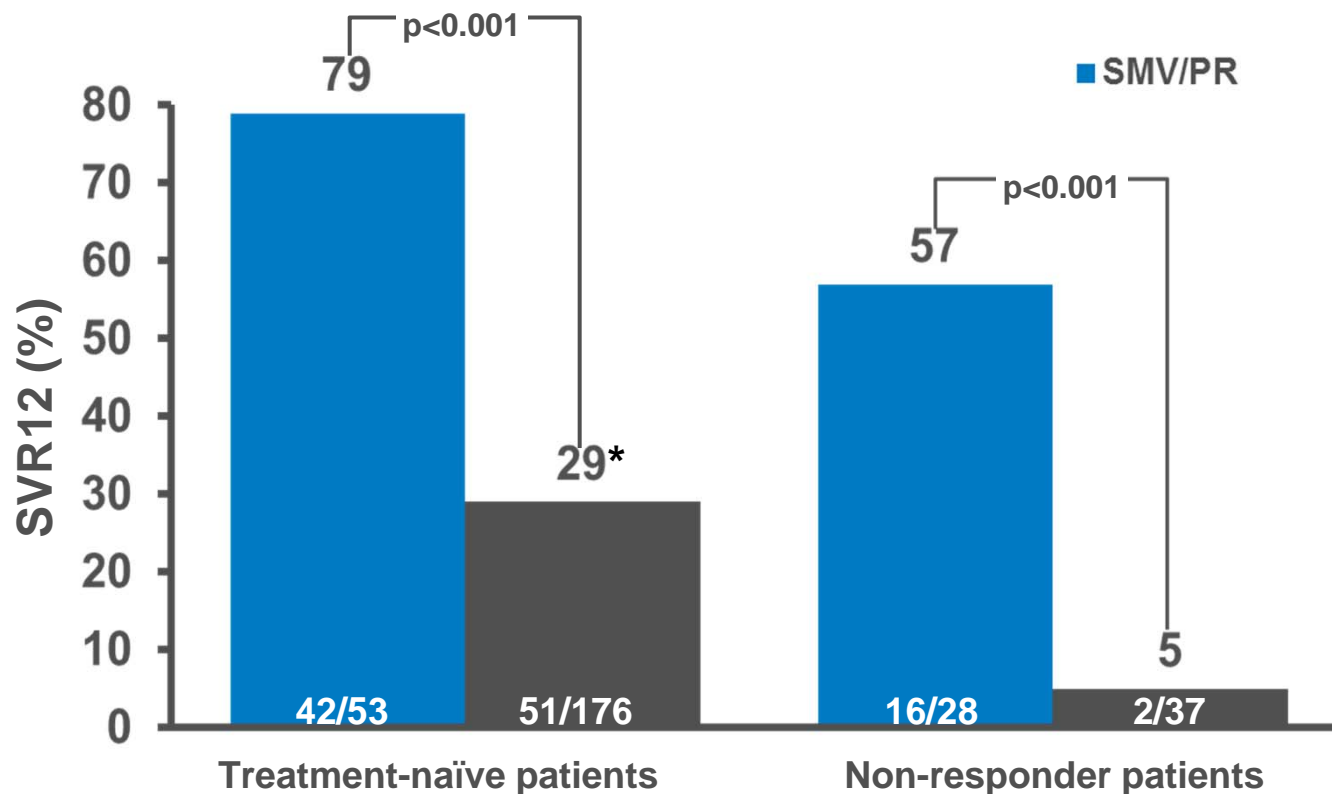
Regional expansion - China

- A pivotal study of Efficacy, Safety & Tolerability and Pharmacokinetics in treatment naïve GT1 HCV patients - results expected H2-14

