



Medivir

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

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Medivir - the emerging European pharma

- **Spinout from AstraZeneca's** antiviral research unit, currently 170 employees (out of which 50 in Cross Pharma – parallel import of pharmaceuticals in Sweden)
- Research driven pharmaceutical company **focused on infectious disease**, with a strong track record in **partnerships as part of the business model**
- World leading expertise in polymerase and protease drug targets – **strong pipeline** of innovative infectious disease drugs
- First in-house developed product on the market, a **cold sore product with unique profile**
- **Strong position in HCV drug development**, four programs including all three validated target classes, two in-house driven.
- **Simeprevir** (TMC435) in partnership with Janssen is considered as the best in class PI, **phase III results expected at year end**
- **Fifteen marketed products in the Nordics**, generating annual sales of ~85 MUSD with an EBITDA of ~16MUSD
- **Strong financial position**
- **Broad institutional shareholder base**, 30% outside Nordic region



Strategic direction and ongoing activities

R&D Operations

Further development of R&D platform

- Continued focus in HCV and on infectious diseases
- Evaluate new therapeutic areas based on proteases and polymerases

Create new partnership/collaborations

- Continue to build new partnerships

Commercial Operations

Expand commercially

- Add new products for the Nordic market
- Fine-tune organisation for Nordic launch of simeprevir
- Further development of business and therapy scope



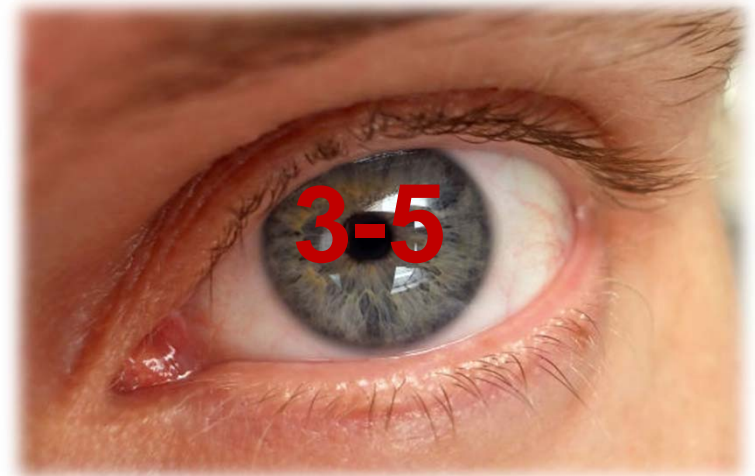
The Leading European Pharma in a 3-5 year perspective

Structure

- Partner of choice for both pharmaceuticals and development programs
- Continued commitment on targets in infectious diseases
- Addressing of new therapeutic areas based on core competence
- Aggressive expansion of product portfolio, including simeprevir and other in-house developed pharmaceuticals
- Broader, risk balanced, R&D pipeline

External perspective

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



Value proposition



Interesting pipeline assets

- Collaborative and innovative pharmaceutical company with an R&D focus on infectious diseases
- World class expertise in polymerase and protease drug targets



Strong position in HCV drug development – both partnered and internal programs

- The front runner, simeprevir, is considered “best in class PI” in HCV, regulatory filing ~H1 2013
- Simeprevir has an attractive profile and will have an important role in future interferon-free combination treatments
- Our in-house programs will offer new opportunities



Integrated company - commercial presence in the Nordics

- Strong brand names, annual sales ~85 MUSD
- New pharmaceuticals will be added
- Commercial platform for the launch of simeprevir in the Nordics



**Strongly committed to innovation driven R&D
- developing novel pharmaceuticals**

In-house developed cathepsin inhibitors



Cathepsin K inhibitor

Disease

Osteoporosis, osteoarthritis and metastatic bone disease

Mechanism of action

Cathepsin K inhibition leads to:

- Reduced bone resorption and cartilage breakdown
- Maintained bone formation in contrast to other anti-resorptives

MIV-711: Phase I ongoing

- Adaptive, placebo controlled, double-blind study in healthy volunteers incl. post menopause women
- Ascending single and multiple once daily dosing
- Biomarkers for bone and cartilage turnover
- Phase I completed and data available H1-2013

