Medivir

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

Börsveckans småbolagsdag 4 september 2013

Rein Piir, EVP Corporate Affairs & IR

Medivir - the emerging European pharma company

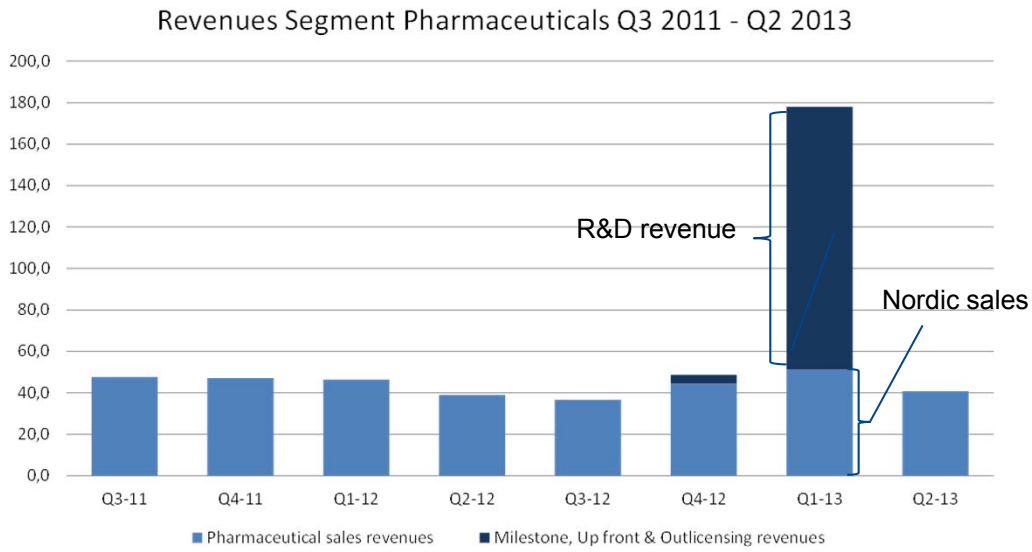
- **World leading expertise in polymerase and protease drug targets**
- **First in-house developed product on the market – second on its way**
- **Fifteen marketed products in the Nordics -** generating annual sales of ~SEK 180m with an EBITDA of ~SEK 75m
- **Strong position in HCV drug development - Simeprevir (TMC435) in partnership with Janssen, considered as the best in class PI - filed globally during 2013**
- **Solid financial position**

Recent highlights

- **To increase focus in our Nordic pharmaceuticals business we divested our parallel trading franchise, Cross Pharma, which strengthened our financial position**
- **Positive efficacy and safety data were presented from four Japanese phase III studies with simeprevir**
- **All interferon-free combination trials with simeprevir continue to make progress. The phase II trial (HELIX-1) with simeprevir and samatasvir (IDX719) was initiated**
- **We refocused the internal HCV efforts and are exploring the nucleotide-based polymerase inhibitors following a discontinuation of our NS5A program**
- **The Cathepsin K phase I trial was completed**
- **The Cathepsin S project is moving towards CD selection during H2, 2013**

P&L and quarterly pharmaceutical sales

(SEK m)	2013 Jan-June	2012 Jan-June	2012 Jan-Dec
Net turnover	218.8	85.2	170.6
Gross profit	183.8	54.1	109.3
EBITDA	43.6	-79.6	-165.3
EBIT	14.7	-99	-201.3
Profit/loss before tax	14.5	-98.4	-210.8
Profit/loss after tax	7.5	-107.2	-234.1



R&D

Pipeline status

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
Anivirals									
Labial herpes	Xerclear (Zoviduo, Zovirax Duo)	GlaxoSmithKline (GSK)							
Hepatitis C	Simeprevir (TMC435), NS3 protease inhibitor	Janssen Pharmaceuticals							
Hepatitis B	Lagociclovir valactate (MIV-210)	Daewoong							
Hepatitis C	NS5B nucleotide-based polymerase inhibitor	Janssen Pharmaceuticals							
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HIV	Protease inhibitor	Janssen Pharmaceuticals							
Other indications									
Bone related disorders	Cathepsin K inhibitor								
Neuropathic pain	Cathepsin S inhibitor								

