

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 and bottom sides.

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.

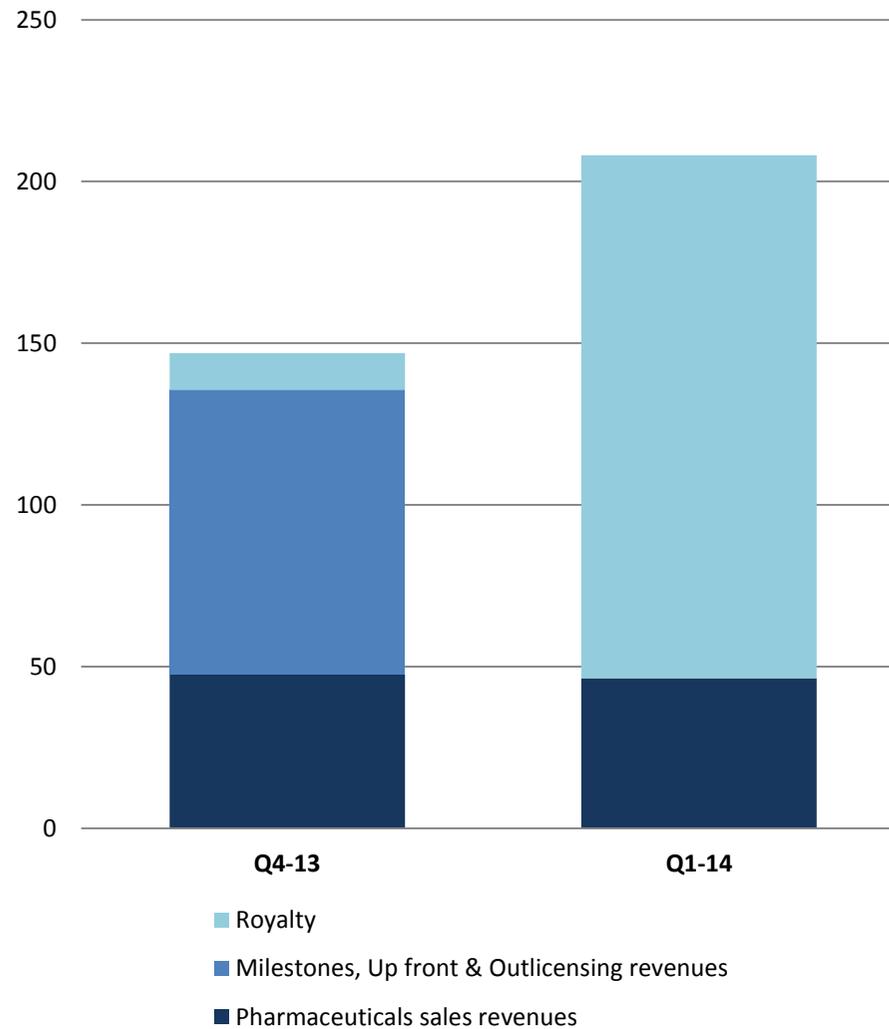
Consolidated income statement

CONSOLIDATED INCOME STATEMENT SUMMARY	Q1	Q1	FY
Continuing operations (MSEK)	2014	2013	2013
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

