

# Q1-2014 Conference Call 8 May 2014

## Presenting team

**Maris Hartmanis, President and CEO**  
**Charlotte Edenius, EVP Development**  
**Richard Bethell, EVP Discovery Research**  
**Rein Piir, EVP Corporate Affairs & IR**

The logo for Medivir, featuring the word "MEDIVIR" in a bold, blue, sans-serif font. The text is enclosed within a blue rectangular frame that has a slight 3D effect with a shadow on the right side.

**MEDIVIR**

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



## **Reflections on first quarter 2014**

**Maris Hartmanis, CEO**

## First quarter 2014 – things are on track and moving

### Our pharmaceuticals

- Our pharmaceutical portfolio comprises 16 prescription pharmaceuticals that are marketed in the Nordic region, where we in the future will have a strong focus on specialty pharmaceuticals in the growth phase.
- During the first quarter, our pharmaceutical sales experienced a slight downturn, primarily due to fewer unit sales for Mollipect as a result of a mild influenza and common cold season. In April, we re-launched Suscard, an established pharmaceutical for the treatment of angina pectoris.
- The pharmaceutical portfolio generated a turnover of SEK 46.4 million.
- During the first quarter Medivir received SEK 161 million in royalty from our partner J&J.
- Adasuve was launched in April, a new specialist pharmaceutical for the treatment of agitation associated with bipolar disorder and schizophrenia.
- The organisation is well prepared for the launch of simeprevir in the Nordic region, which we expect to happen at the end of the second quarter.

