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

Q4-2013 Conference Call 24 February 2014

Presenting team

Maris Hartmanis, CEO
Charlotte Edenius, EVP Development
Rein Piir, EVP Corporate Affairs & IR
Göran Pettersson, Chairman of the Board

Reflections on 2013

Maris Hartmanis, CEO

2013 - a very successful and important year

Structure

- We streamlined the company's operations by divesting Cross Pharma AB, the parallel imports business.
- We established a Nordic M&S presence in preparation for anticipated launches of new pharmaceuticals, such as simeprevir and Adasuve.
- We reviewed our R&D portfolio, which resulted in more focused activities to get the best possible return on investments.

Internal programs

- The nucleotide-based polymerase inhibitor project, targeting hepatitis C, developed successfully.
- MIV-247 was selected as a candidate drug in the cathepsin S project and entered pre-clinical development for the treatment of neuropathic pain.
- Solid phase I data with MIV-711 were presented in our cathepsin K program for bone-related disorders.
- Evaluation of Medivir's future research and development strategy is ongoing.

Our pharmaceuticals

- Our pharmaceutical portfolio with 15 Rx products (continuing operations) generated solid full-year sales of 176,1 MSEK, a year-on-year growth of 7% in net turnover and of 4% in the number of units sold.
- A strong Nordic commercial organisation is in place, giving Medivir an increased presence in the Nordics. This is an important stage in our preparations for the anticipated market launch of new pharmaceuticals.
- Our cold sore pharmaceutical licensed to GSK will be launched in new important European markets during 2014.

Simeprevir

- Simeprevir was approved and launched in Japan, US and Canada, which triggered milestone payment of 30 MEUR to Medivir. We also received the first royalty based on the sales of simeprevir in December.

- Our partner Janssen acquired an NS5A replication complex inhibitor from GSK, now called JNJ-56914845. Simeprevir will be evaluated with JNJ-56914845 in upcoming interferon-free trials.

- One of the important goals for the further development of simeprevir is to produce an interferon- and ribavirin-free treatment. Two additional interferon-free phase II studies, now with the addition of two direct acting antiviral agents to simeprevir, were initiated during the fourth quarter. In the first study, the patients will be treated with simeprevir, TMC647055 and two different doses of JNJ-56914845, without ribavirin, while in the other study, HELIX-2, simeprevir, samatasvir and TMC647055 will be evaluated with and without ribavirin.

- Positive interim data from the interferon-free COSMOS study were presented with simeprevir and sofosbuvir, with or without ribavirin, in the most difficult-to-treat patient groups.