Cathepsin S inhibitor

Disease

Neuropathic pain and autoimmune disease

Mechanism of action

Neuropathic pain

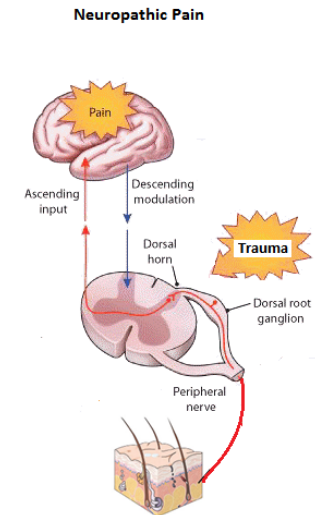
- Inhibition of Cathepsin S prevents inflammatory damage to the sensory system in the spinal cord by blocking fractalkine activation

Autoimmune disease

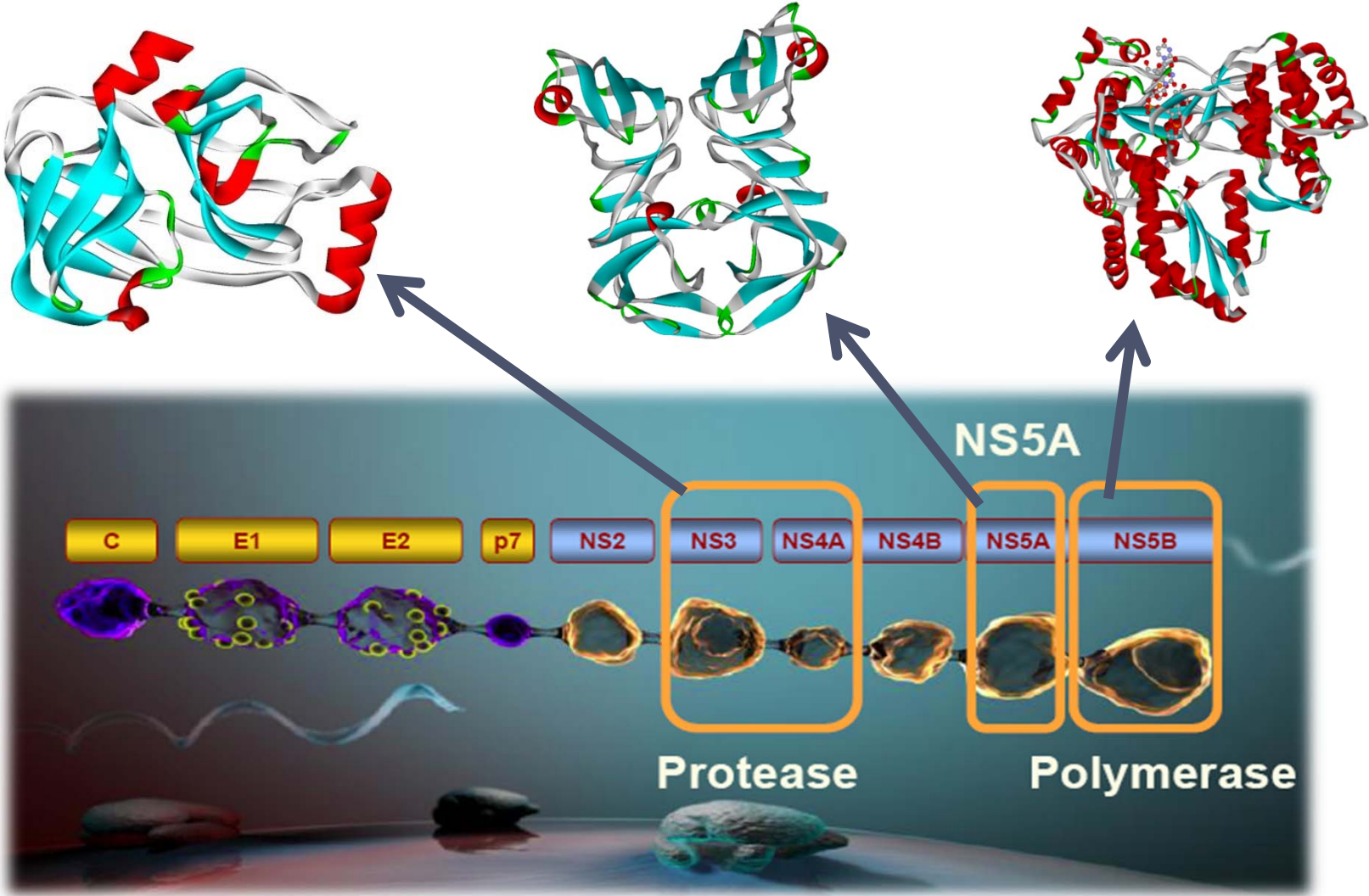
- Crucial role in MHC Class II antigen presentation, which is key to establishing and perpetuating an immune response disease