Patient population expansion

- **Genotype 4 HCV infected patients**
- **HIV/HCV co-infected patients**

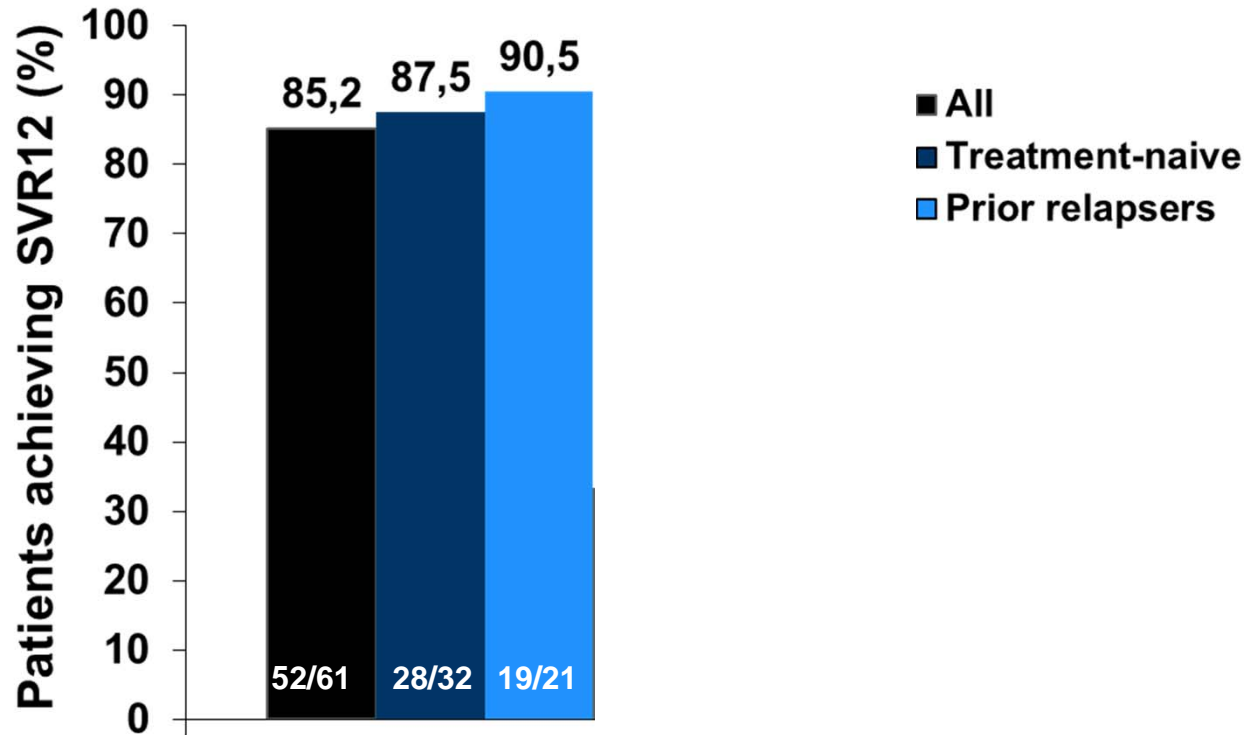
HCV/HIV-1 co-infection treatment-naïve and non-responders vs historic PR control



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

*From PEGASYS® USPI, co-infected patients; †from INCIVEK™ USPI, mono-infected patients