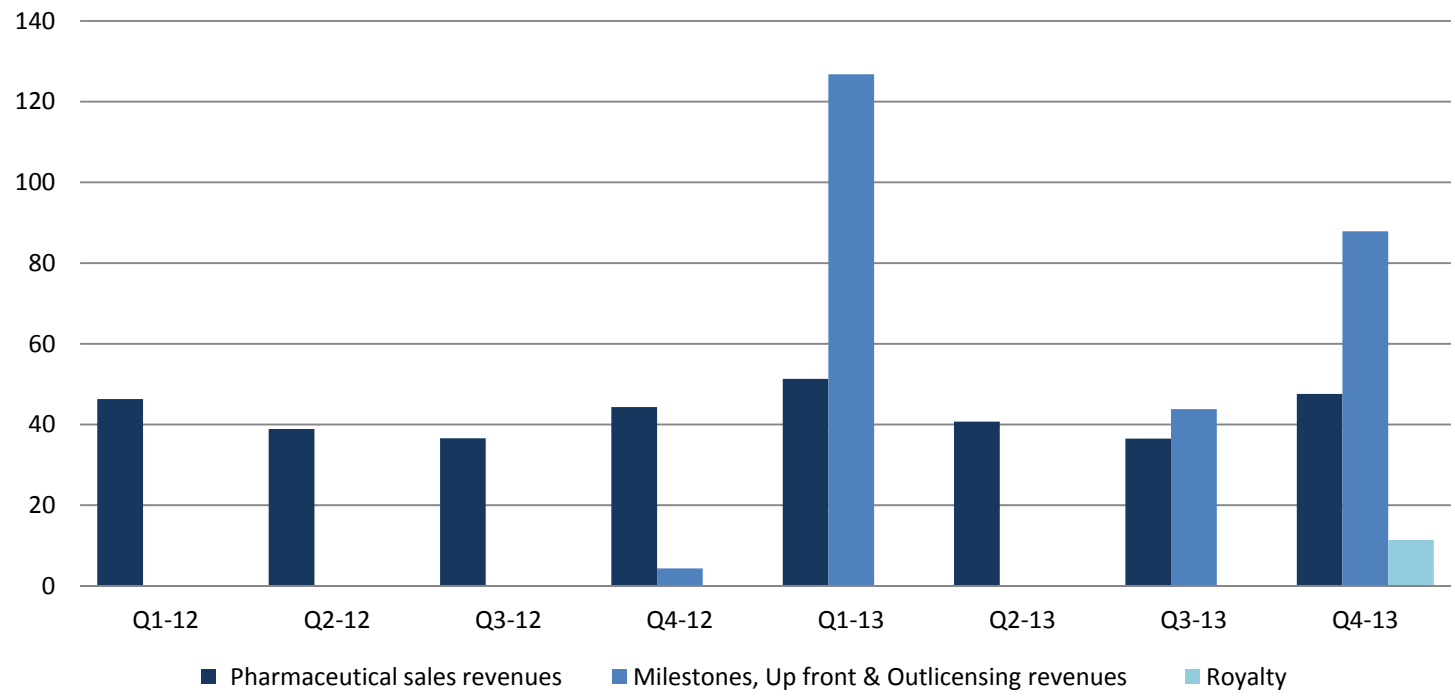
Consolidated income statement

Consolidated income statement summary Continuing operations (MSEK)	**2013** **Oct-Dec**	**2012** **Oct-Dec**	**2013** **Jan-Dec**	**2012** **Jan-Dec**
Net turnover	147.1	48.8	446.1	170.6
Gross profit	126.5	32.4	374.3	109.3
EBITDA	32.0	-44.9	76.4	-165.3
EBIT	20.6	-53.8	25.2	-201.4
Profit/loss before tax	22.8	-58.7	27.7	-210.8
Profit/loss after tax	19.3	-70.6	16.0	-234.1