Next milestone

CD-selection Q1-2013



A broad development approach in HCV



Many ongoing activities in HCV

Project	Therapy area	Partner	Preclinical phase		Clinical phase				Market	
			Research	Development	Phase I	Phase IIa	Phase IIb	Phase III		
Simeprevir (TMC435)	Hepatitis C	Janssen / J&J	Triple combination							
HCV POL Nucleotide	Hepatitis C	Janssen / J&J								
Nucleotide inhibitor	Hepatitis C	In-house								
NS5A Inhibitor	Hepatitis C	In-house								

Simeprevir (TMC435)

- triple combination summary

Potent → low dose (150mg)

- One tablet once daily
- 12 weeks duration

Three large phase IIb trials demonstrating highly efficacious in

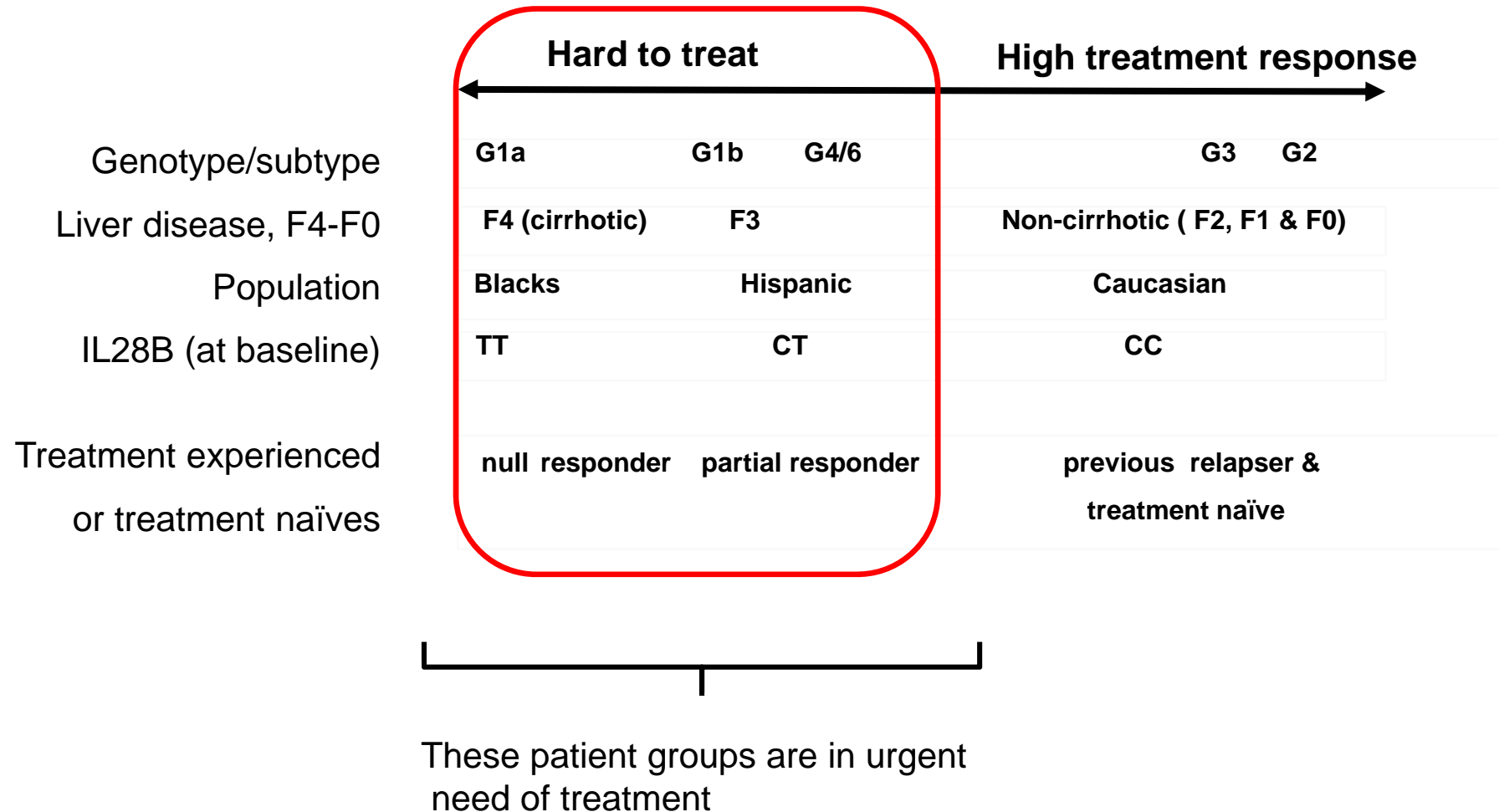
- G1a and G1b
- Treatment naïve and treatment experienced
- Cirrhotic and non-cirrhotic patients
- Regardless of IP-10 level or *IL28B* genotype

