Medivir

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

J.P. Morgan Healthcare Conference
2013

Presenting team

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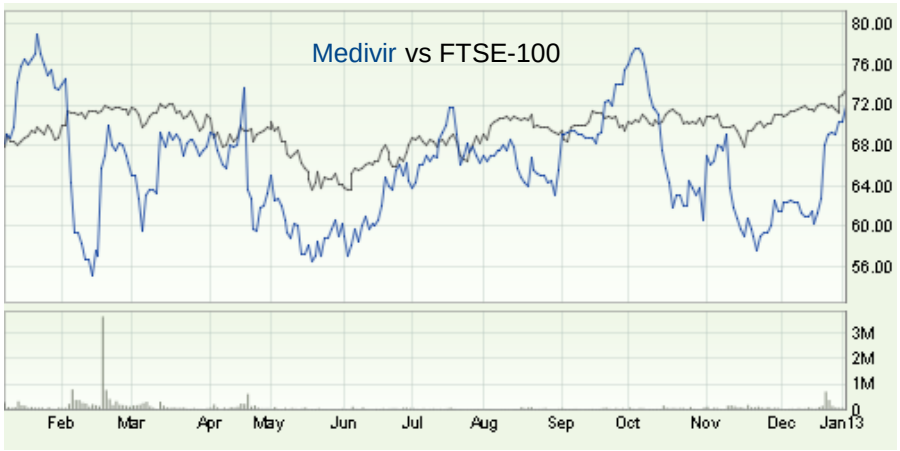
Introduction

Medivir - the emerging European pharma company

- Research driven pharmaceutical company **focused on infectious disease**
- **World leading expertise in polymerase and protease drug targets** –
- **First in-house developed product on the market**, Xerclear/Xerese
- **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, **global filing expected during H1-2013**
- **Fifteen marketed products in the Nordics,** generating annual sales of ~85 MUSD with an EBITDA of ~16MUSD
- **Stable financial position**
- **Broad institutional shareholder base,** 30% outside Nordic region

Broad institutional shareholder base

Market cap MUSD	**350**
Shares outstanding (m)	31.3
Fully diluted (opt)	31.7
Avg Daily vol.	92.000



Category

Category	Holdings%
Foreign Owners	29.3
Swedish Owners	70.7
whereof	
Institutions	40.7
Retail	30.0

By Country top 5

Country	Holdings%
Sweden	71.1
UK	7.5
US	6.0
Luxembourg	5.0
Norway	2.0
Sum Top 5	91.6

Stable financial position -

Commercial presence in the Nordics plays an important role for financing R&D

Annual total burn rate: ~46 MUSD

Total revenue ~85 MUSD, with an EBITDA of ~16 MUSD

Net burn rate ~30 MUSD

Cash in the bank at end Q3 2012: 55 MUSD

Future revenues

Adding new prescription products:

- Simeprevir in 2014
- Other Rx products

Remaining simeprevir milestone payments at filing and approval during 2013/14: ~40 MUSD

Strategy

Strategic direction and ongoing activities

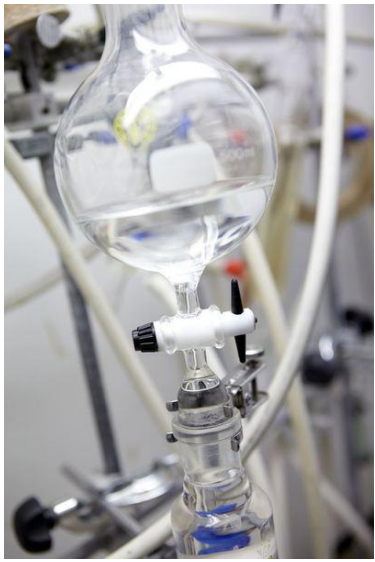
R&D Operations

Commercial Operations

Further development of R&D platform
- Continued focus on HCV and infectious diseases
- Evaluate new therapeutic areas based on proteases and polymerases as drug targets

Create new partnership/collaborations
- Continue to develop R&D assets via partnerships

Expand commercially
- Add new products for the Nordic market
- Build organisation for Nordic launch of simeprevir
- Further development of business and therapy scope



Medivir in a 3-5 year perspective

Structure

- Partner of choice for both pharmaceuticals and development programs
- Continued commitment on targets in infectious diseases
- Adressing 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

Nordic Platform

Our commercial presence in the Nordics

- Addition of new products to the Nordic commercial platform – will allow Medivir to approach its goal of becoming profitable