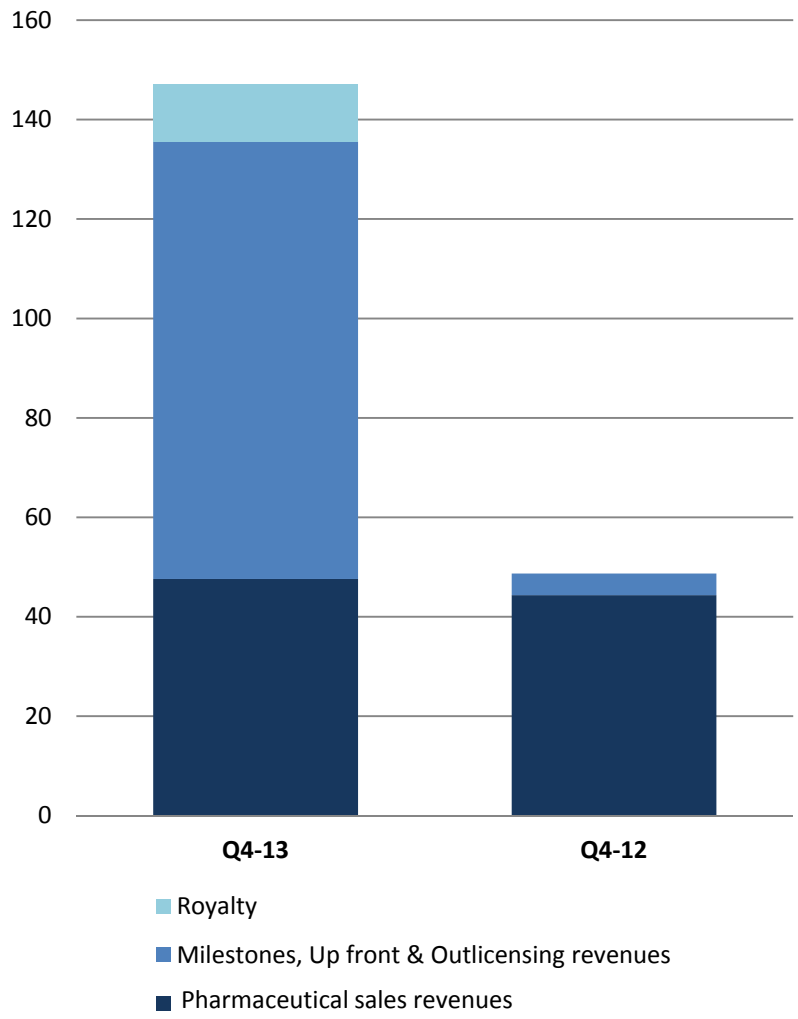
Net turnover breakdown

Net turnover breakdown (MSEK)	2013 Oct-Dec	2012 Oct-Dec	2013 Jan-Dec	2012 Jan-Dec
Out-licensing and partnership agreements: Non-recurrent payments	88.0	4.4	258.5	4.4
Pharmaceutical sales	47.6	44.3	176.1	164.9
Royalties	11.5	-	11.5	-
Other services	-	0.1	-	1.3
Total	**147.1**	**48.8**	**446.1**	**170.6**

Net turnover continuing operations per quarter, MSEK



Net turnover continuing operations per quarter, MSEK



2014 – we are building a momentum

- Today, Medivir is a growing Nordic pharmaceuticals company that combines successful R&D activities with a strong Nordic commercial organisation.
- As simeprevir has reached the market, the company is entering a commercialization phase that brings new opportunities and challenges.
- We have an ambition to broaden the R&D pipeline and enter into new partnerships for our internally driven projects.
- We are looking at adding new pharmaceuticals to our Nordic product portfolio.

- We look forward to an eventful 2014 with continued growth and important steps in the development and provision of innovative pharmaceuticals that improve peoples' health and quality of life.

Key R&D highlights from Q4 2013

Charlotte Edenius, EVP Development

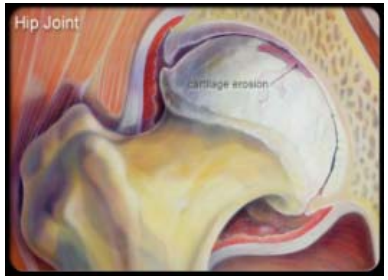
The pipeline is Medivir's value driver

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							
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 osteoarthritis
- Cathepsin K degrades collagen in both bone and cartilage



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

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

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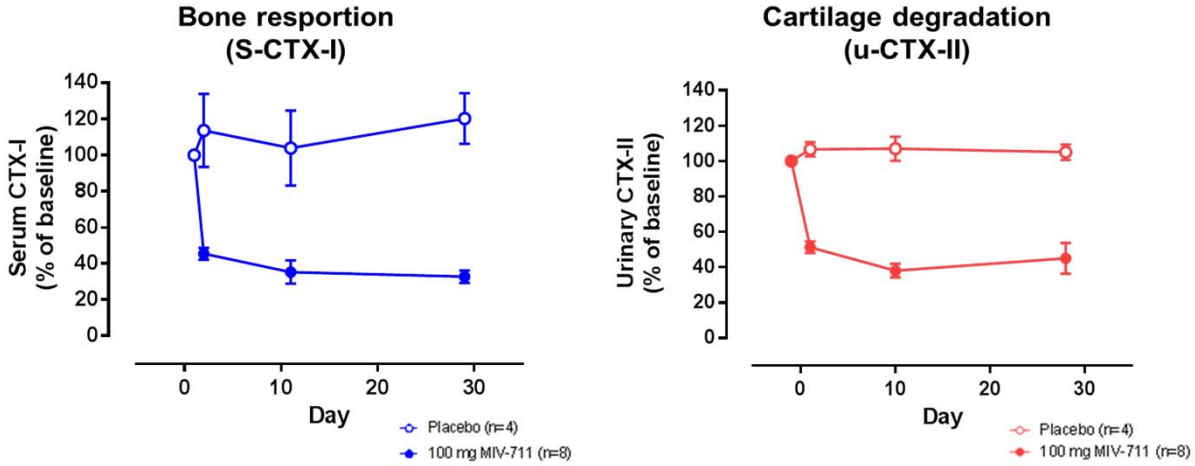
MIV-711 - preclinical OA models and clinical data

In preclinical osteoarthritis models once daily MIV-711:

- ✓ attenuated joint pathology in preclinical OA models were paralleled by decreased urinary CTX-I and CTX-II levels