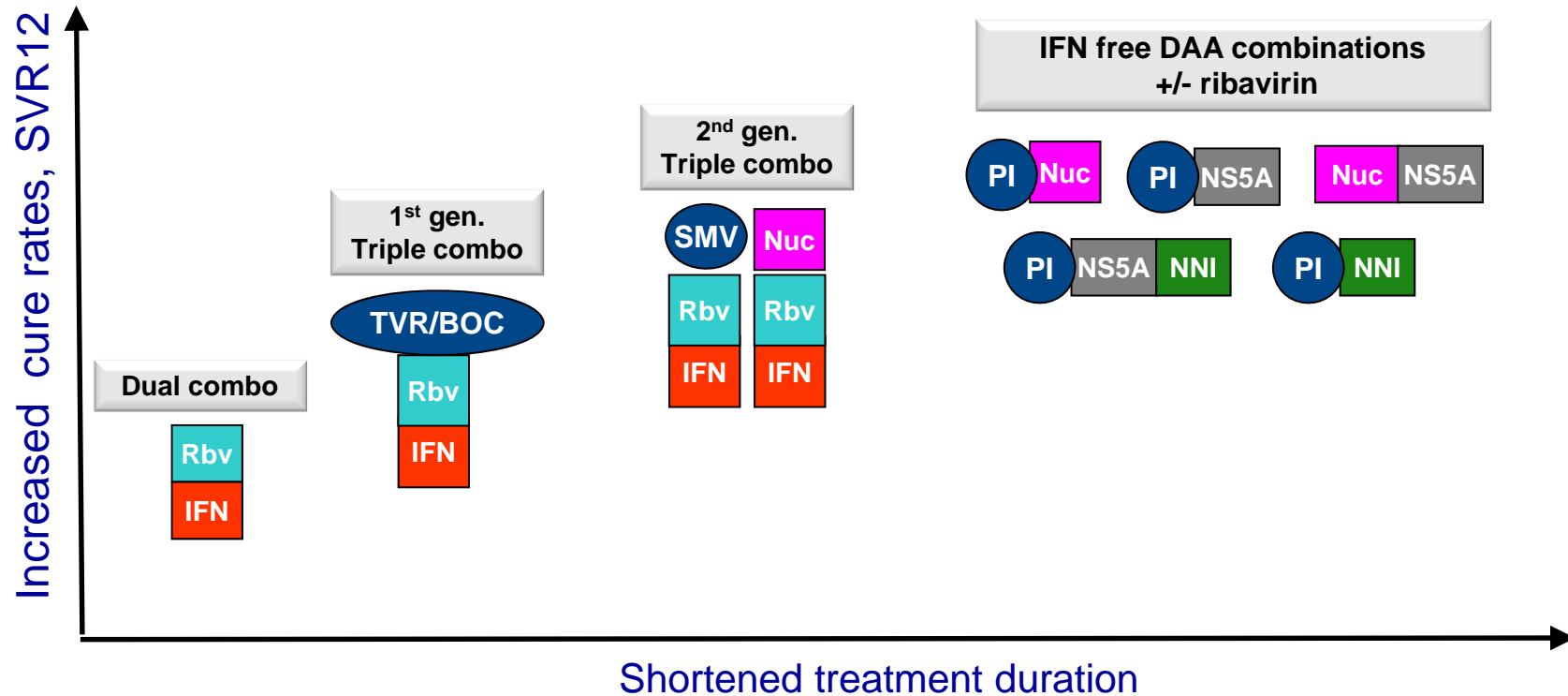
High SVR rates in HCV genotype 4 infected patients - interim analysis*