Will be done by

- Strengthening Medivir's position via adding new products for the Nordic markets – M&A, licensing or acquisitions

- Building the commercial platform for launch of simeprevir in the Nordic region 2014

Consolidated profit performance

(MUSD)	2012 Q3	2011 Q3	2012 Q1-Q3	2011 Q1-Q3	2011 FY
Net sales	17,5	18,8	61,5	87,2	107,5
Gross profit	4,7	2,7	16,5	65,1	70,0
EBITDA	-5,9	-7,8	-17,1	26,3	20,8
Profit/loss after tax	-8,5	-8,2	-23,7	25,7	17,5

Net sales split - Quarterly trend

(MUSD)	2012 Q3	2012 Q2	2012 Q1	2011 Q4
Pharmaceutical sales	5,5	6,0	7,1	7,3
Parallel imports	12,0	16,7	14,1	13,0
Other services	0,2	-	-	- 0.1
Total	17,6	22,7	21,2	20,3

Value proposition

Collaborative and innovative pharmaceutical company

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

Strong position in HCV – both partnered and internal programs

- Simeprevir (TMC435), considered “best in class HCV protease inhibitor”
  - partnered with Janssen Pharmaceuticals with retained Nordic rights
  - regulatory filing in H1 2013 as triple combination treatment with PegIFN/ribavirin
  - optimal profile for future interferon-free combination treatments
- In-house HCV programs will offer combination opportunities

BioPhausia – a Medivir sales company

Commercial presence in the Nordic region

- Solid brand names, annual sales of ~85 MUSD
- New pharmaceuticals will be added
- Commercial platform for the launch of simeprevir in the Nordics in 2014

R & D

Medivir – Research and Development

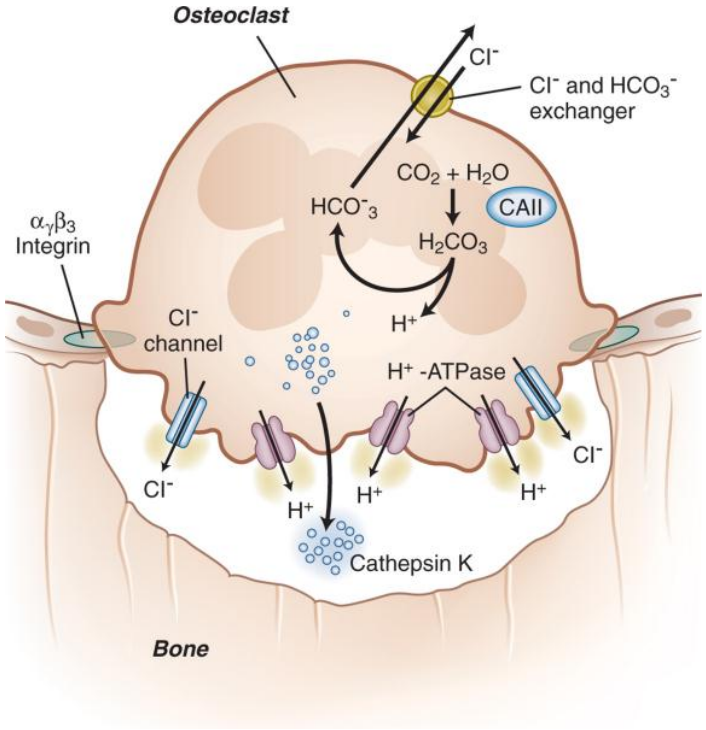
- Leading expertise in polymerase and protease research
- Long experience of antiviral/anti-infective research (e.g. HCV, HBV, HSV, HIV, VZV, dengue)
- Integrated, agile drug discovery unit from hit to IND with CMC, regulatory affairs and clinical capabilities
- Large network of collaborators with in academia, SMEs and CROs
- Strong deal track record with > 25 partnerships including major pharma companies

A focused project portfolio

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 inhibitors - mechanism of action

Osteoporosis/osteoarthritis/metastatic bone disease



Osteoporosis and osteoarthirits

- cathepsin K dissolves collagen I in bone and collagen II in cartilage
- genetic, animal and human data shows that cat K inhibition improves bone quality

Metastatic bone disease

- invasive tumour cells express high levels of cathepsin K, which increase bone resorption and the invasiveness of cancer cells