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

- ✓ similar attenuation of biomarkers were seen as in the OA models



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

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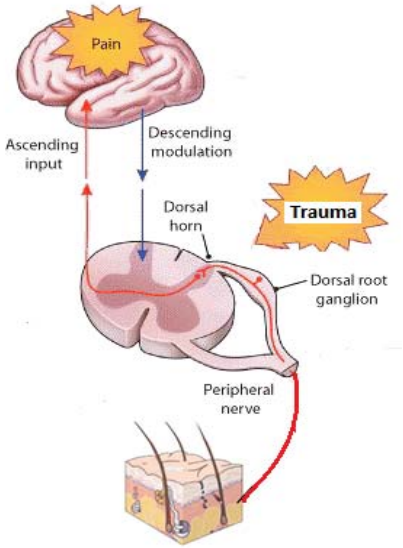
Cathepsin S inhibitor for neuropathic pain

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

Current treatments incl. anticonvulsants and antidepressants

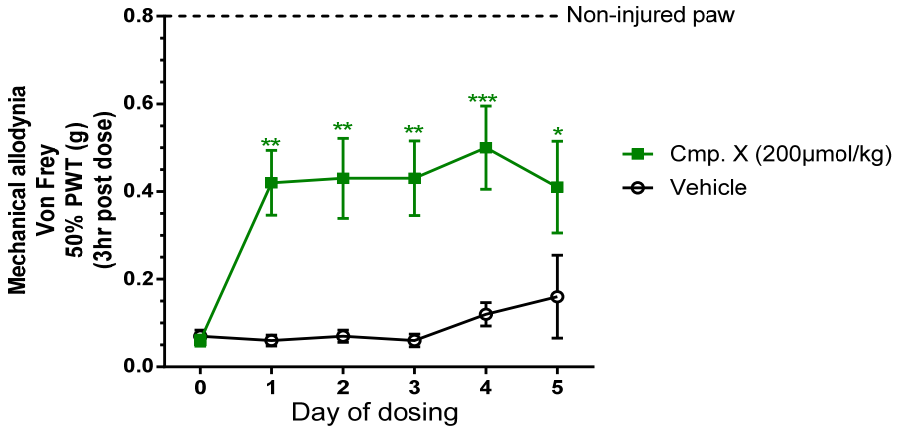
- Pain persists in 75% patients with at best a 50% reduction in overall pain
- Significant side effects e.g. dizziness, somnolence

Mechanism of action

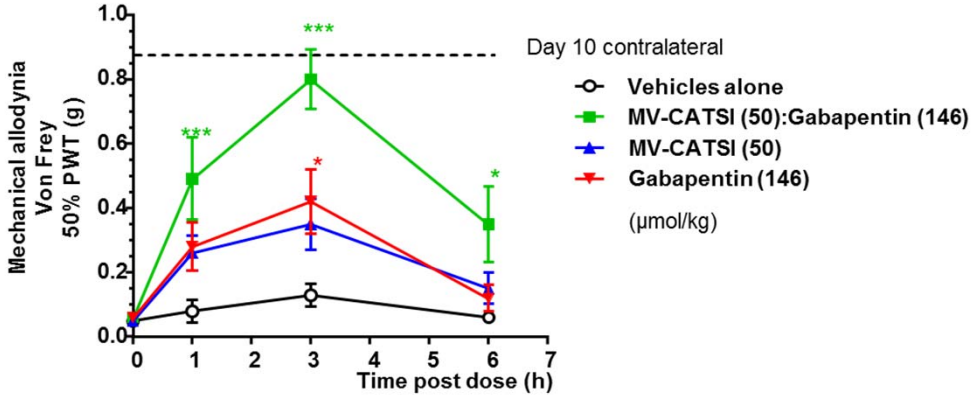
- Inhibition of Cathepsin S prevents inflammatory damage to the sensory nervous system by blocking fractalkine release
- A candidate drug has been selected for further development

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

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



Combination therapy:
Additive effects with a cathepsin S inhibitor and gabapentin at *minimal* effective doses



MIV-247 designated as a Candidate Drug and upscaling is on-going for IND preparatory package

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Simeprevir on the market:

- ✓ **Japan (SOVRIAD™)**
- ✓ **Canada (GALEXOS™)**
- ✓ **USA (OLYSIO™)***

* 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

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

ATTAIN

- **Simeprevir vs telaprevir** in genotype 1 prior null or partial responder patient *(n=744, results expected H1-14)*