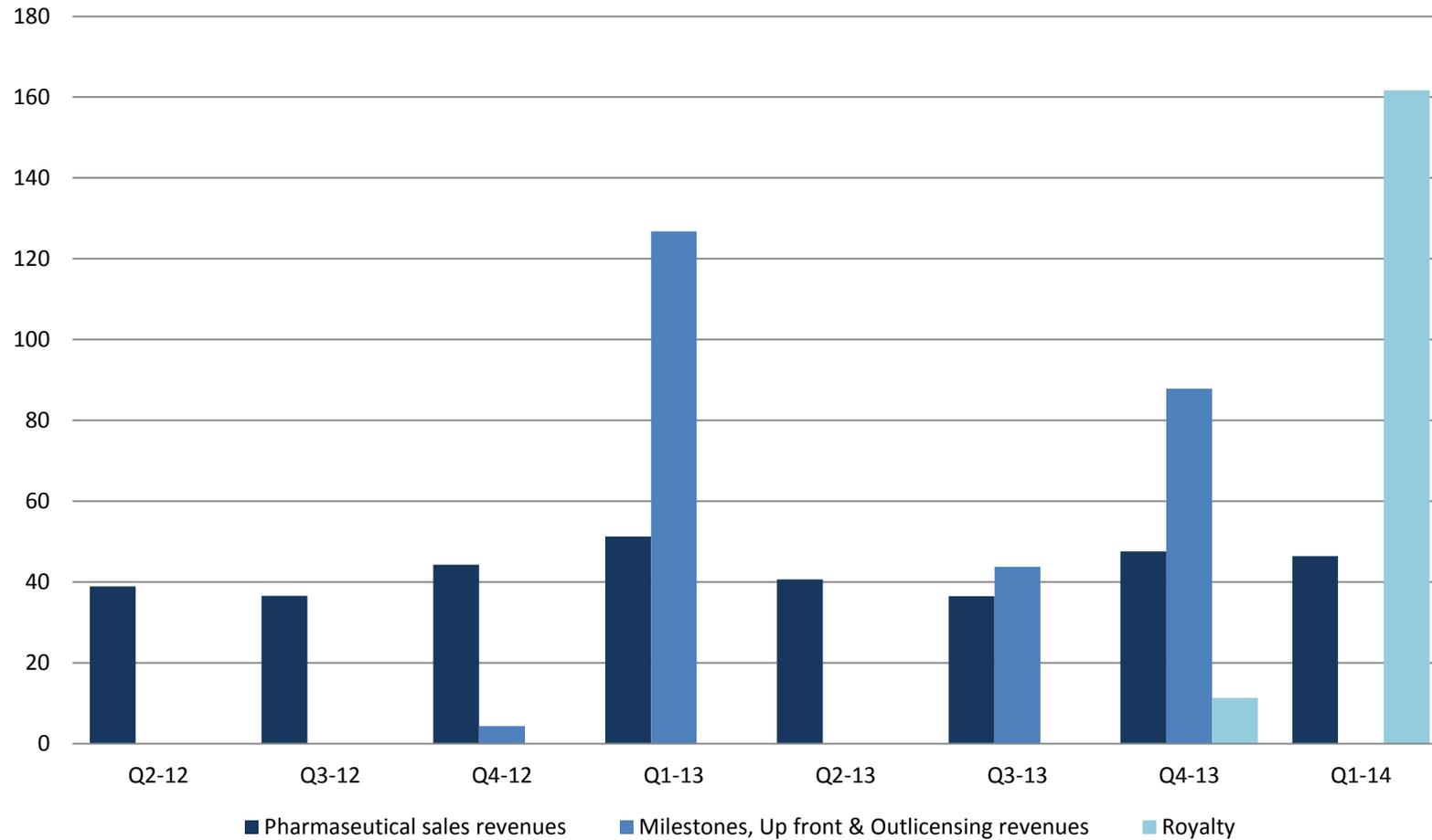
Net turnover breakdown

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	-	-	-
Total	208.1	178.1	446.1

Net turnover continuing operations per quarter, MSEK



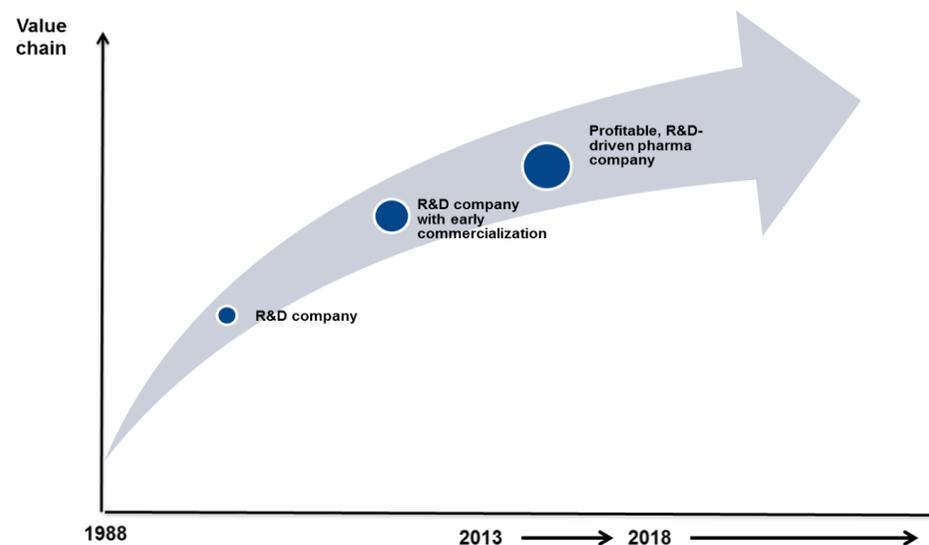
Net turnover continuing operations per quarter, MSEK