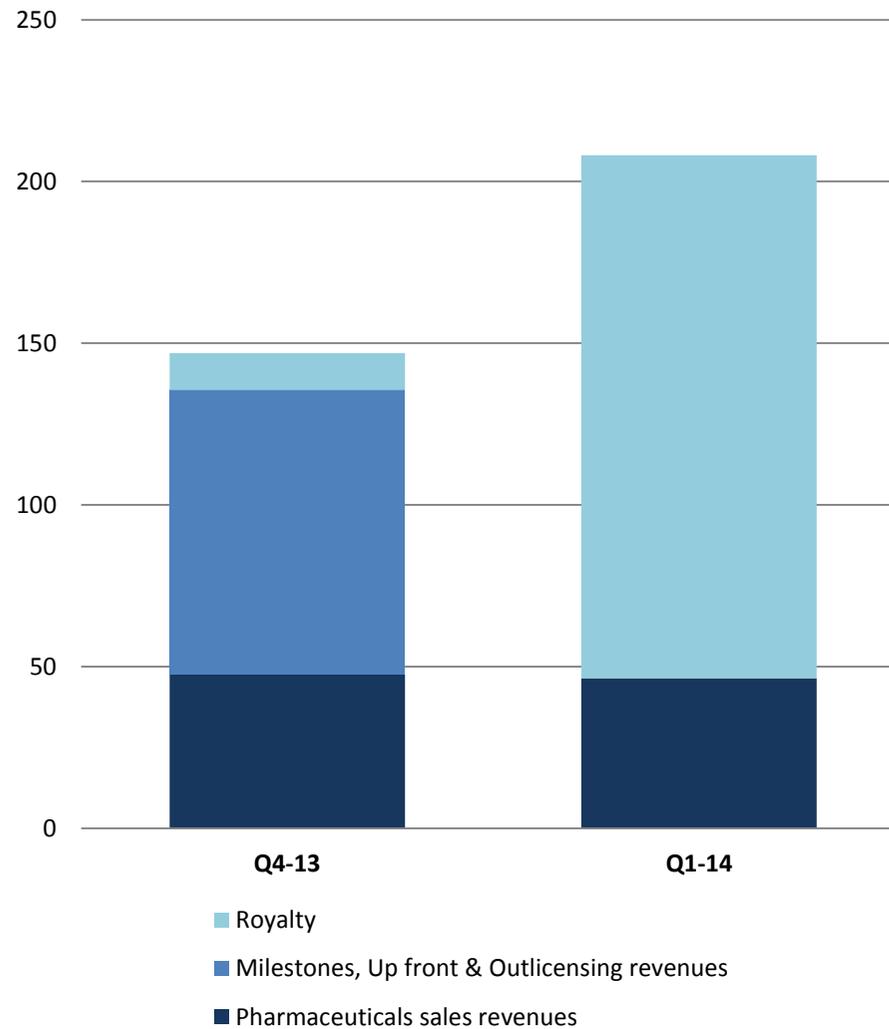
## Consolidated income statement

<b>CONSOLIDATED INCOME STATEMENT SUMMARY</b>	<b>Q1</b>	<b>Q1</b>	<b>FY</b>
Continuing operations (MSEK)	<b>2014</b>	<b>2013</b>	<b>2013</b>
Net turnover	208.2	178.1	446.1
Gross profit	182.1	160.2	374.3
EBITDA	96.7	90.5	76.4
EBIT	88.6	76.7	25.2
Profit/loss before tax	90.3	76.6	27.7
Profit/loss after tax	283.8	71.1	16.0