HCV genotype 4 accounts for ~20% of all cases of chronic HCV worldwide

*presented at HepDart 2013

Evolution towards interferon-free HCV treatment



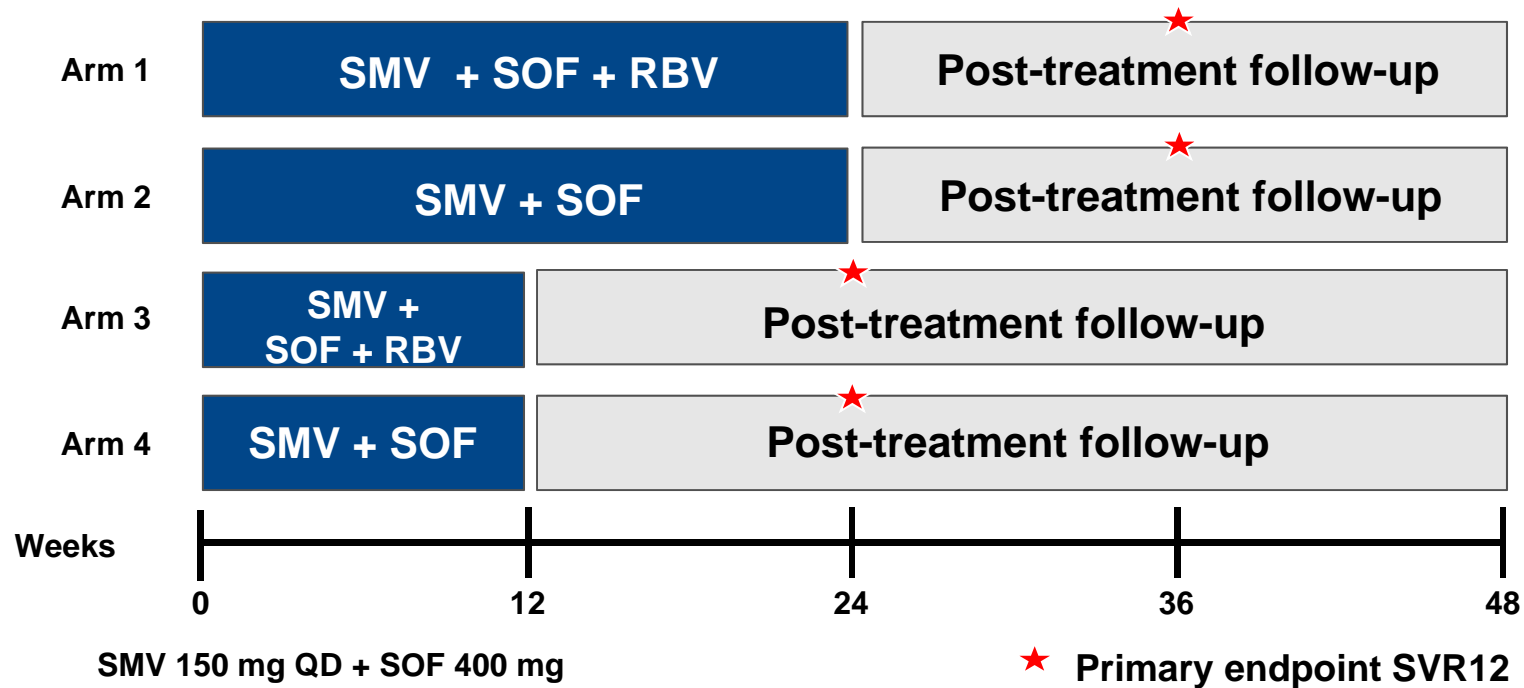
Ongoing IFN-free studies including simeprevir

- data driven approach to exploring different interferon free simeprevir combinations

Compound	Class	Partner	Status
Simeprevir / Sofosbuvir	PI NI	Janssen Gilead	COSMOS: Cohort A: nulls ; Cohort B: nulls + naives (F3 and F4)
Simeprevir / Daclatasvir	PI NS5a	Janssen BMS	Naives and nulls, F0-F4
Simeprevir / GSK805 / TMC055	PI NS5a NNI	Janssen Janssen Janssen	Phase II started Dec-13
Simeprevir / IDX719	PI NS5a	Janssen Idenix	HELIX-1: Phase II on-going (Gt1b and 4)
Simeprevir / IDX719 / TMC055	PI NS5a NNI	Janssen Idenix Janssen	HELIX-2: Phase II started Dec-13 (Gt1)
Simeprevir / VX135	PI NI	Janssen Vertex	DDI finished, Phase II being planned