12 week treatment duration

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

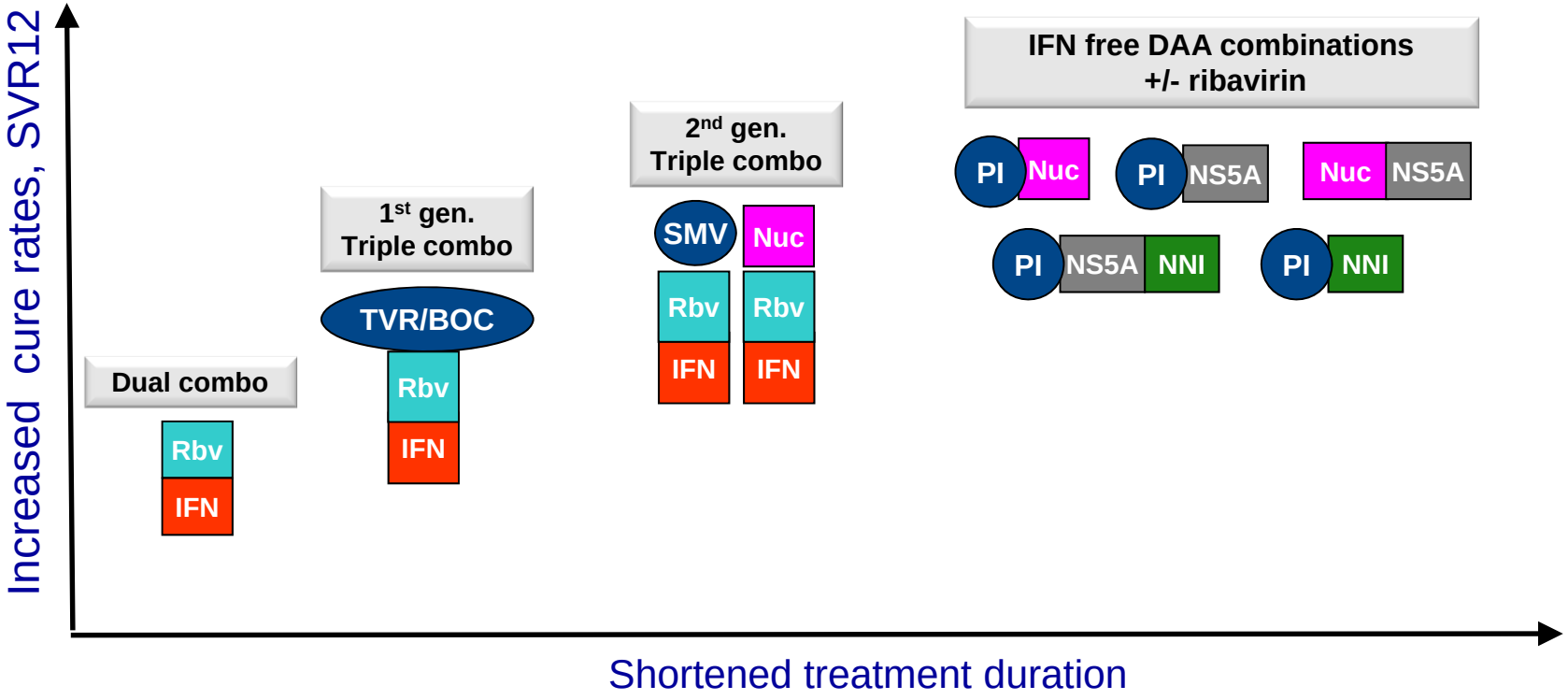
Regional expansion - China

- A pivotal study of Efficacy, Safety & Tolerability and Pharmacokinetics in treatment naive GT1 HCV patients *(fully recruited)*

Patient population expansion

- **Genotype 4 HCV infected patients** *(interim data reported)*
- **HIV/HCV co-infected patients** *(primary analysis reported)*