Safe and well tolerated

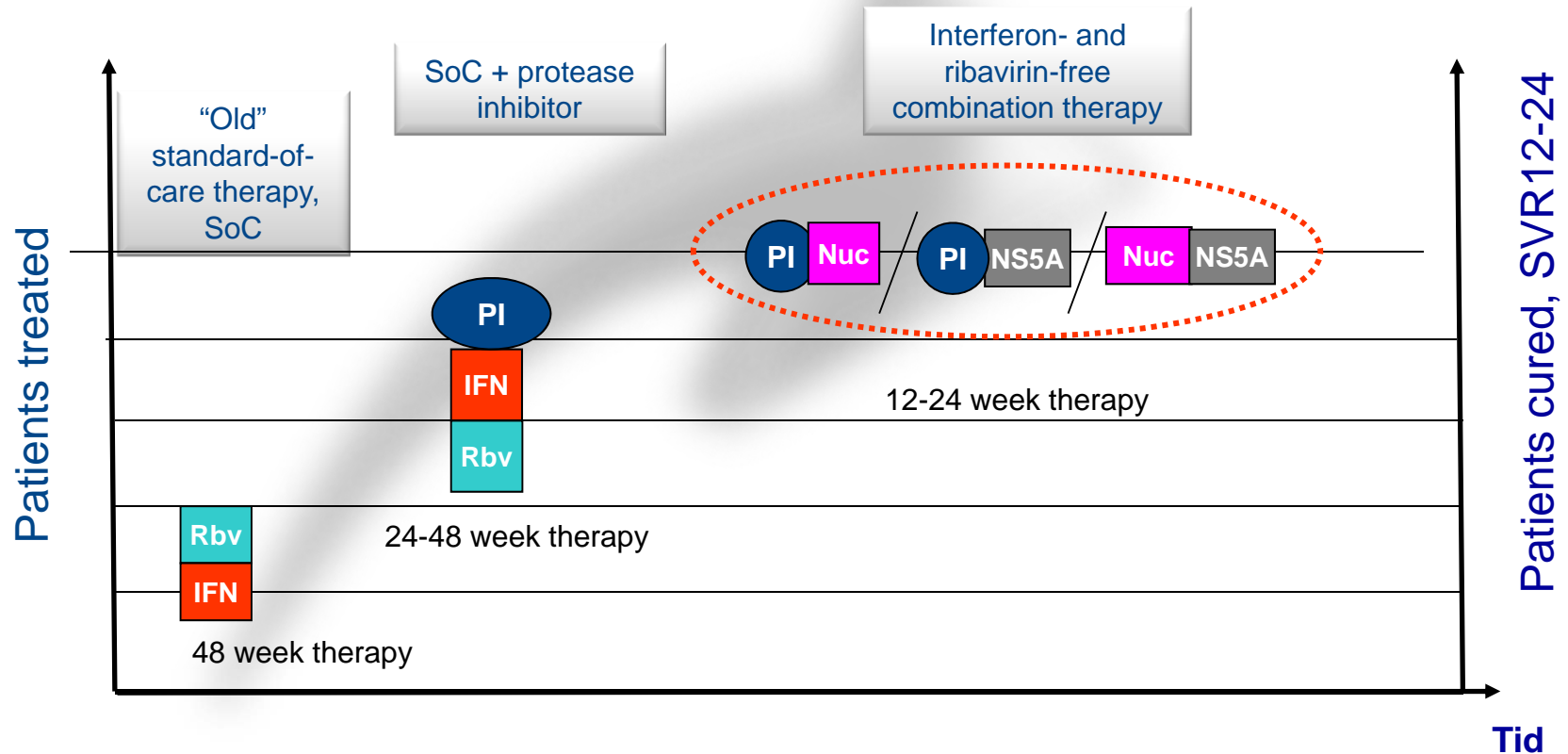
- Close to 1800 patients have completed TMC435 treatments showing it to be safe and well tolerated - important for compliance once on the market
- Long patent life, IP extending to 2026 and 2028

Simeprevir + PegINF/Ribavirin = A best-in-class triple combination phase III results expected around year end