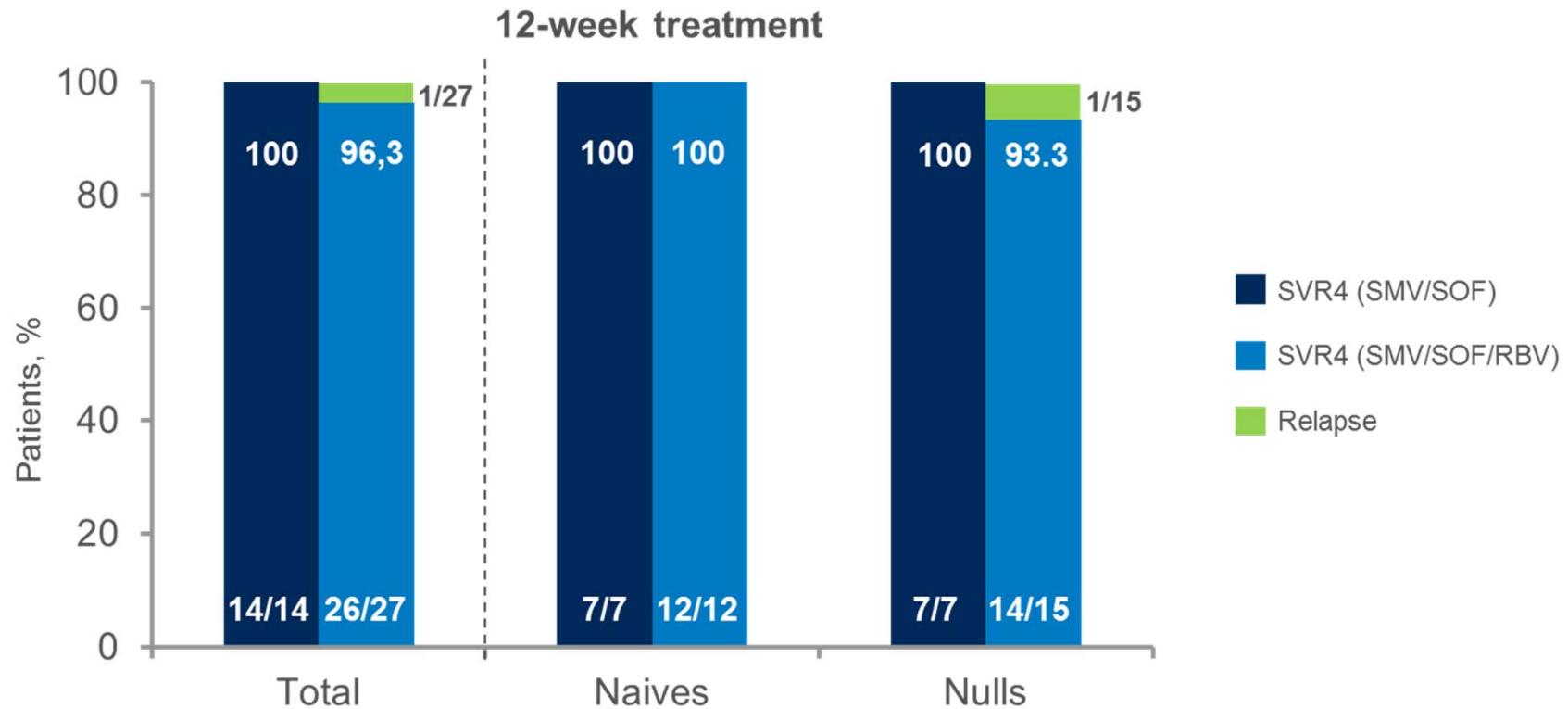
COSMOS study

– combining two “best in class” compounds



Cohort 1: nulls, F0-F2 - SVR12 available
Cohort 2: naives & nulls F3-F4 - SVR4 available