2014 – our momentum is strong

- Moving towards sustainable profitability, simeprevir being an 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		
Antivirals									
Latent herpes	Kenclear (Zovirax, Zovirax Duo)	Gilead/Boehringer (GSK)							
Hepatitis C	Simeprevir (TMC435), protease inhibitor	N33 Janssen Pharmaceuticals							
Hepatitis C	N33B nucleotide-based polymerase inhibitor	Janssen Pharmaceuticals							
Hepatitis C	N33B nucleotide-based polymerase inhibitor	Unpartnered							
HIV	Protease inhibitor	Janssen Pharmaceuticals							
Other indications									
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

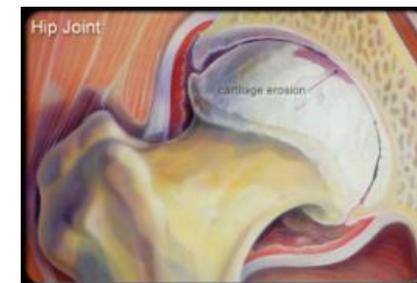
- The most common joint disease, affecting 10-15% of the US population and with more than 80M sufferers in the US, Europe and Japan*

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

*Datamonitor, 2009

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

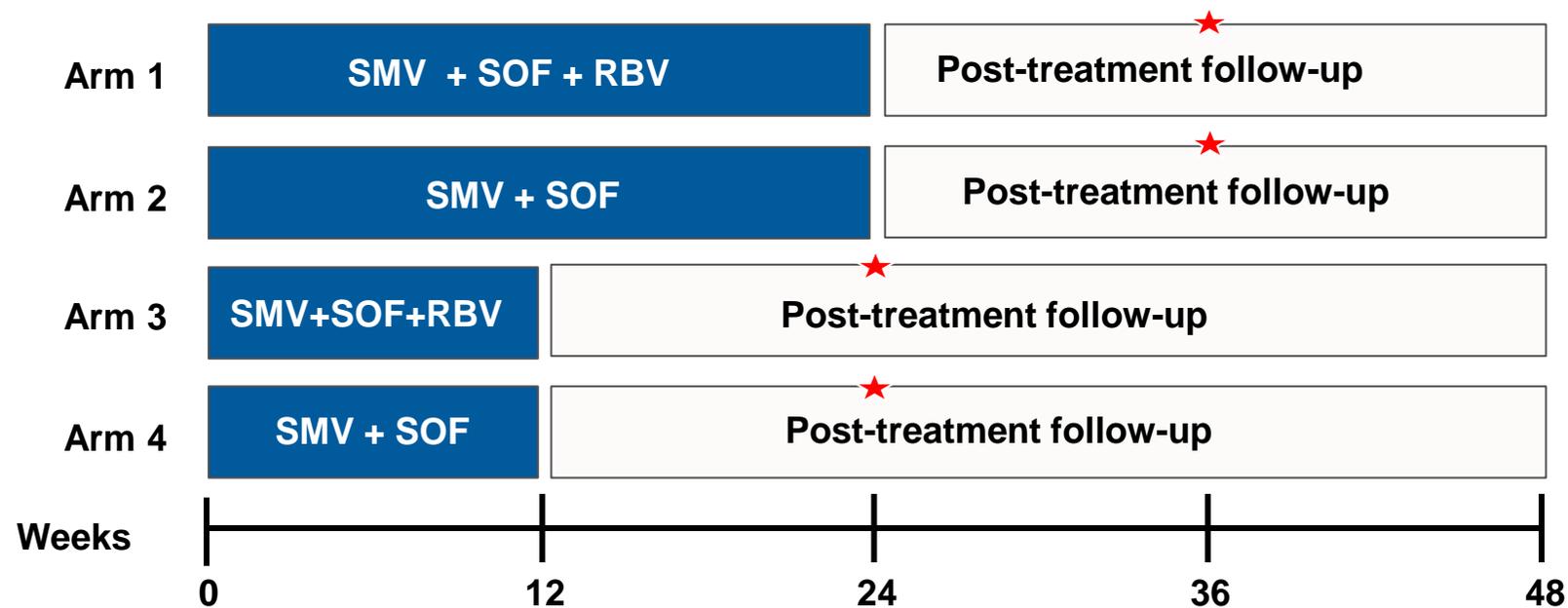
EASL (London, April)