Patient response to treatment – a complex picture



Evolution of HCV therapy in G1 infection



Most competitive HCV therapy will consist of dual DAA combos with outstanding properties; e.g. TMC435/GS7977 or VX-135 (PI/nuke), GS7977/daclatasvir or GS5885(nuke/NS5A) or TMC435/daclatasvir (PI/NS5A)

TMC435 – A best in class protease inhibitor with dual MoA

Simeprevir, triple combination therapy with PegINF/RBV - summary phase IIb data

Best-in-class potential based on Phase II data

- Safe and efficacious with excellent tolerability (150 mg, q.d., 12 w)

Study	Number of patients	Patient population	SVR24(%)	SVR24 control (P/R)(%)	Delta
Pillar	386	Treatment naive	83	65	18
Dragon	92	Treatment naive (JPN)	82	46	36
Aspire	462	Relapser	85	37	48
		Partial responders	76	9	67
		Null responders	51	19	32
		Subgroup analysis			
		Relapser, F4	73	0	73
		Partial responders, F4	82	0	82
		Null responders, F4	31	0	31



Large safety data base with approximately 1800 patients treated today

Simeprevir (TMC435), clinical development programs in HCV G1 & 4 infected patients

Regulatory filings for triple combination in first half of 2013 in US, EU & Japan

Ongoing pivotal phase III studies:

- **QUEST 1** treatment-naïve; n=375
- **QUEST 2** treatment-naïve; n=375
- **PROMISE (C3007)** prior relapsed; n=375
- **Japan** naïve & experienced; n=417 (four studies)

Selected other ongoing phase III studies:

- **C3001** comparing TMC435 and telaprevir, in prior null or partial responders; n=744
- **C3011** naïve or treatment experienced, HCV genotype-4 infected patients; n=100
- **C212** HIV co-infected patients; n=94

Ongoing IFN free combination studies

- **Simeprevir and GS-7977, a nucleotide NS5B inhibitor.**

12/24 weeks, +/- ribavirin, G1 null responder patients; +/- cirrhotics, n=180

- **Simeprevir and daclatasvir (BMS-790052), an NS5A inhibitor.**

12/24 weeks, +/- ribavirin in G1 naïve and null responder patients

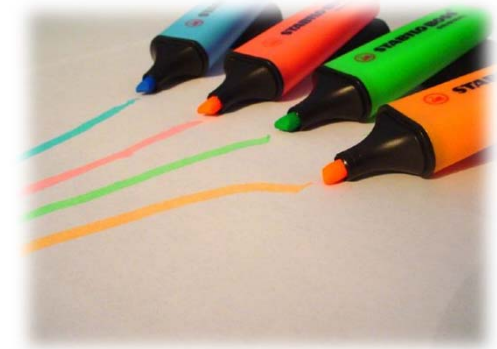
- **Simeprevir and TMC647055, once daily an NNI (non-nucleoside inhibitor).**

12 weeks, +/- ribavirin in G1 naïve, relapser and null responder patients

- **Simeprevir and VX-135, a Nucleotide NS5B inhibitor**

12 weeks, +/- ribavirin in G1 naïve

Key news flow highlights



- ✓ Q2-12 Janssen creates new division to launch simeprevir in EMEA
- ✓ Q2-12 Start of DAA phase II combination study with simeprevir and daclatasvir
- ✓ Q3-12 Start of Phase Ib clinical trials with MIV-711, a cathepsin K inhibitor
- Q1-13 Potential CD selection in Cathepsin S (neuropathic pain) program
- Q1-13 Start of Cohort 2 with simeprevir and GS7977 phase II study
- Q1-13 EoT and partial SVR data from Cohort 1 with simeprevir and GS7977 phase II study
- Q1-13 Top line results from phase III trials with simeprevir (Quest 1+2 and Promise)
- H1-13 Results from the phase I-study with MIV-711 (bone related disorders)
- H1-13 Start of phase II study with simeprevir and VX-135
- H1-13 Expected CD selection in our internal Nucleotide NS5B inhibitor program
- H1-13 Goal to start phase 1 trials with Medivir/Janssen nucleotide NS5B-inhibitor
- H1-13 EoT-data from the phase II combination study with simeprevir and daclatasvir
- H1-13 Filing of simeprevir in US/EU and Japan
- H1-13 Step two in GSK launch strategy for Xerclear® (ZoviDuo), launch in major European OTC markets

The background of the slide is a blurred image of laboratory glassware, including a beaker and a graduated cylinder, set against a light blue background. The glassware is out of focus, creating a sense of depth and scientific precision.

Medivir

www.medivir.com

Ticker: MVIR

Exchange: OMX / NASDAQ

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