Evolution towards interferon-free HCV treatment



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

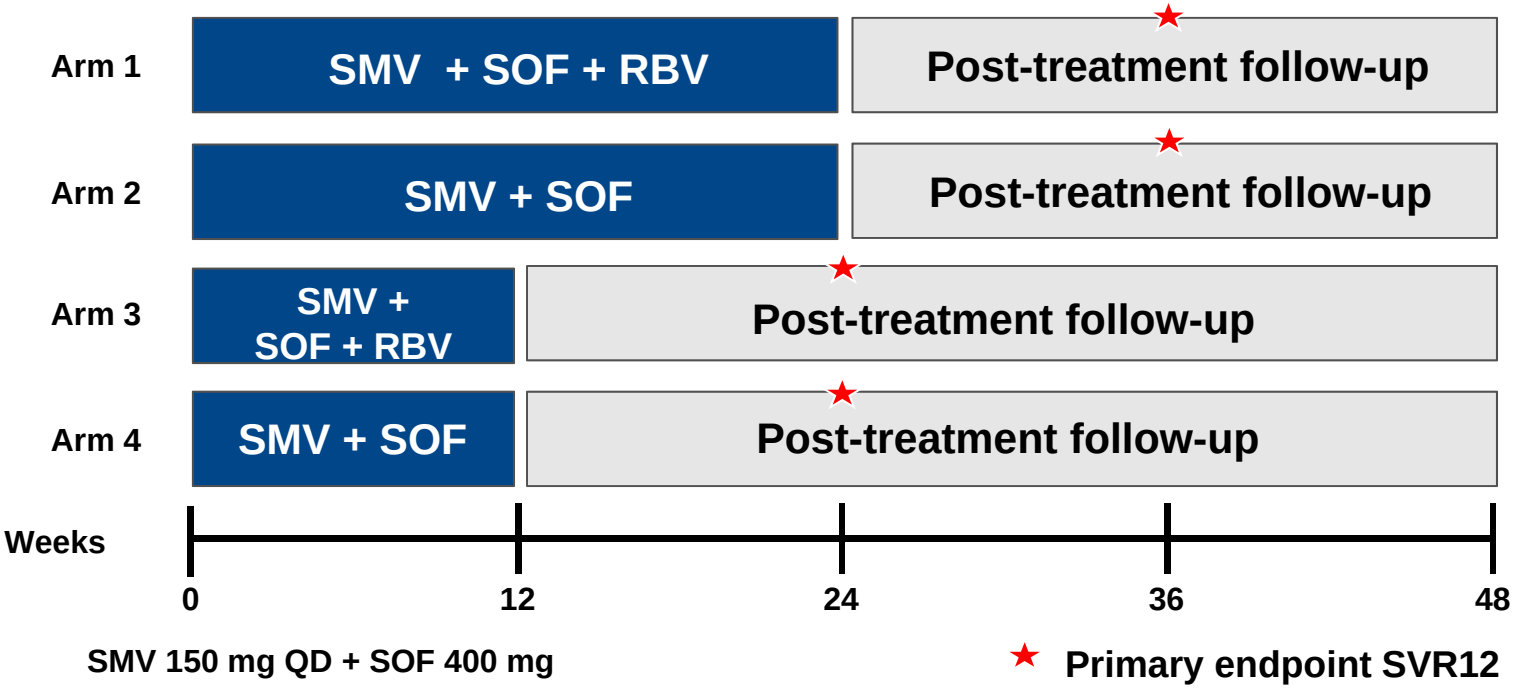
Ongoing IFN-free studies including simeprevir

- data driven approach to exploring different interferon free combinations

Class	Compound	Partner	Status
PI + Nuc	Simeprevir Sofosbuvir	Janssen Gilead	**COSMOS**: Cohort A: nulls (F0-2); Cohort B: nulls + naives (F3 and F4)
PI + NS5A	Simeprevir Daclatasvir	Janssen BMS	Naives and nulls, F0-F4
	Simeprevir IDX719	Janssen Idenix	HELIX-1: Phase II on-going, Gt1b and 4 (150 mg SMV + 50 mg SAM + RBV-> 85% SVR4)
	Simeprevir JNJ-56914845	Janssen	DDI in healthy Japanese participants
PI + NS5A + NNI	Simeprevir IDX719 TMC055	Janssen Idenix Janssen	HELIX-2: Phase II started Dec-13 (Gt1)
	Simeprevir JNJ-56914845 TMC055	Janssen	Phase II started Dec-13

IFN, interferon; Nuc, nucleotide polymerase inhibitor; NNI, non-nucleoside polymerase inhibitor; NS5A, NS5A replication complex inhibitor; PI, protease inhibitor

