Medivir

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

Stockholm Corporate Finance / Financial Hearings
Life Science / Healthcaredag 13 mars 2013

Rein Piir, EVP Corporate Affairs / IR

2012 – Summary

R&D operations

- Progress in R&D pipeline, both internally driven and partnered projects
- Simeprevir phase III data showed strong and consistent results, followed by filing in Japan
- Broadening of research platform and know-how through new collaborations and an acquisition

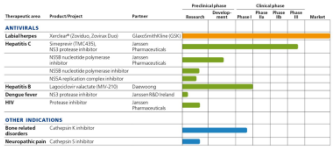
Pharmaceuticals

- Consistent product portfolio performance, earnings in line with expectations at the acquisition in 2011, with a EBITDA contribution of ~100 MSEK
- GSK started OTC launch in Europe and obtained OTC approval in Russia with the Medivir developed cold sore pharmaceutical branded as Zoviduo/Zovirax Duo
- Preparations and awareness building around simeprevir in the Nordics made strong progress

Finance

- Solid financial position at year end with ~300 MSEK in cash
- Stable cost base with a net burn rate of ~200 MSEK

2013 - Setting the framework for becoming
The Emerging European Pharma Company



Structure

- 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

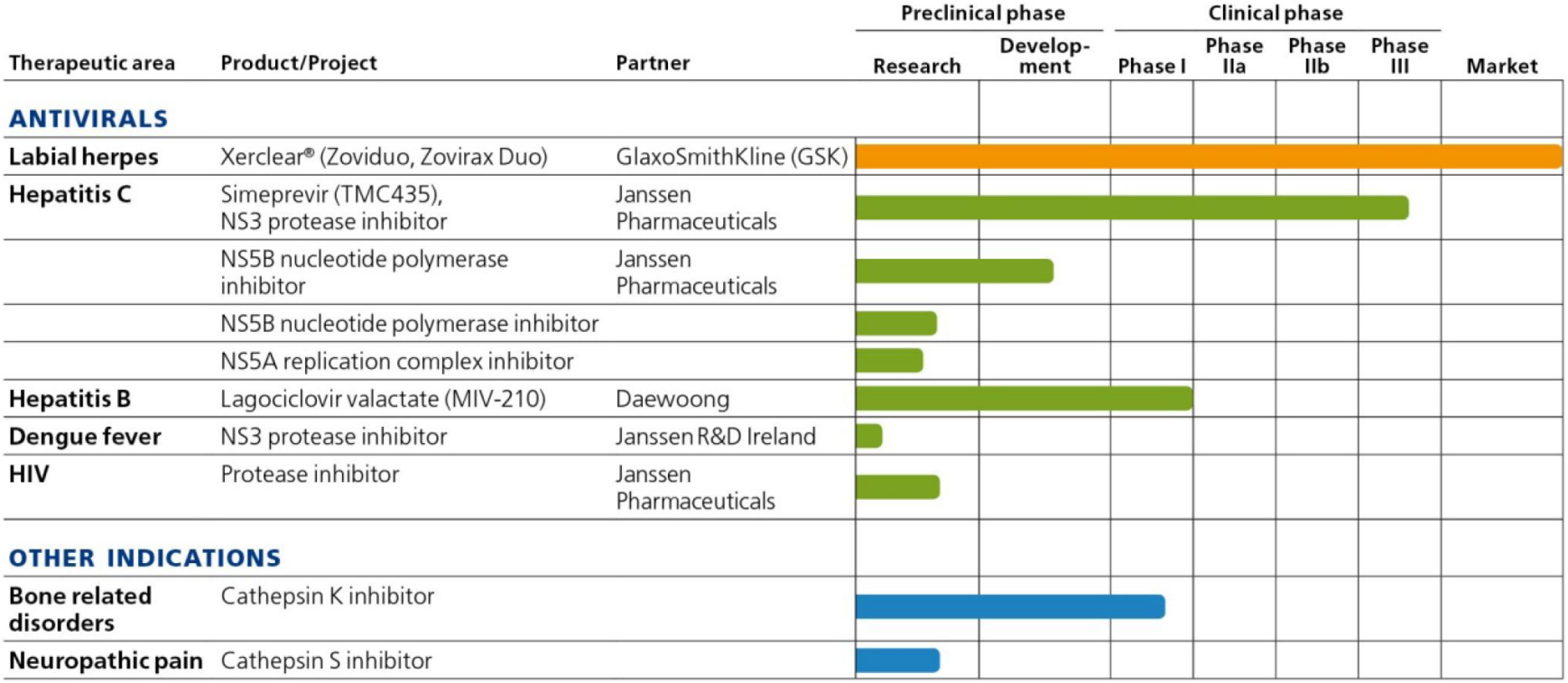
- Expansion of product portfolio, including simeprevir and other in-house developed pharmaceuticals