Simeprevir

- A potent HCV protease inhibitor in registration phase

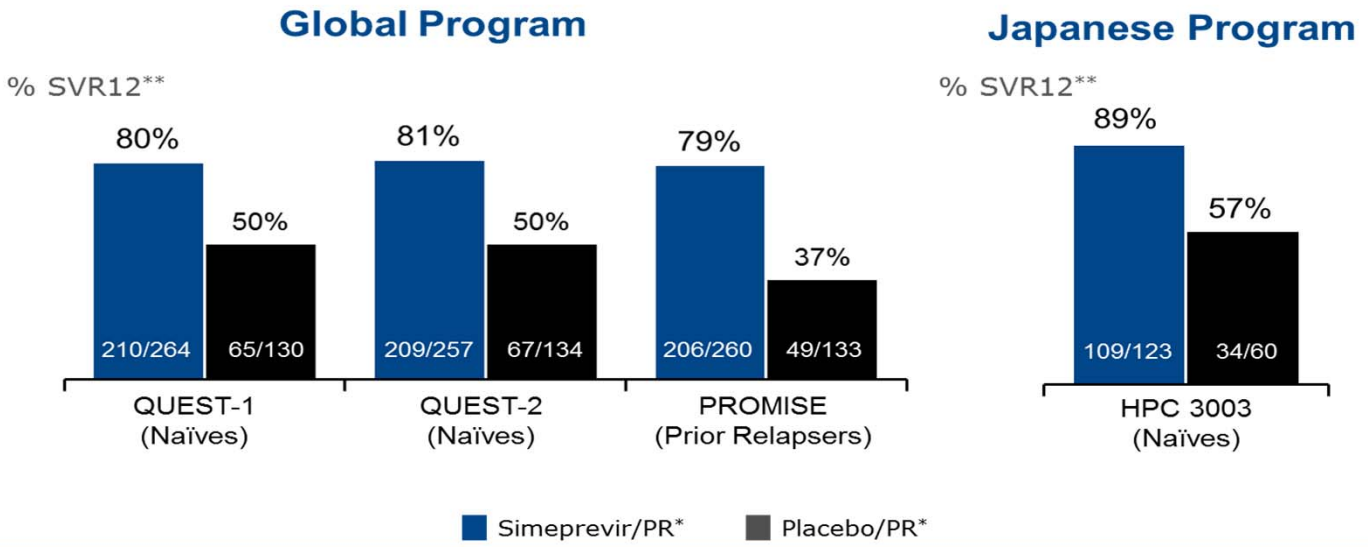
Simeprevir - Regulatory status and summary phase III (triple)

Regulatory applications filed in:

- **Japan** for hepatitis C genotype 1, naïve, prior non-responders or relapsed – Feb, 2013
- **US** for hepatitis C genotype 1 – Priority Review granted in May, 2013
- **EU** for hepatitis C genotype 1 and 4 – April, 2013

Excellent safety and tolerability

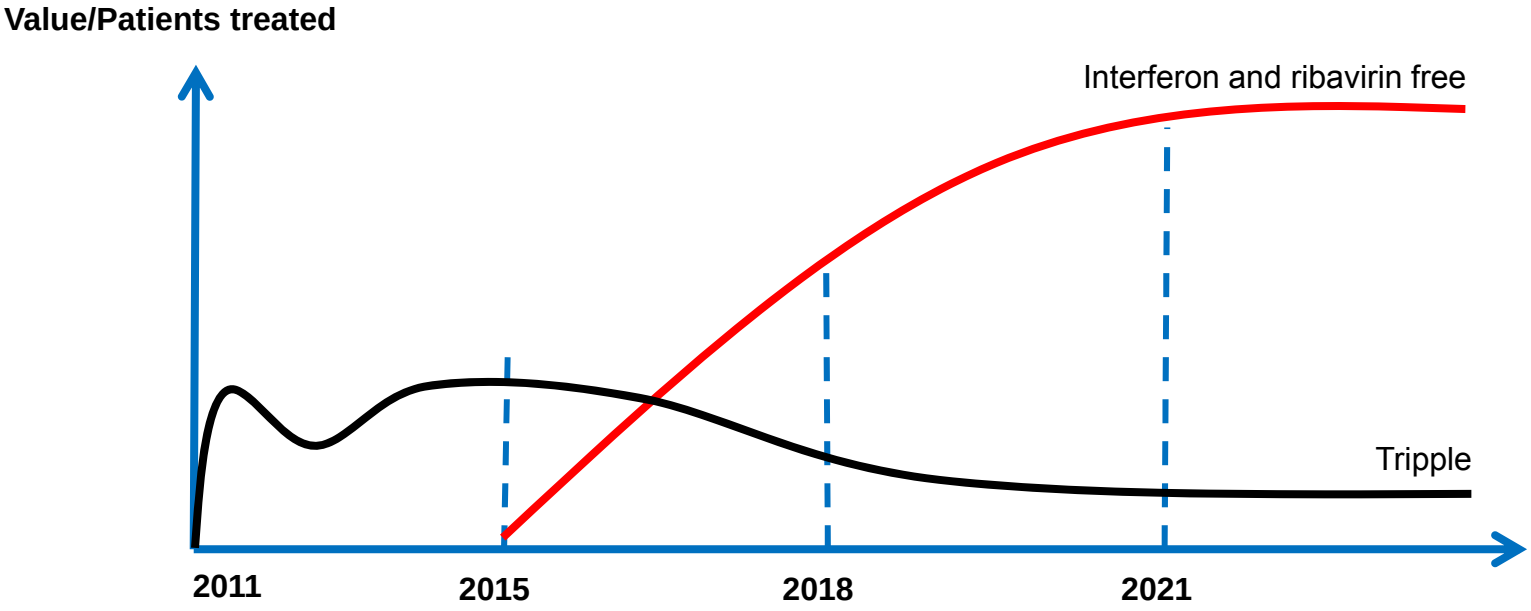
- Overall incidence of adverse events similar to placebo, including rash and anemia
- Safety and tolerability confirmed in Japanese program