Recent data suggest that cat K inhibitor reduces fracture risk in humans

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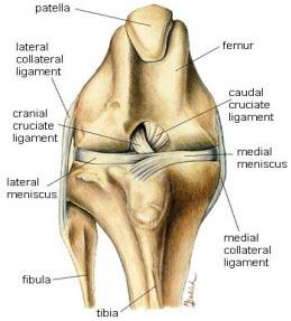
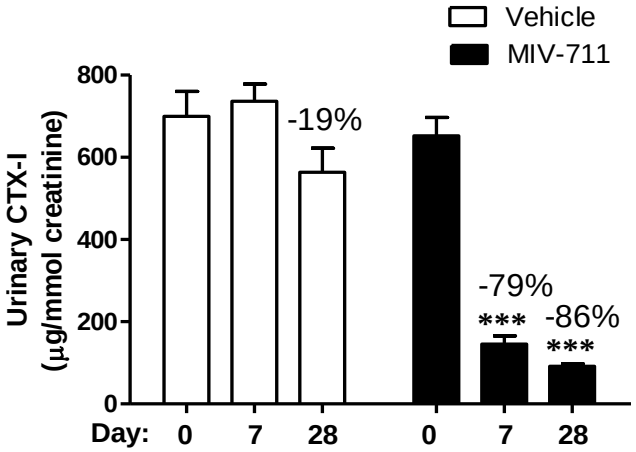
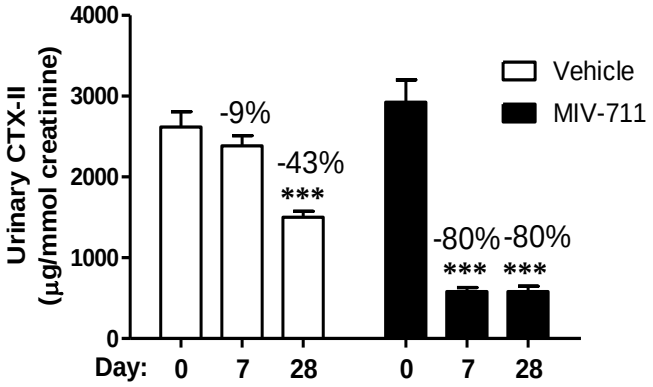
MIV-711 – Partial medial meniscectomy; an experimental osteoarthritis model in dog



Reduced urinary levels of CTX-I, a bone resorption biomarker



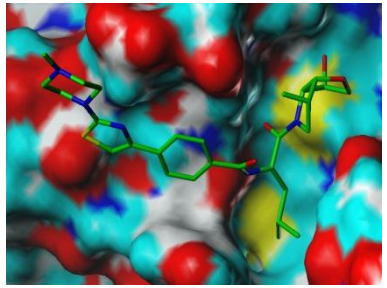
Reduced urinary levels of CTX-II, a cartilage resorption biomarker



MIV-711 dosed at 30 µmol/kg (p.o.) once daily for 28 days, n=15

MIV-711 reduced bone and cartilage degradation biomarkers in dog osteoarthritis model

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

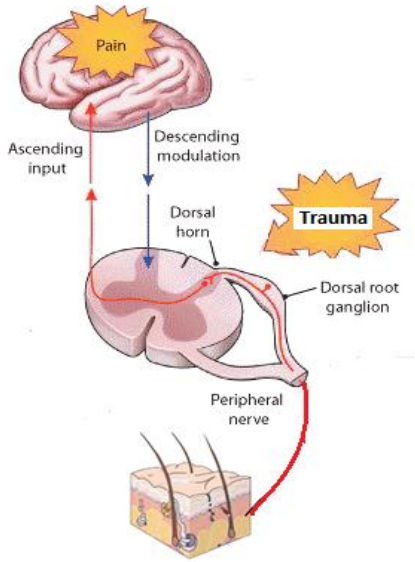
- Phase I completed and data available H1-2013

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:

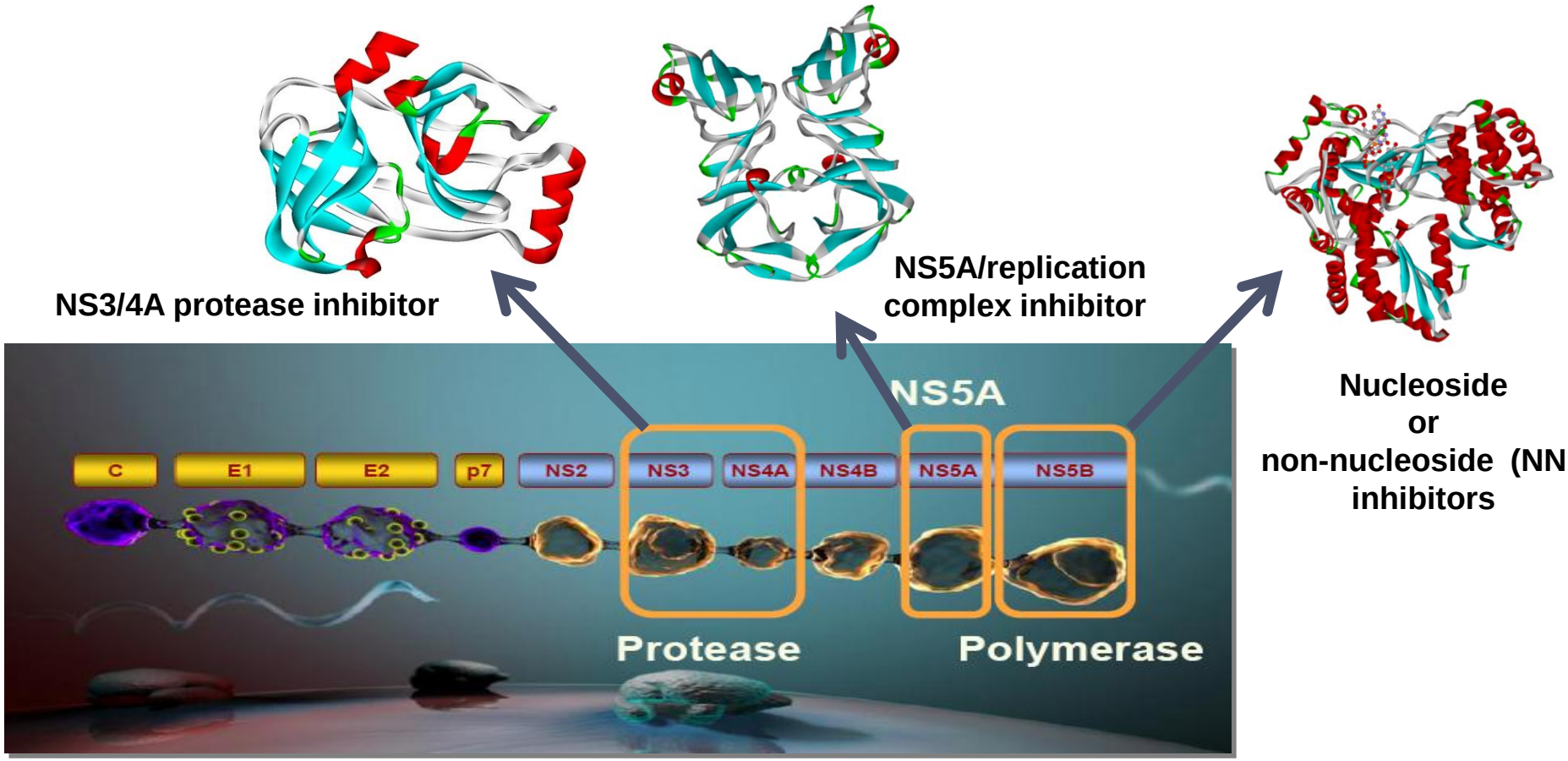
- Inhibition of Cathepsin S prevents inflammatory damage to the sensory system in the spinal cord by blocking fractalkine activation

Cathepsin S inhibitor program

- Potent, selective and orally bioavailable inhibitors available
- Aiming for candidate drug selection in Q1 2013

Simeprevir (TMC435) soon to reach the market in a rapidly evolving treatment landscape

Strong commitment in hepatitis C
– four major programs versus the three major targets



Simeprevir – An efficacious, safe and tolerable protease inhibitor*

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

Strong commitment in hepatitis C – four major programs on-going

Protease inhibitor – Simeprevir (TMC435)

- Convenient : one pill, once daily,
- Potent antiviral activity in patients
- Excellent safety and tolerability profile
- Regulatory filing expected in H1 2013 as triple combination with PegIFN/RBV
- In Phase II clinical development with four INF free combinations

Nucleotide polymerase inhibitor

- Liver targeted nucleotide polymerase inhibitor program
- Candidate Drug selected and IND preparatory activities on-going

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Nucleotide polymerase inhibitor

- Properties similar to the most advanced clinical nucleotides
- Aiming for Candidate Drug selection in H1, 2013

NS5A inhibitor

- A next generation NS5A inhibitor with high barrier to resistance
- Preclinical optimization phase

Internal unpartnered projects

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HCV genotype-1 infection is the most common and has the poorest treatment prognosis

There are six main genotypes, G1-G6 (G1-3 most common)