External perspective

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

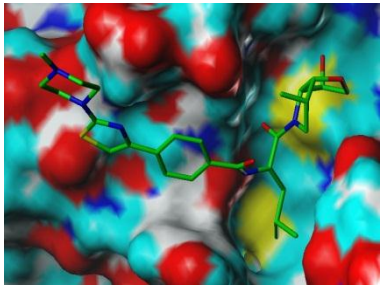
The R&D portfolio will evolve over time

- New infectious disease research programs underway
- New therapeutic areas will be evaluated



Therapeutic area	Product/Project	Partner	Preclinical phase: Research	Preclinical phase: Develop-ment	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							
	NS5B nucleotide polymerase inhibitor	Janssen Pharmaceuticals							
	NS5B nucleotide polymerase inhibitor								
	NS5A replication complex inhibitor								
Hepatitis B	Lagociclovir valactate (MIV-210)	Daewoong							
Dengue fever	NS3 protease inhibitor	Janssen R&D Ireland							
HIV	Protease inhibitor	Janssen Pharmaceuticals							
OTHER INDICATIONS									
Bone related disorders	Cathepsin K inhibitor								
Neuropathic pain	Cathepsin S inhibitor								

Cathepsin K inhibitor
- a phase I clinical program



Disease

Osteoporosis, osteoarthritis and metastatic bone disease

MIV-711: Phase I clinical trial ongoing

- Adaptive, placebo controlled, double-blind study in healthy volunteers incl. post meno-pausal women
- Ascending single and multiple (7 - 28 days) once daily dosing
- Biomarkers for bone and cartilage turnover

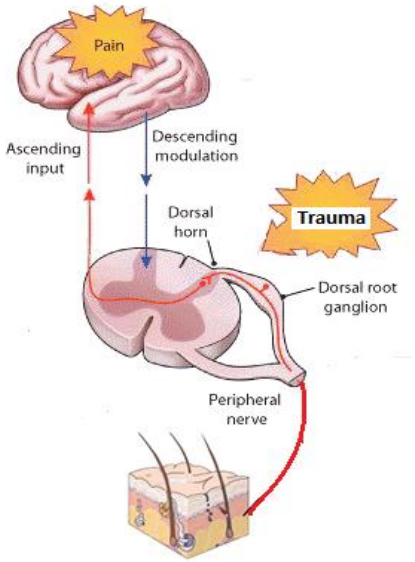
- Phase I completed and data available H1-2013

MIV-711 - a phase I clinical candidate efficacious on bone and cartilage biomarkers in osteoarthritis and osteoporosis models

Cathepsin S inhibitor – neuropathic pain and rheumatoid arthritis

Principle for neuropathic pain (NP)

- Associated with a lesion or disease affecting the somatosensory system
- Includes e.g. diabetic neuropathic pain, post-herpetic neuralgia & neuropathic lower back 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
- 25M people in the 7 MM suffer from NP