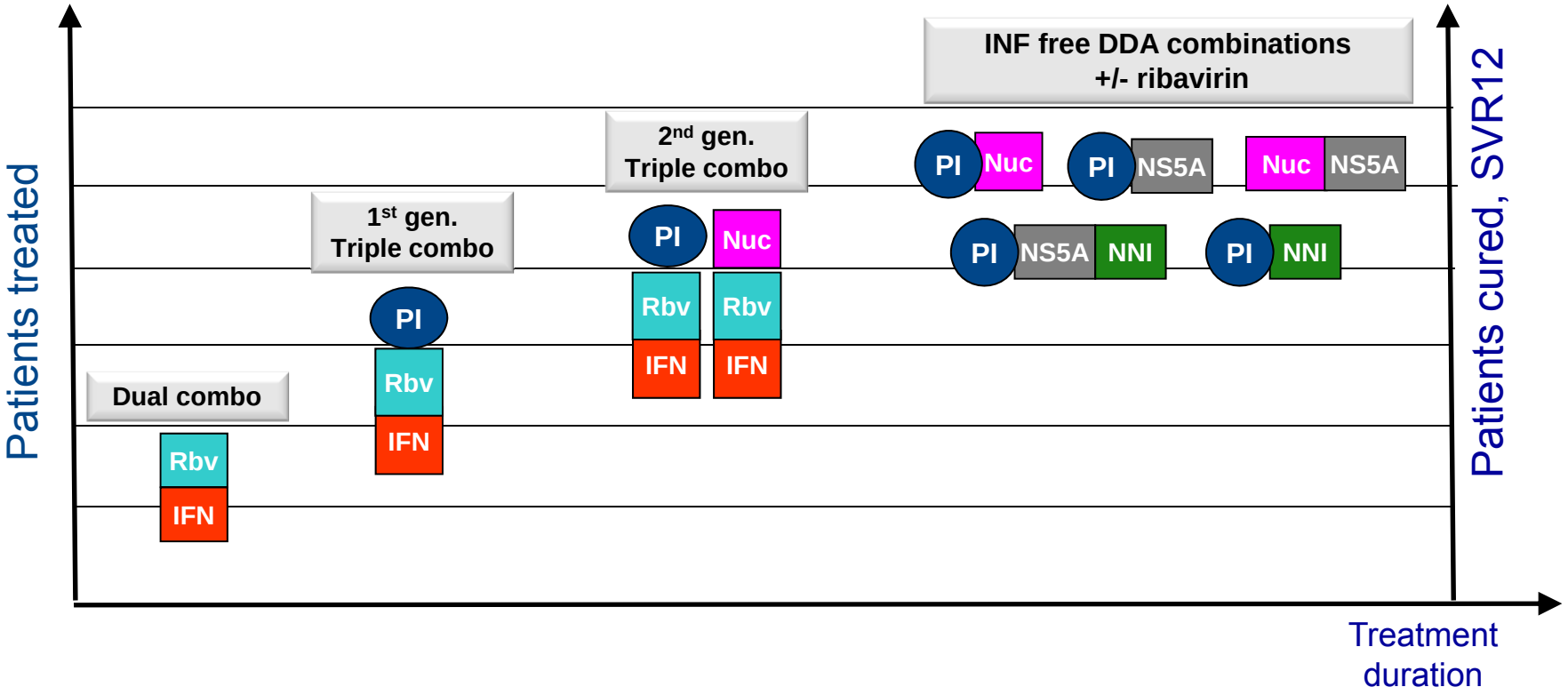
Long term goal - eradication of hepatitis C

The evolution in treating hepatitis C will expand the market value, number of patients treated and regions over the next 10-15 years

Market value, peak sales > 20 bn USD



Evolution of HCV therapy



The most competitive HCV therapies will consist of IFN- and RBV-free dual DAA combos, each DAA having outstanding properties