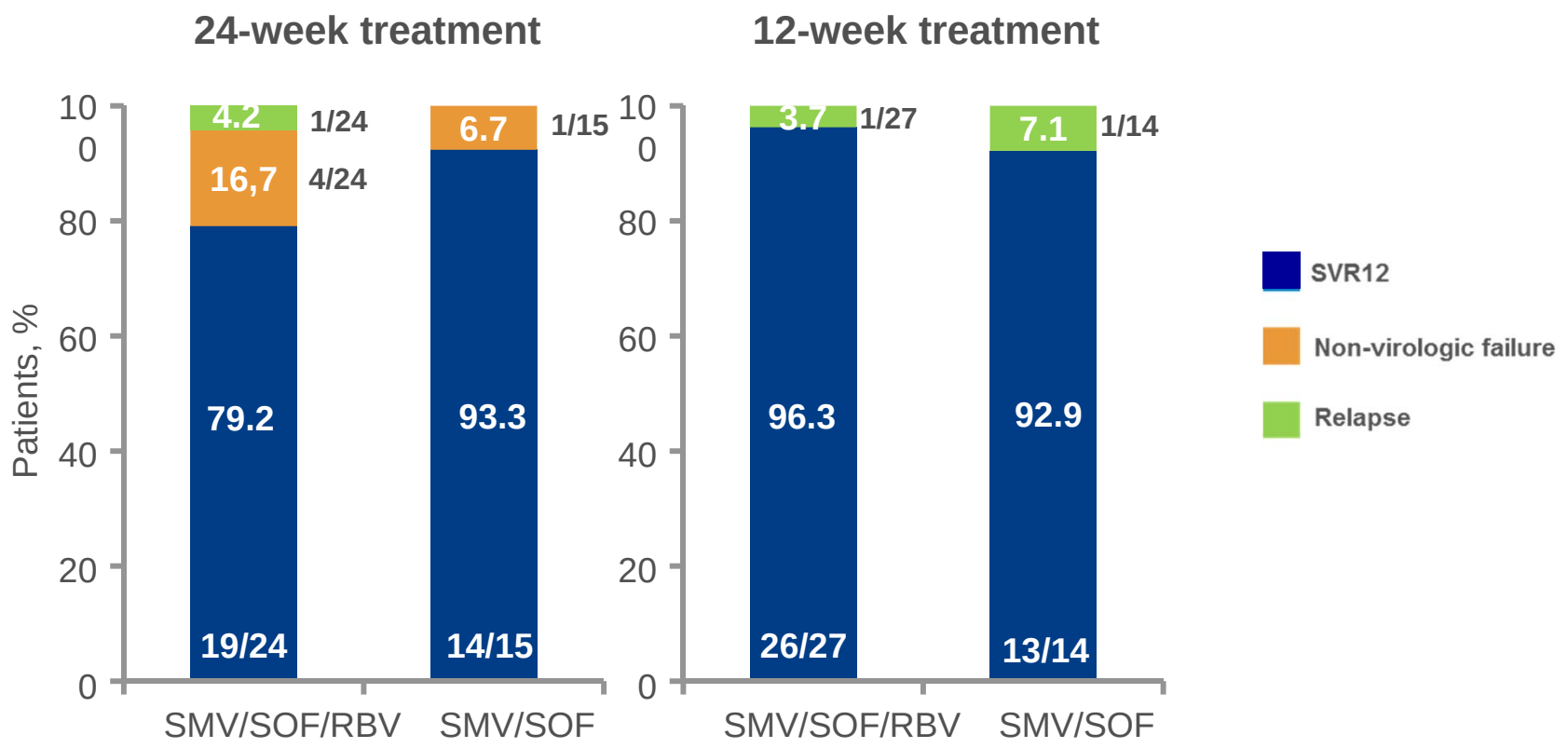
COSMOS study
– combining two “best in class” compounds