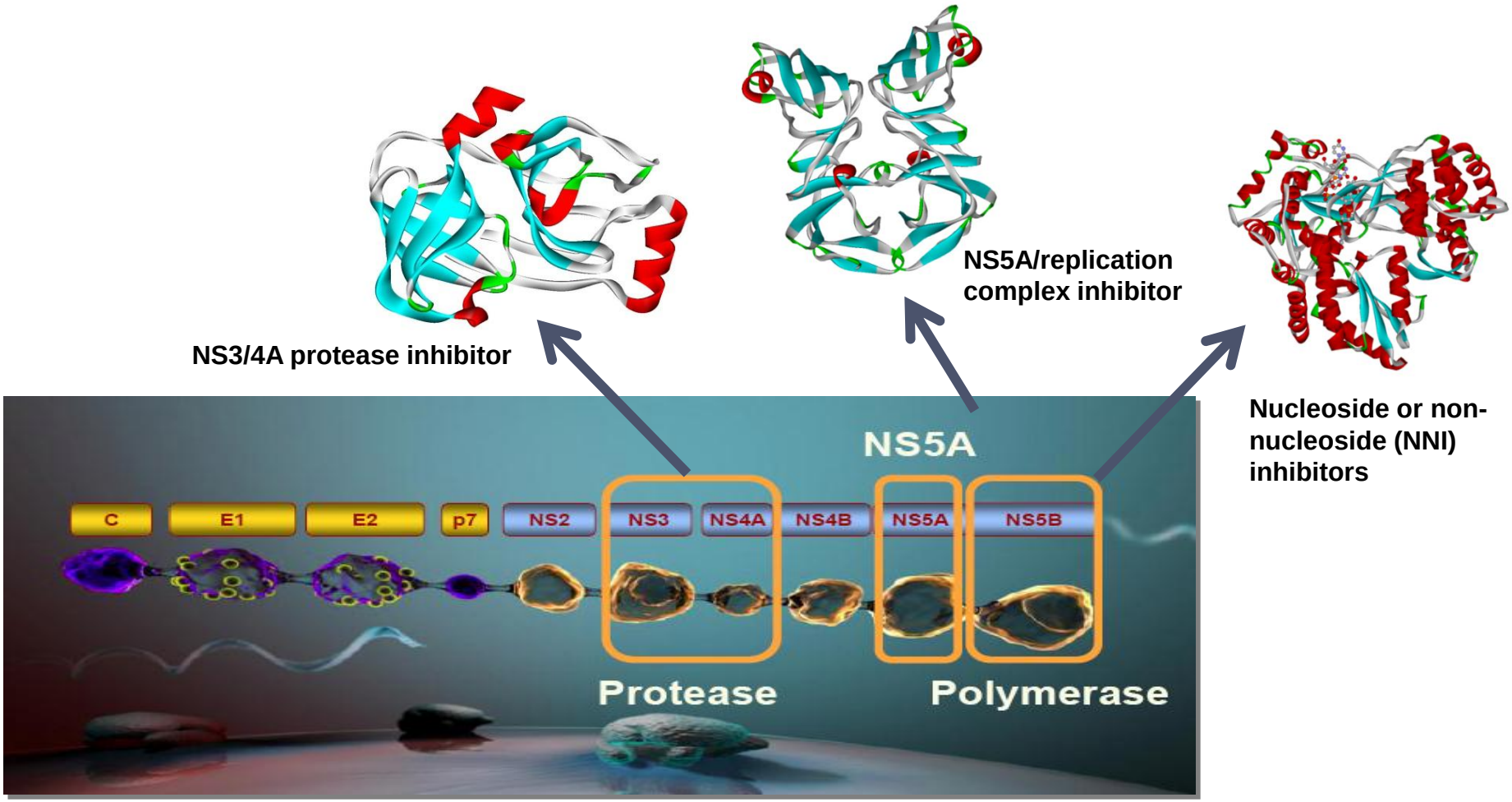
Mechanism of action:

- Inhibition of Cathepsin S prevents inflammatory damage to the sensory system in the spinal cord by blocking fractalkine activation

Cathepsin S inhibitor program

- Potent, selective and orally bioavailable inhibitors available
- Aiming for candidate drug selection in H1 2013

Our commitment in hepatitis C



Simeprevir – An efficacious, safe and tolerable protease inhibitor*

*as demonstrated in 3 pivotal phase III studies in GT1 HCV infected naive and relapser patients

Simeprevir - clinical development programs in HCV G1 & G4 infected patients

Pivotal phase III studies:

- **QUEST 1** treatment-naïve
- **Quest 2** treatment-naïve
- **PROMISE** prior relapsed

Top-line data available

- **Japan** naïve & experienced (four studies)

Regulatory file submitted Feb. 22, 2013

Other ongoing phase III studies:

- **China:** Efficacy, PK, safety and tolerability in naïve patients
- **ATTAIN:** Simeprevir vs telaprevir in prior null or partial responders
- **HCV genotype 4 infected** naïve or treatment experienced patients
- **HIV** co-infected patients

Regulatory filings for simeprevir triple combination H1, 2013 in US, EU & Japan

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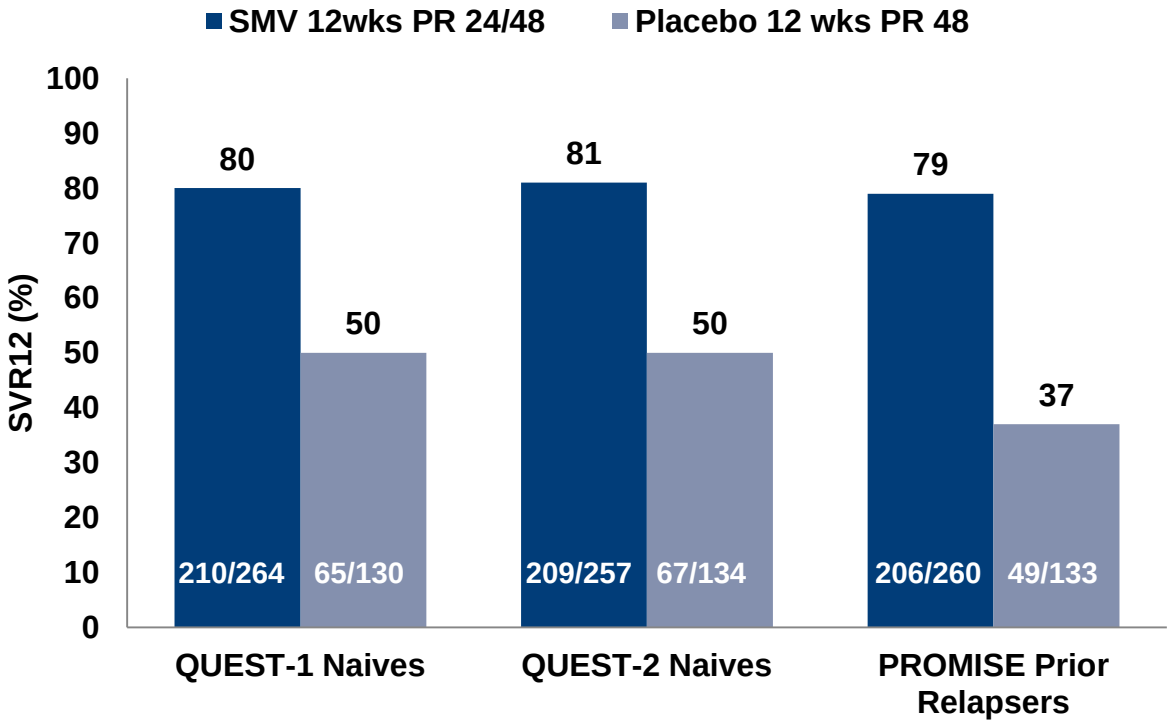
For additional information, please see www.clinicaltrials.gov

Simeprevir - Phase III triple therapy
Efficacy – SVR12 (cure rate)



Statistically significant difference vs placebo control in all studies

Robust efficacy in all three studies (79-81% SVR12) confirming phase II studies

Simeprevir - Phase III triple therapy (global and Japan)
Summary

Robust efficacy with high cure rates (SVR12):

- Naive and relapser patients in three global studies: 79-81%[1]
- Confirmed in Japan program, where high cure rates where demonstrated[2]

Shorter treatment duration

- 85-93% could stop all treatment at week 24 (naïve and relapser patients; global trials)

Excellent safety and tolerability

- Overall incidence of adverse events, including rash and anemia, similar to placebo
- Confirmed in Japan program, where favourable safety profile was demonstrated

Phase III data support simeprevir as a new treatment for G1 HCV, with advantages versus marketed 1st generation protease inhibitors