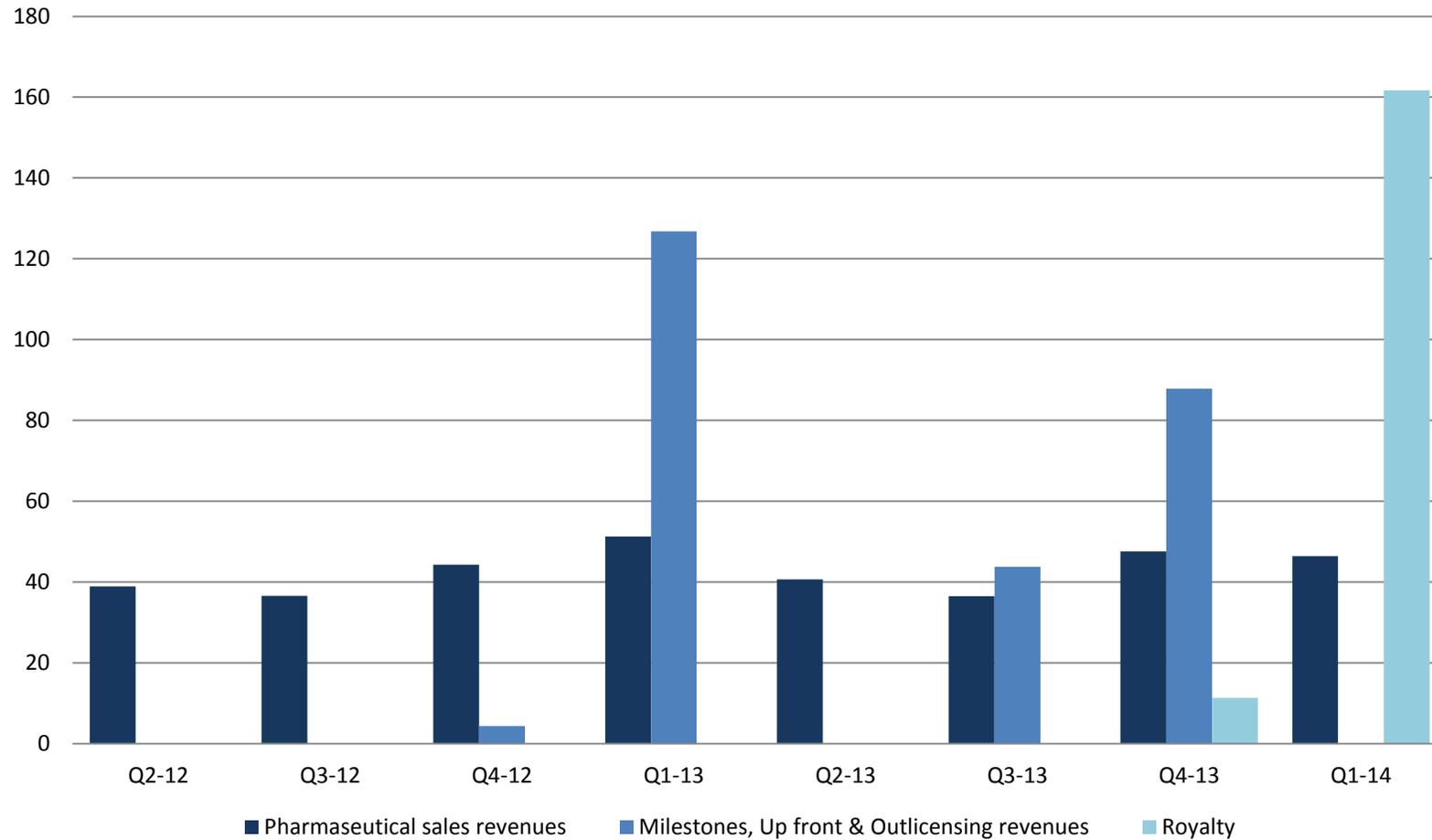
## Net turnover breakdown

Net turnover breakdown (MSEK)	Q1 2014	Q1 2013	FY 2013
Outlicensing and partnership agreements: Non-recurrent payments	-	126.8	258.5
Pharmaceutical sales	46.4	51.3	176.1
Royalties	161.7	-	11.5
Other services	-	-	-
<b>Total</b>	<b>208.1</b>	<b>178.1</b>	<b>446.1</b>

# Net turnover continuing operations per quarter, MSEK



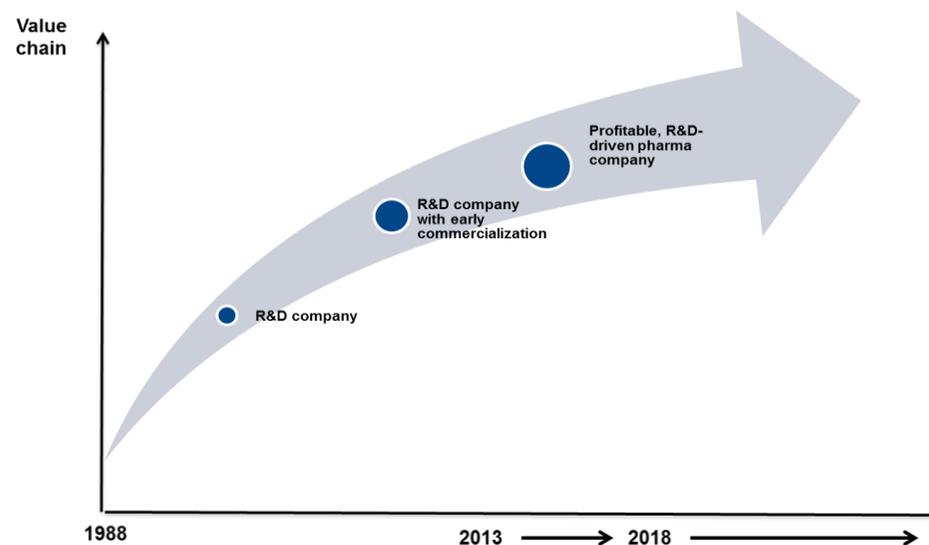
# Net turnover continuing operations per quarter, MSEK



# 2014 – our momentum is strong

- Moving towards sustainable profitability, simeprevir being a important component.
- Simeprevir is selling well – part of the only IFN-free regimen currently in use based on recent guidelines from January 2014.
- During the first quarter simeprevir had a ~50% market share in Japan, a ~20% market share in the US and continues to develop positively.
- Our Nordic commercial organization will sell simeprevir and enable additional opportunities such as Adasuve.
- Our R&D pipeline has three internally driven projects, which all are advancing and will enable new partnerships or joint ventures.
- This will enable us to focus on value creation and risk diversification.

Field	Project	Partner	Preclinical phase			Clinical phase			Market
			Re- search	Devs- support	Phase I	Phase II	Phase III		
<b>Antivirals</b>									
Latent herpes	Kenclear (Zovirax, Zovirax Duo)	Gilead/Boehringer (GSK)							
Hepatitis C	Simeprevir (TMC435), protease inhibitor	NS3 Janssen Pharmaceuticals							
Hepatitis C	NS5B nucleotide-based polymerase inhibitor	Janssen Pharmaceuticals							
Hepatitis C	NS5B nucleotide-based polymerase inhibitor	Unpartnered							
HIV	Protease inhibitor	Janssen Pharmaceuticals							
<b>Other indications</b>									
Bone related disorders	Cathepsin K inhibitor	Unpartnered							
Neuropathic pain	Cathepsin B inhibitor	Unpartnered							



## Simeprevir

- After the launch in December, simeprevir sales have grown rapidly: ~20% market share in the US currently.
- The global first quarter net sales of simeprevir were 354 MUSD, of which 291 MUSD were sales in the US.
- Medivir's royalties based on these sales were 161 MSEK (18 MEUR) for the first quarter.
  
- Simeprevir received a positive recommendation from EMA's advisory committee, the Committee for Medicinal Products in Human Use (CHMP), for the treatment of adults with chronic hepatitis C and was approved in Russia.
  