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

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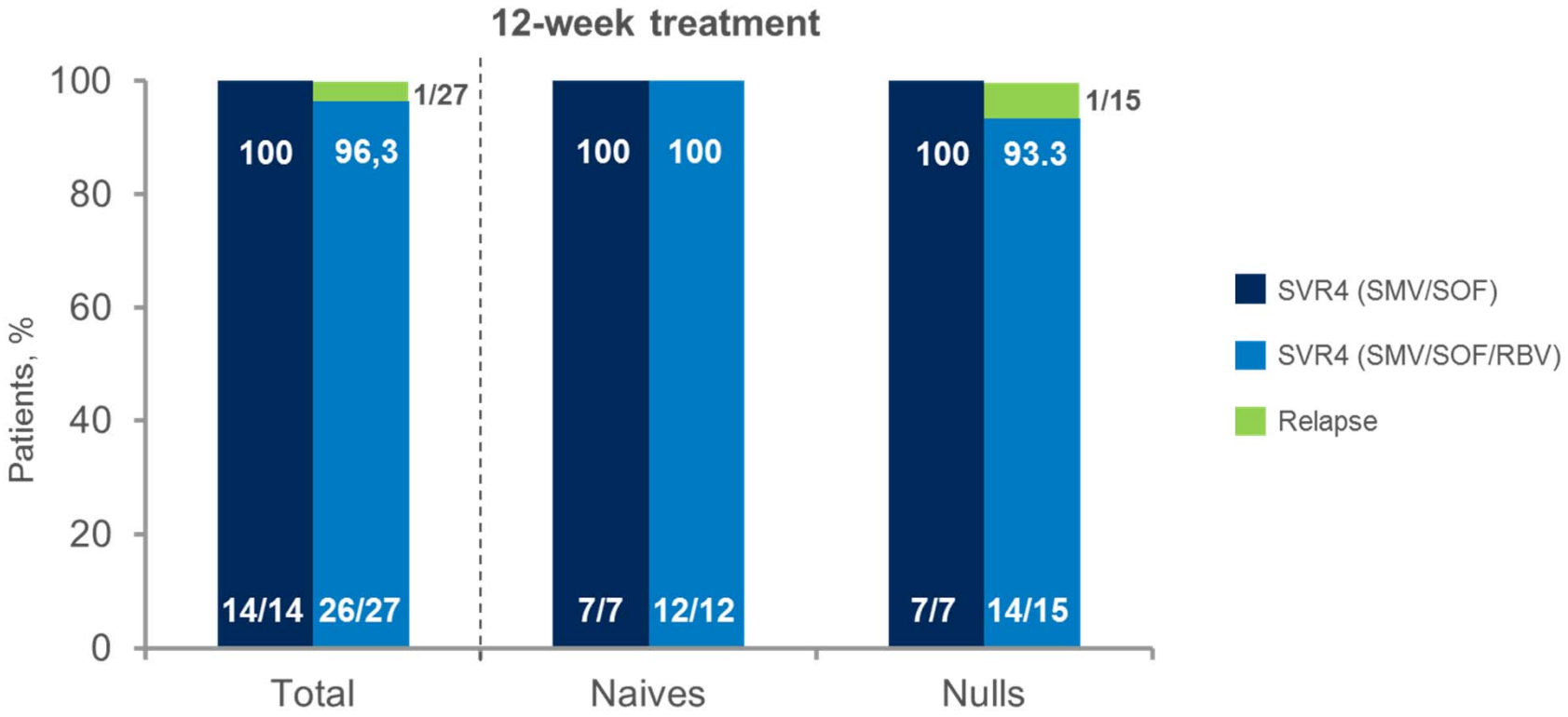
ITT, intent-to-treat
SMV: simeprevir; SOF: sofosbuvir; RBV: ribavirin
Sustained Virological Response 12 weeks (SVR12) after end of treatment.

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



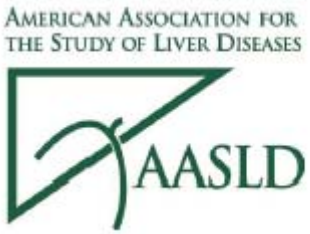
**SVR4 data was only available for 12-week arms at time of interim analysis cut-off*

High efficacy in hardest to cure HCV patients also without ribavirin

Medivir

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

Treatment recommendations in the US (Jan 2014)



Recommendations for Testing, Managing, and Treating Hepatitis C

Recommended regimen for treatment-naive patients with HCV genotype 1 who are not eligible to receive IFN.

Daily sofosbuvir (400 mg) plus simeprevir (150 mg), with or without weight-based RBV (1000 mg [<75 kg] to 1200 mg [≥75 kg) for 12 weeks is recommended for IFN-ineligible patients with HCV genotype 1 infection, regardless of subtype.

Rating: Class I, Level B

Q / A

www.medivir.com

Ticker: MVIR
Exchange: OMX / NASDAQ

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