Simeprevir

- All oral interferon-free combination update

Simeprevir in interferon-free combinations

			Ribavirin		
Simeprevir	**+**	**Sofosbuvir** (nucleotide)	**+/-**	12w	N=80 Cohort a: nulls, F0-F2 N= 87 Cohort b: only METVIR score **F3 and 4 patients** (nulls + naives)
			+/-	24w	
Simeprevir	**+**	**Daclatasvir** (NS5A inhibitor)	**+/-**	12w	N=180 Naives and nulls **Incl. F3/4 up to 35 %**
			+/-	24w	
Simeprevir	**+**	**TMC647055/r** (NNI; non-nucleoside)	**+/-**	12w	Naives/relapser and nulls Non-cirrhotics
Simeprevir	**+**	**VX-135** (nucleotide)	**+/-**	12w	DDI study completed Phase II to start H2 2013 on track
Simeprevir	**+**	**IDX719** (NS5A inhibitor) **+/- TMC647055/r**	**+/-**	12w	HELIX-1 Phase II started during Q2 HELIX-2 to start during Q3

Simeprevir is strongly positioned to become a principal component of future IFN-free therapies

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For additional information, please see www.clinicaltrials.gov

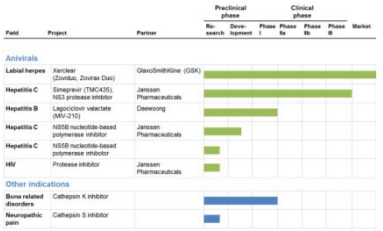
COSMOS study – Efficacy results
(Cohort 1 and 2 interim analysis)

	Cohort 1* Prior null responder HCV patients (METAVIR score F0-F2)		Cohort 2 Prior null responder and treatment naïve HCV patients (METAVIR scores F3 or F4)	
	SMV / SOF+ RBV (n=27)	SMV / SOF (n=14)	SMV / SOF + RBV (n=27)	SMV / SOF (n=14)
SVR4	26/27(96%)	13/14(93%)	26/27(96%)	14/14(100%)
SVR8	26/27(96%)	13/14(93%)	-	-

In cohort 1 the patients in the **12 week arms** who achieved SVR8 – **24/24** who reached post-treatment Week 12 had achieved **SVR12**

[1]RVR is based on patients with available data at Week 4 (2 patients discontinued before Week 4)
EOT, end of treatment; RVR, rapid virologic response; SMV, simeprevir;
SOF, sofosbuvir; SVR, sustained virologic response

Key events in the coming 12 month



H2-13 Results from phase I-study with MIV-711, our cathepsin K inhibitor (bone related disorders)

H2-13 Start of the phase II study - HELIX-2 (simeprevir + TMC647055 and samatasvir - IDENIX)

H2-13 Start of Phase II with simeprevir and VX-135 (Vertex)

H2-13 Potential CD selection in Cathepsin S (neuropathic pain) program

H2-13 Anticipated approval in Japan for simeprevir

H2-13 Goal to start phase I trials with Medivir/Janssen nucleotide NS5B-inhibitor

H2-13 Data from the phase II combination study with simeprevir and daclatasvir (BMS)

H2-13 Presentations at AASLD

H2-13 SVR data from Cohort 2 with simeprevir and sofosbuvir phase II study

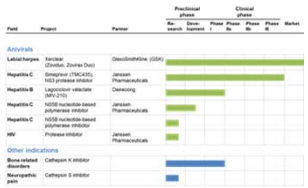
H1-14 Anticipated approval of simeprevir in the US

H1-14 Anticipated approval of simeprevir (triple) in EU

H1-14 Potential CD selection in our internal Nucleotide NS5B inhibitor program

H1-14 Presentations at EASL

Value proposition – setting the framework towards profitability



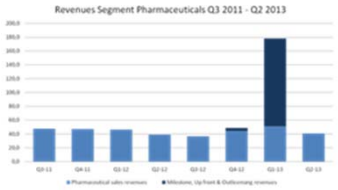
Innovative portfolio will evolve over time

- World class expertise in polymerase and protease drug targets
- Broader, risk balanced, R&D pipeline
- Continued commitment towards targets in infectious diseases
- Addressing new therapeutic areas based on core competence
- Partner of choice for both pharmaceuticals and development programs

Long term commitment in the HCV area

- Simeprevir, partnered with Janssen Pharmaceuticals
  - Regulatory files submitted in EU, US and Japan
  - On-going interferon-free combination trials will guide us in treatment opportunities
- In-house un-partnered HCV nucleotide-based polymerase inhibitor program will offer new combination treatment opportunities

Commercial presence in the Nordic region creates revenue



- 15 solid Rx pharmaceutical brands with annual sales of ~SEK 180m
- Commercial platform for the launch of simeprevir in the Nordics in 2014
- Expansion of product portfolio

External perspective

- Top ranked as a listed company
- Profitable and fast growing Nordic based pharmaceutical company

www.medivir.com

Ticker: MVIR
Exchange: OMX / NASDAQ

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