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



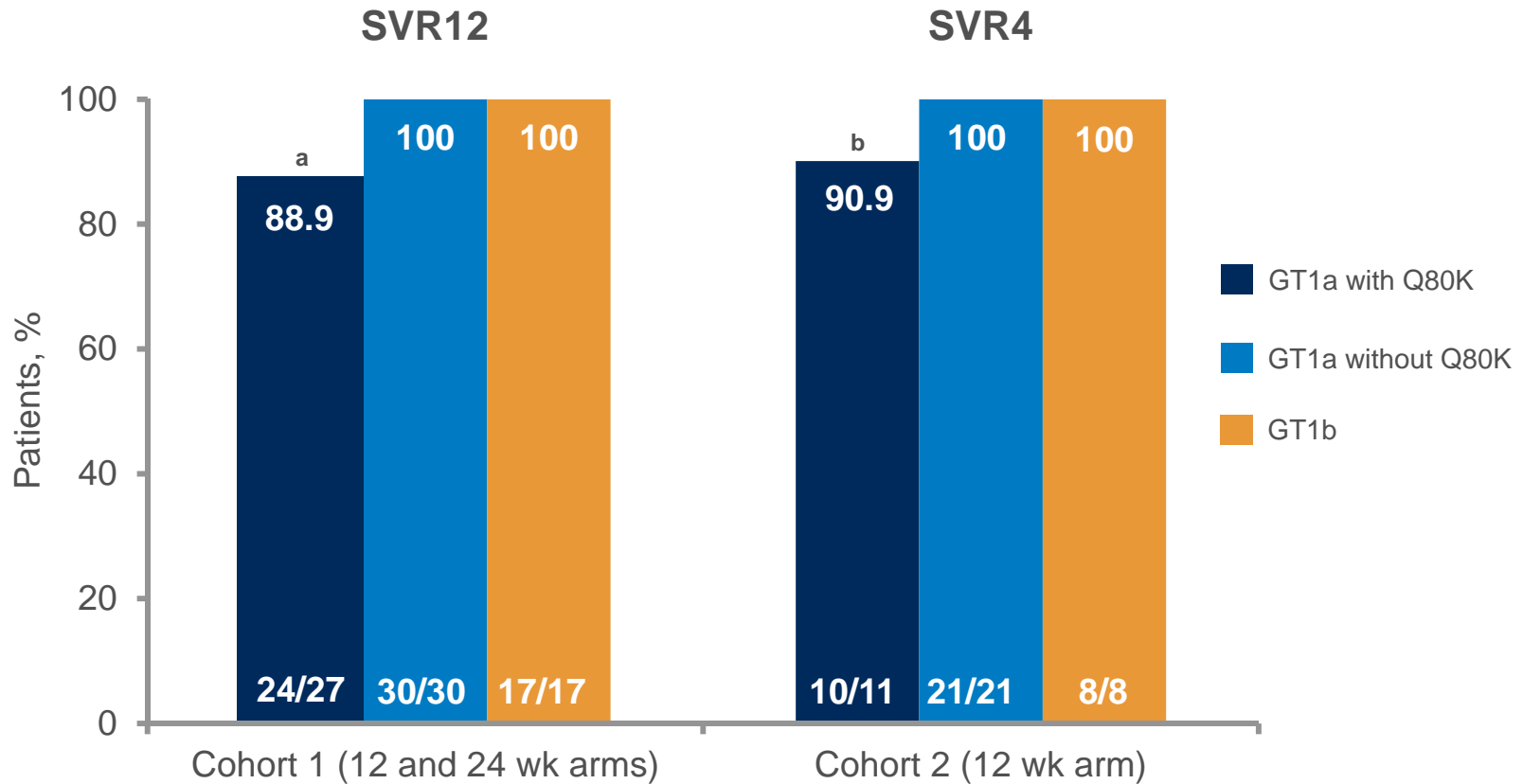
*SVR4 data was only available for 12-week arms at time of interim analysis cut-off