- **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



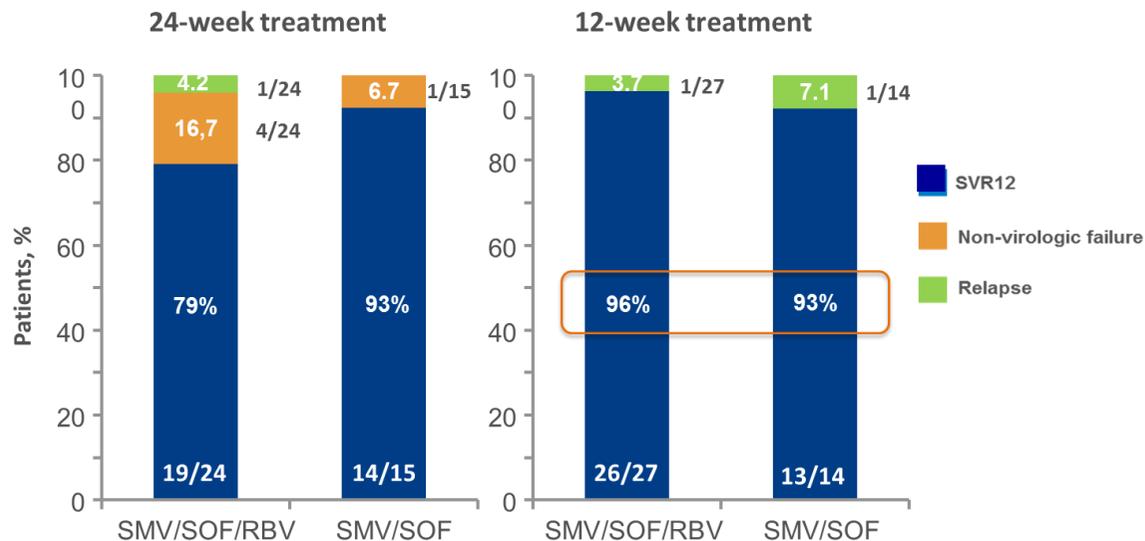
SMV 150 mg QD + SOF 400 mg QD

★ Primary endpoint SVR12

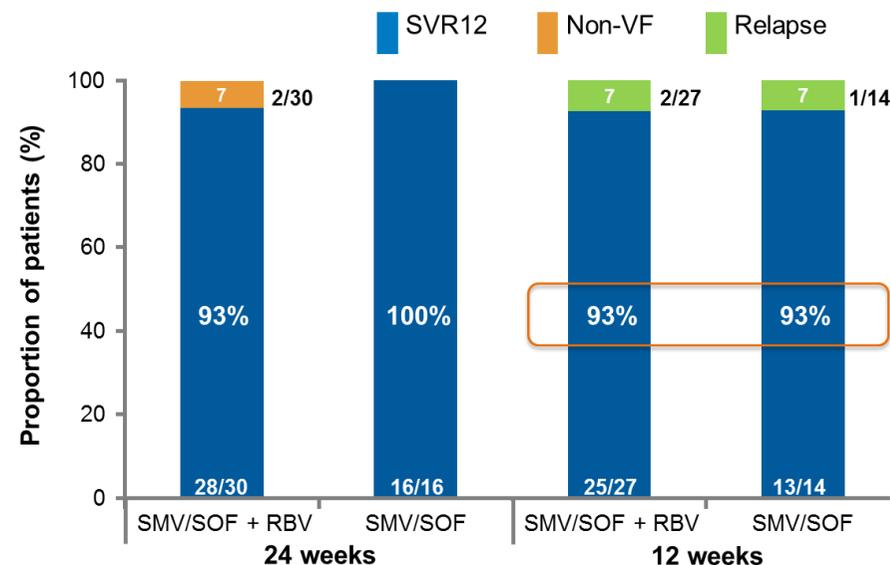
Cohort 1: METAVIR F0-F2, prior null responders to PR therapy (n=80)

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)

SVR12	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	OPTIMIST 1: null + naives (F0-3), 8 or 12 weeks (n=300) OPTIMIST 2: 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

Ticker: MVIR
Exchange: OMX / NASDAQ

**For more information please contact
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