Regulatory filings for simeprevir triple combination H1, 2013 in US, EU & Japan

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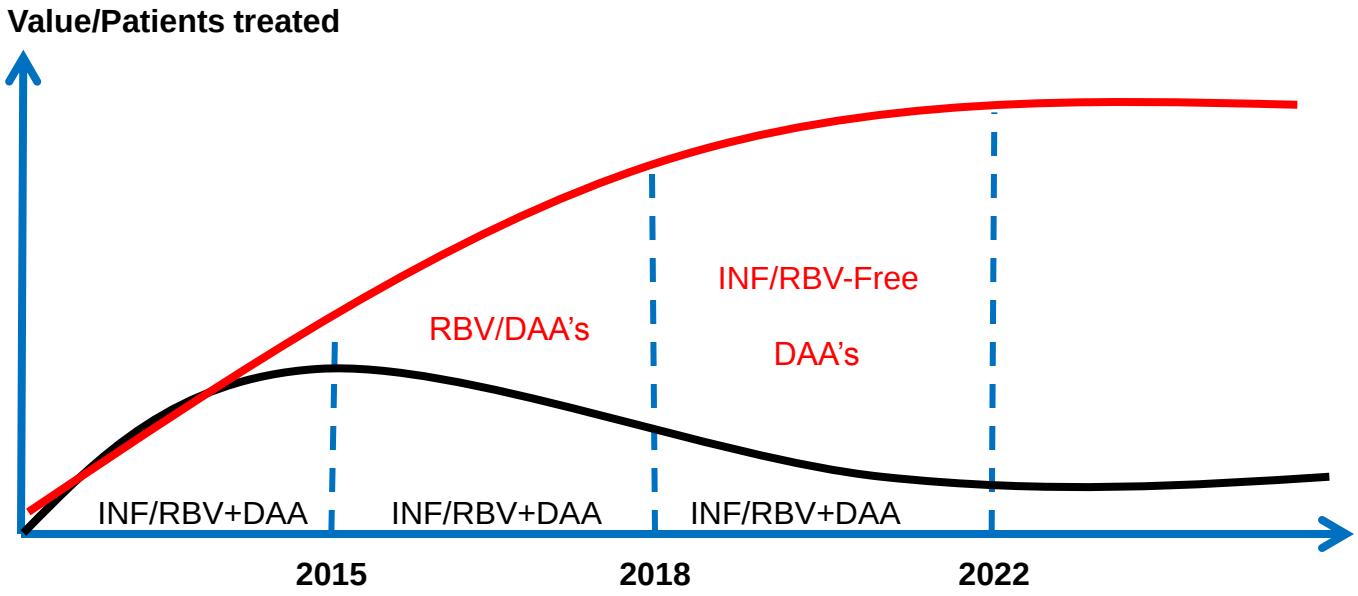
1 All three trials included difficult-to-treat patients with advanced liver fibrosis/cirrhosis (METAVIR score F3-F4)