High efficacy in hardest to cure HCV patients also without ribavirin

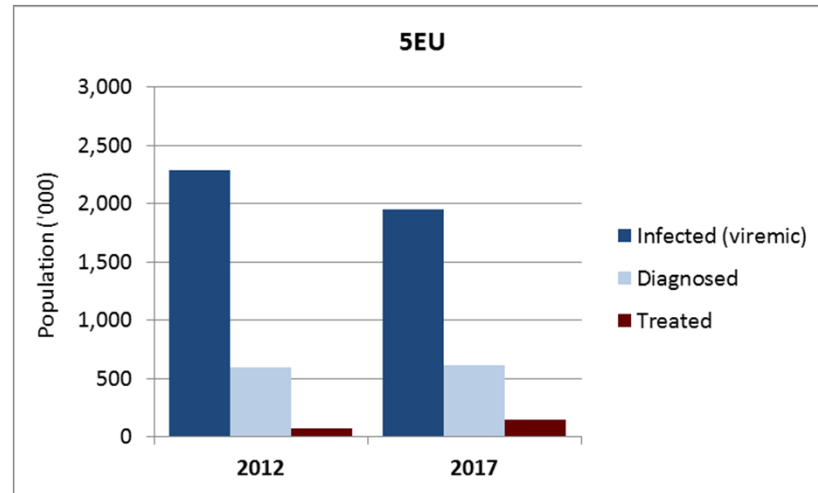
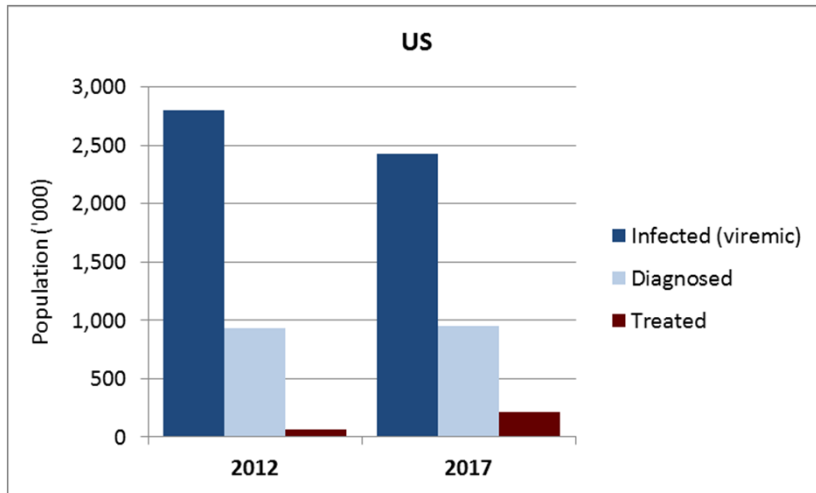


COSMOS Study: SVR rates according to HCV subtype: Cohorts 1 (nulls, F0-2) and cohort 2 (F3-F4)