- Interim results (SVR4) presented from a phase II all-oral combination study of simeprevir and samatasvir (IDX719).
- Final results (SVR12) presented from a phase IIa study evaluating simeprevir and daclatasvir in hepatitis C patients of genotype 1.
- Final results presented from the phase III ATTAIN study (treatment with simeprevir and telaprevir).
- Final results (SVR12) were reported from the COSMOS study of simeprevir and sofosbuvir in cirrhotic and non-cirrhotic patients.
  
- Two phase III studies evaluating treatment of hepatitis C-infected patients with simeprevir and sofosbuvir have recently been initiated.
- A supplemental New Drug Application has been submitted to the FDA in the US for once-daily use of simeprevir in combination with sofosbuvir.



## **Development Highlights Q1 2014**

**Charlotte Edenius, EVP Development**

# MIV-711 - a cathepsin K inhibitor in clinical development for osteoarthritis (OA)

## Osteoarthritis

- A chronic progressive disease characterized by excessive bone resorption and cartilage degradation leading to pain and disability

## Medical need

- The most common joint disease, affecting 10-15% of the US population and with more than 80M sufferers in the US, Europe and Japan\*

## MIV-711 – mechanism of action

- Inhibits cathepsin K, which degrades both bone and cartilage collagen
- Reduces biomarkers reflecting these processes
- Protects from structural changes in OA models

**Two abstracts with MIV-711 data presented at the OA conference, Paris (April 24-29):**

- Non-clinical: novel results demonstrate that once daily MIV-711 reverse subchondral bone loss in an experimental model of OA
- Clinical: 28 days treatment of post menopausal women (100 mg, OD) reduced urinary biomarkers for bone resorption and cartilage degradation with up to 98% and 55%, respectively



**MIV-711 - preparing for clinical phase II and partnership**

## 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

- Cathepsin S is a validated target in a broad range of preclinical models of pain
- Inhibition of Cathepsin S prevents inflammatory damage to the sensory nervous system

## MIV-247

- Non-clinical *in vivo* studies support the development of MIV-247:
  - as monotherapy (fast and sustained efficacy seen in models of neuropathic pain)
  - as combination therapy (improved efficacy shown when combined with e.g. gabapentin)

**MIV-247 - IND phase towards clinical trials**



✓ Japan (SOVRIAD™)



✓ Canada (GALEXOS™)



✓ USA (OLYSIO™)\*



✓ Russia (SOVRIAD™)

✓ EU: Positive recommendation from CHMP, approval expected in May

\* A supplemental New Drug Application has been submitted to the U.S. FDA for simeprevir in combination with sofosbuvir based on the data from the COSMOS trial

## *APASL (Brisbane, Feb)*

- **ATTAIN study (simeprevir vs telaprevir, prior null or partial responder patients (N=744))**
  - Simeprevir demonstrated non-inferiority while having a superior safety profile (lower adverse event frequency, fewer serious adverse events, and a lower incidence of anaemia)
- **GT1b patient subgroup analyses of phase III data (of importance for the Asian markets)**
  - 85% and 86% cure rates in treatment naïve and prior relapsed HCV GT1b infected patients