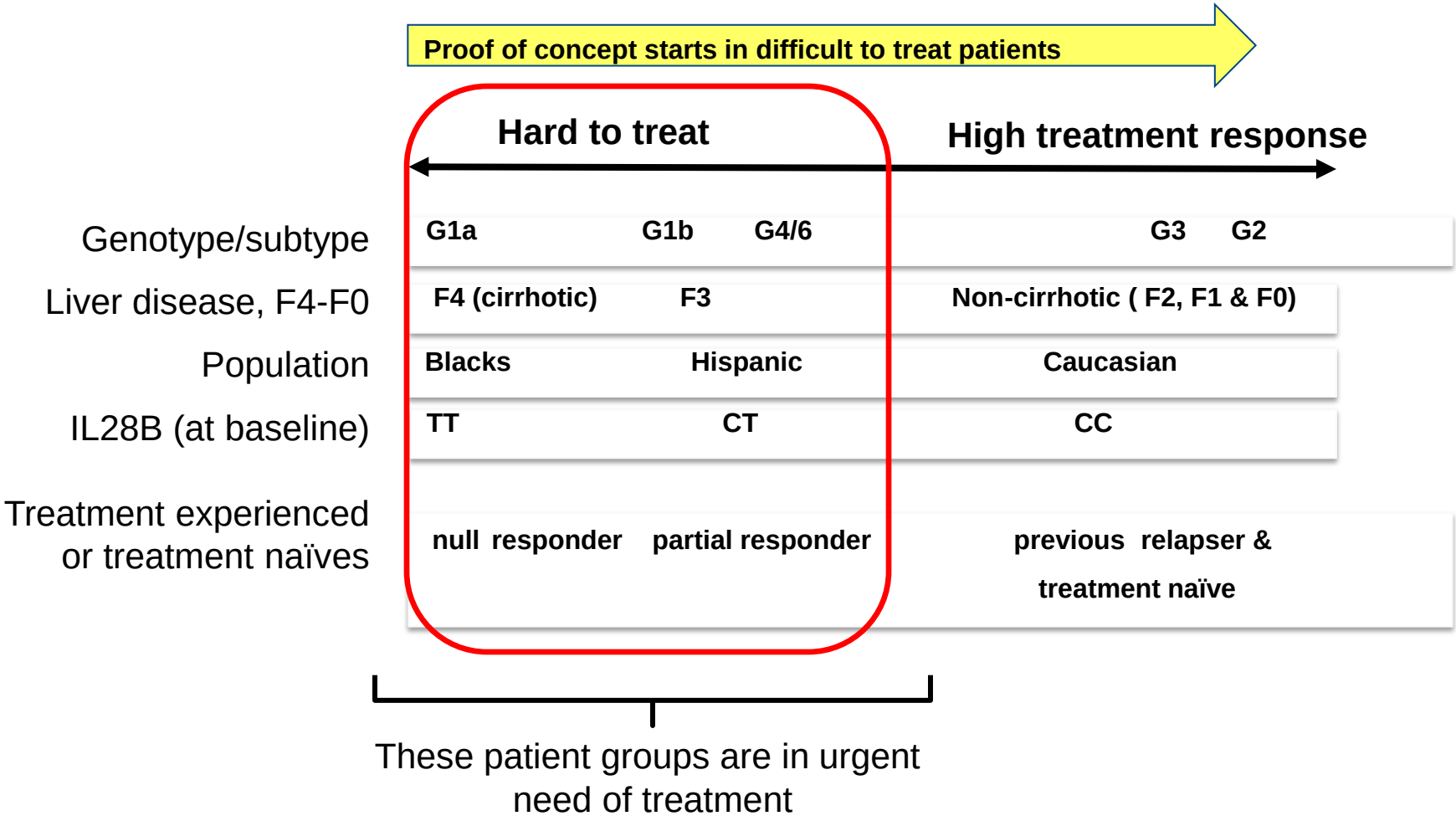
2 To be presented at an upcoming medical meeting

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



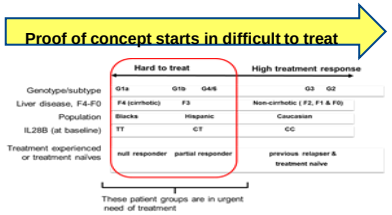
Patient response to treatment – a complex picture



Simeprevir has demonstrated efficacy in difficult to treat G1 patients with severe liver disease

Interferon-free combinations in HCV null responders

- Prior null responders to pegIFN/RBV have limited treatment options
- PegIFN/RBV-containing treatments are difficult to tolerate and contraindicated in many patients
- All patients without cirrhosis



Danoprevir/r + Mericitabine + RBV	Roche	**55%** SVR12 (GT 1b)	
Daclatasvir + asunaprevir	BMS	**64- 91%** SVR12 (GT 1b)	24 week duration
ABT-450/r + ABT-267 + RBV	Abbott	**89%** SVR12	
ABT-450/r + ABT-267 + ABT-333 + RBV		**93%** SVR12	
ABT-450/r + ABT-333 + RBV		**47%** SVR12	
Sofosbuvir + RBV	Gilead	**10%** SVR12	
Sofosbuvir + ledipasvir + RBV		**100%** SVR12 (9/9 patients)	
Simeprevir + Sofosbuvir +RBV	Medivir/J&J	**97%** SVR8 (26/27 patients)	
Simeprevir + Sofosbuvir		**93%** SVR8 (13/14 patients)	