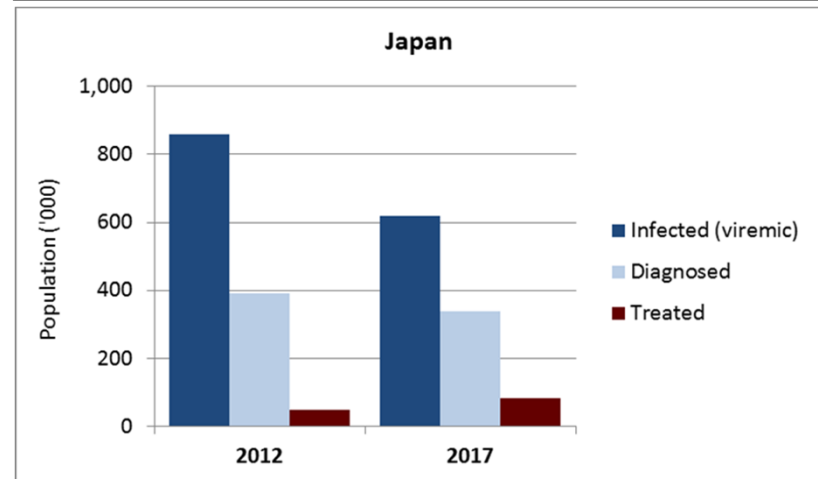
Excludes non-virologic failures



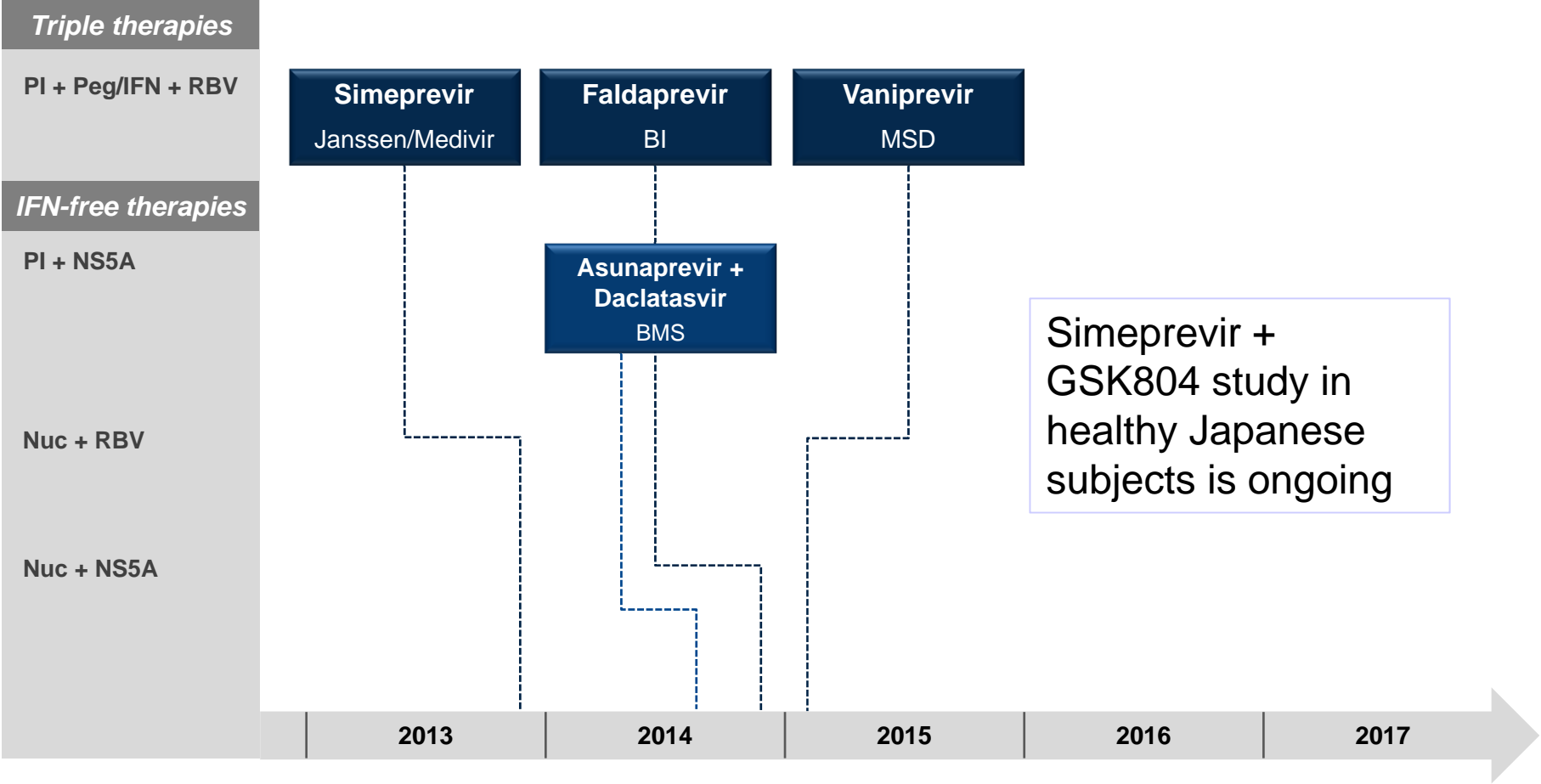
Hepatitis C dynamics can provide long-term market growth through increases in treatment and diagnosis rates



Genotype	US (%)	5EU (%)	JP (%)
1a	54	15	3
1b	20	55	66
2	16	9	30
3	7	14	1
4	1	6	0
5&6	2	1	0



Simeprevir has a head start on the competition in Japan with INF free option on its way





Simeprevir on the market:

- ✓ **Japan (Sovriad™)**
- ✓ **Canada (Galexos™)**
- ✓ **USA (OLYSIO™)**

www.medivir.com

Ticker: MVIR
Exchange: OMX / NASDAQ

**For more information please contact
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