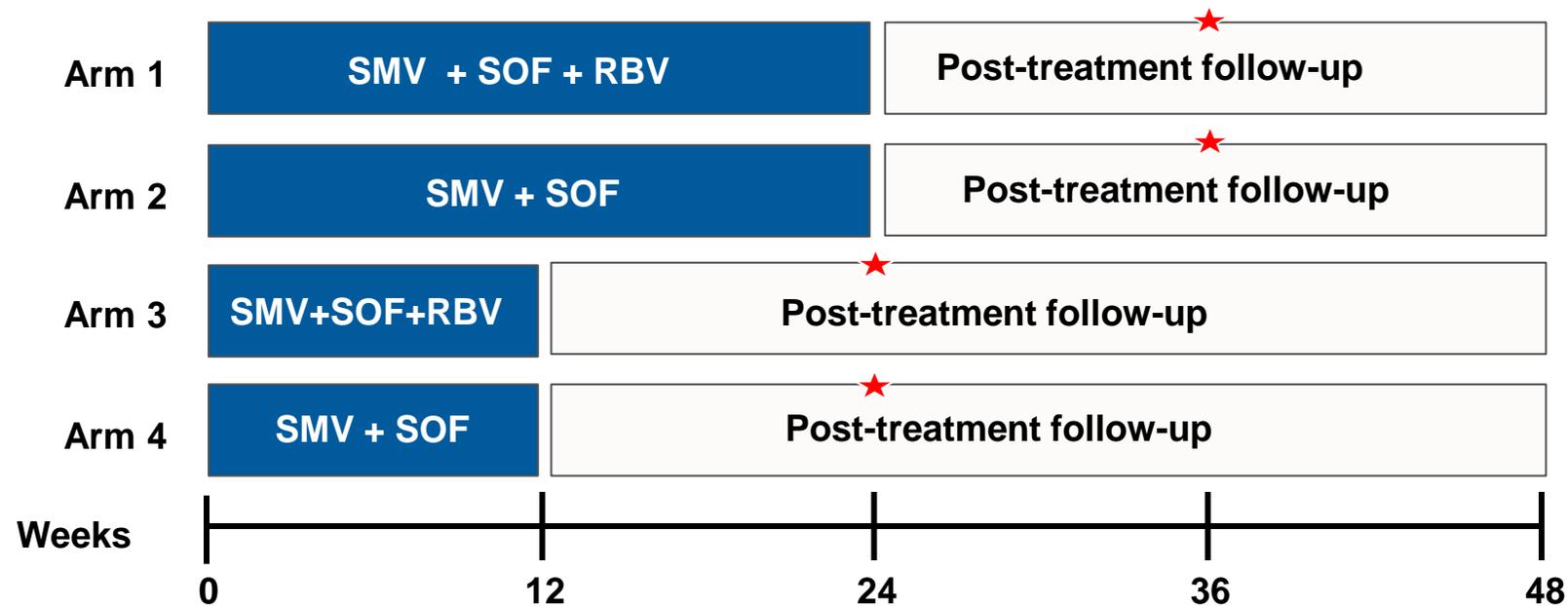
## *EASL (London, April)*

- **European patient subgroup analyses of phase III data**
  - 87% and 88% cure rates in treatment naïve and prior relapsed HCV GT1 patients
- **RESTORE (HCV GT4 treatment naïve *and* experienced *including cirrhotics*)**
  - high SVR12 rates (83% in treatment-naïve; 86% in prior relapsers; 60% in partial responders and 40% in null responders)
  - 95% of patients with 24 weeks total treatment duration achieved SVR12

## *On-going studies:*

- **12 weeks full stop** single-arm study in treatment naïve GT1 and GT4 patients
- **China** - efficacy, safety & tolerability and pharmacokinetics in treatment naïve GT1 HCV patients (results available by year end)