COSMOS phase III-study: Efficacy results

Patients	24 weeks		12 weeks	
	SMV + SOF + RBV	SMV + SOF	SMV + SOF + RBV	SMV + SOF
RVR[1], n/N (%)	18/22 (81.8)	10/15 (66.7)	23/27 (85.2)	8/14 (57.1)
Undetectable end of treatment, n/N (%)	10/12 (83.3)	8/9 (88.9)	27/27 (100.0)	14/14 (100.0)
Relapse, n	0	0	1	1
SVR4, n/N (%)	4/6 (66.7)	5/5 (100.0)	26/27 (96.3)	13/14 (92.9)
SVR8, n/N (%)	4/6 (66.7)	5/5 (100.0)	26/27 (96.3)	13/14 (92.9)

Of the patients in the 12 week arms who achieved SVR8
- 24/24 who reached post-treatment Week 12 had undetectable HCV RNA (SVR12)
- 8/8 who reached post-treatment Week 24 had undetectable HCV RNA (SVR24)

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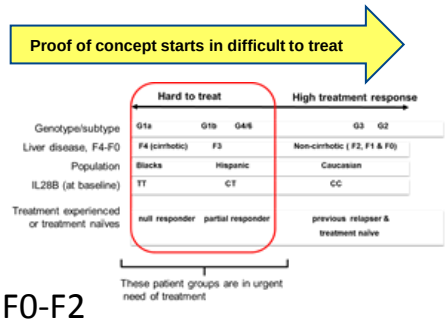
[1]RVR is based on patients with available data at Week 4 (2 patients discontinued before Week 4)
EOT, end of treatment; RVR, rapid virologic response; SMV, simeprevir; SOF, sofosbuvir; SVR, sustained virologic response

Simeprevir in interferon-free combinations



Ribavirin

Simeprevir	+	**Sofosbuvir** (nucleotide)	+/-	12w	N=80+87 ✓Cohort a: nulls, F0-F2 Cohort b: nulls + naives; **F3/4 (cirrhotics)**
			+/-	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 to start Q1, 2013
Simeprevir	+	**IDX719** (NS5A inhibitor) **+/- TMC647055/r**	+/-	12w	DDI study started (simeprevir + IDX719)

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

Value proposition – a platform for growth and profitability

Innovative portfolio that will evolve over time

- World class expertise in polymerase and protease drug targets
- R&D focus on infectious diseases

Strong position in HCV – goal is take part in eradicating hepatitis C

- Simeprevir, partnered with Janssen Pharmaceuticals
  - Regulatory filing began already in Q1, 2013 as a triple combination treatment with PegIFN and ribavirin
  - Many interferon-free combination treatments opportunities
- In-house HCV programs will offer new combination opportunities

Commercial presence in the Nordic region creates stability

BioPhausia® – a Medivir sales company

- Solid brand names with annual sales of ~85 MUSD
- Commercial platform for the launch of simeprevir in the Nordics in 2014
- Pharmaceutical portfolio will be broadened

News flow - highlights

- ✓ Q4-12 Start of Cohort 2 with simeprevir and GS7977 phase II study
- ✓ Q4-12 Top line results from phase III trials with simeprevir (Quest 1+2 and Promise)
- ✓ Q1-13 Filing for regulatory approval in Japan
- ✓ H1-13 EoT and partial SVR data from Cohort 1 with simeprevir and sofosbuvir phase II study
- H1-13 Filing of simeprevir in the US and EU
- H1-13 Potential CD selection in Cathepsin S (neuropathic pain) program
- H1-13 Results from phase I-study with MIV-711, our cathepsin K inhibitor (bone related disorders)
- H1-13 Start of phase II study with simeprevir and VX-135
- H1-13 Step two in GSK launch strategy for Xerclear® (ZoviDuo), launch in major European OTC markets
- H2-13 Potential CD selection in our internal Nucleotide NS5B inhibitor program
- H2-13 Potential CD selection in our internal NS5A inhibitor program
- 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
- H2-13 SVR data from Cohort 2 with simeprevir and sofosbuvir phase II study

www.medivir.com

Ticker: MVIR
Exchange: OMX / NASDAQ

For more information please contact
Rein Piir, EVP Corporate Affairs & IR
(rein.piir@medivir.com)