# COSMOS study – an IFN-free combination study of simeprevir and sofosbuvir in hard-to-cure patients



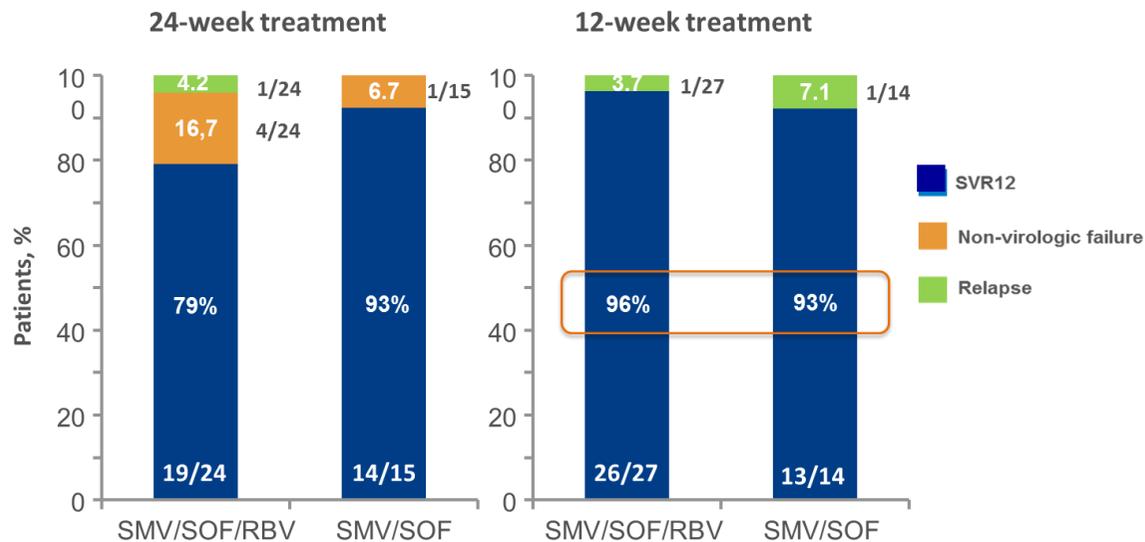
SMV 150 mg QD + SOF 400 mg QD

★ Primary endpoint SVR12

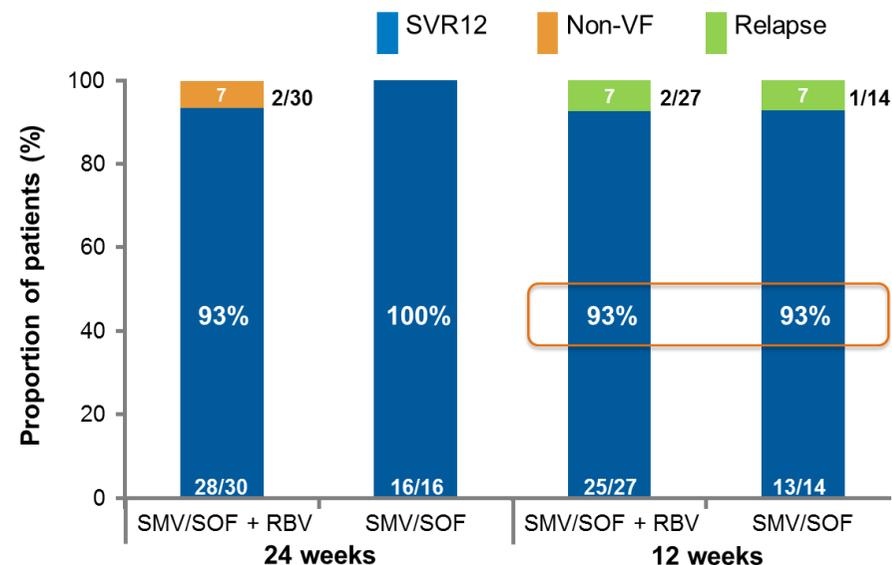
**Cohort 1: METAVIR F0-F2, prior null responders to PR therapy (n=80)**

**Cohort 2: METAVIR F3-F4, prior null responders or treatment-naïve (n=87)**

## Cohort 1: Prior null responders (METAVIR F0-F2)



## Cohort 2: “naïves” and “nulls” (METAVIR F3/4)



- No benefit demonstrated by addition of ribavirin
- High SVR12 rates regardless of baseline characteristics (HCV GT 1 subtype, Q80K polymorphism, METAVIR score, IL28B GT or prior treatment history)
- SMV/SOF QD +/- RBV was safe and well tolerated

**High SVR12 rates, 93- 96%, with 12 weeks once daily treatment with SMV + SOF in hard to cure patients**

## SVR12 among patient subgroups with advanced liver disease (METAVIR scores F3-F4)

	12 weeks treatment	
	SMV/SOF % (n/N)	SMV/SOF + Rbv % (n/N)
All patients	93 (13/14)	93 (25/27)
HCV GT1a without the Q80K polymorphism	88 (7/8)	93 (13/14)
HCV GT1a with the Q80K polymorphism	100 (3/3)	88 (7/8)
HCV genotype 1b	100 (3/3)	100 (5/5)
Patients with METAVIR F4 scores	86 (6/7)	91 (10/11)

# Ongoing IFN-free studies with simeprevir

- data driven approach to exploring different interferon-free combinations



Class	Compound	Partner	Status
	Simeprevir Sofosbuvir	Janssen	<b>OPTIMIST 1:</b> null + naives (F0-3), 8 or 12 weeks (n=300) <b>OPTIMIST 2:</b> null + naïve s (F4), 12 weeks duration (n=100) - no ribavirin in either study
	Simeprevir IDX719	Janssen Idenix	HELIX-1: Phase II , Gt1b and 4 (150 mg SMV + 50 mg SAM + RBV-> 85% SVR4)
	Simeprevir JNJ-56914845	Janssen	Phase II on its way
	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

**Q / A**

**[www.medivir.com](http://www.medivir.com)**

**Ticker: MVIR**  
**Exchange: OMX / NASDAQ**

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