Genotype 1

- the most common, ~75% in the US, EU and JPN.
- the most difficult to treat and to cure, only ~45%, with PegINF/RBV after 48 week treatment in treatment naïve patients

Genotype 2 and 3

- have generally a good treatment prognosis with PegINF/RBV with
- 24 weeks treatment
- Cure rates with 24 w of PegIFN/RBV:
  - G2: 80-93% SVR (cure rates)
  - G3: 66-80% SVR

Simeprevir has broad genotypic coverage (1,2,4,5,and 6)

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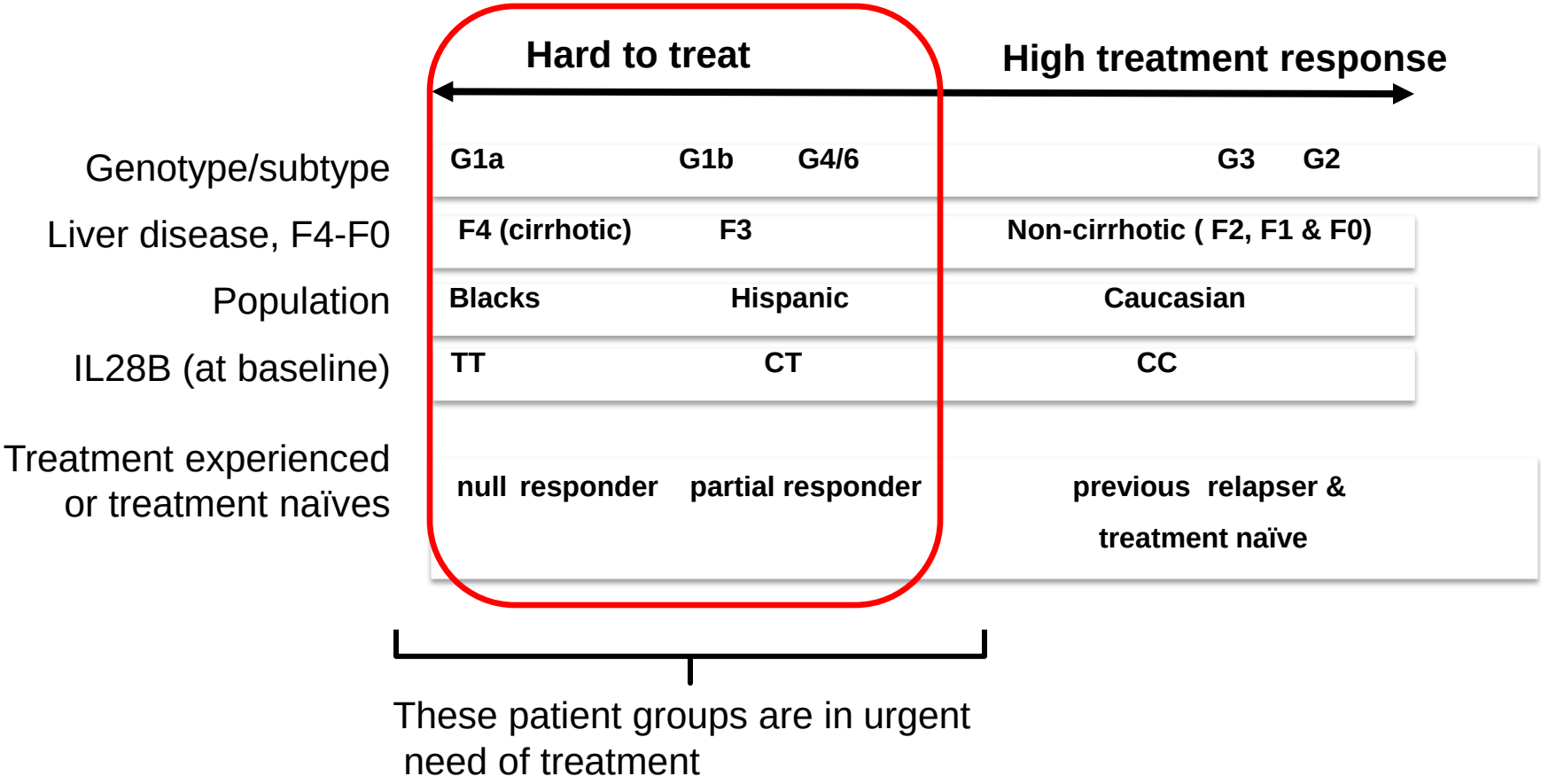
Patient response to treatment – a complex picture



Simeprevir has demonstrated efficacy in difficult to treat GT1 patients with severe liver disease

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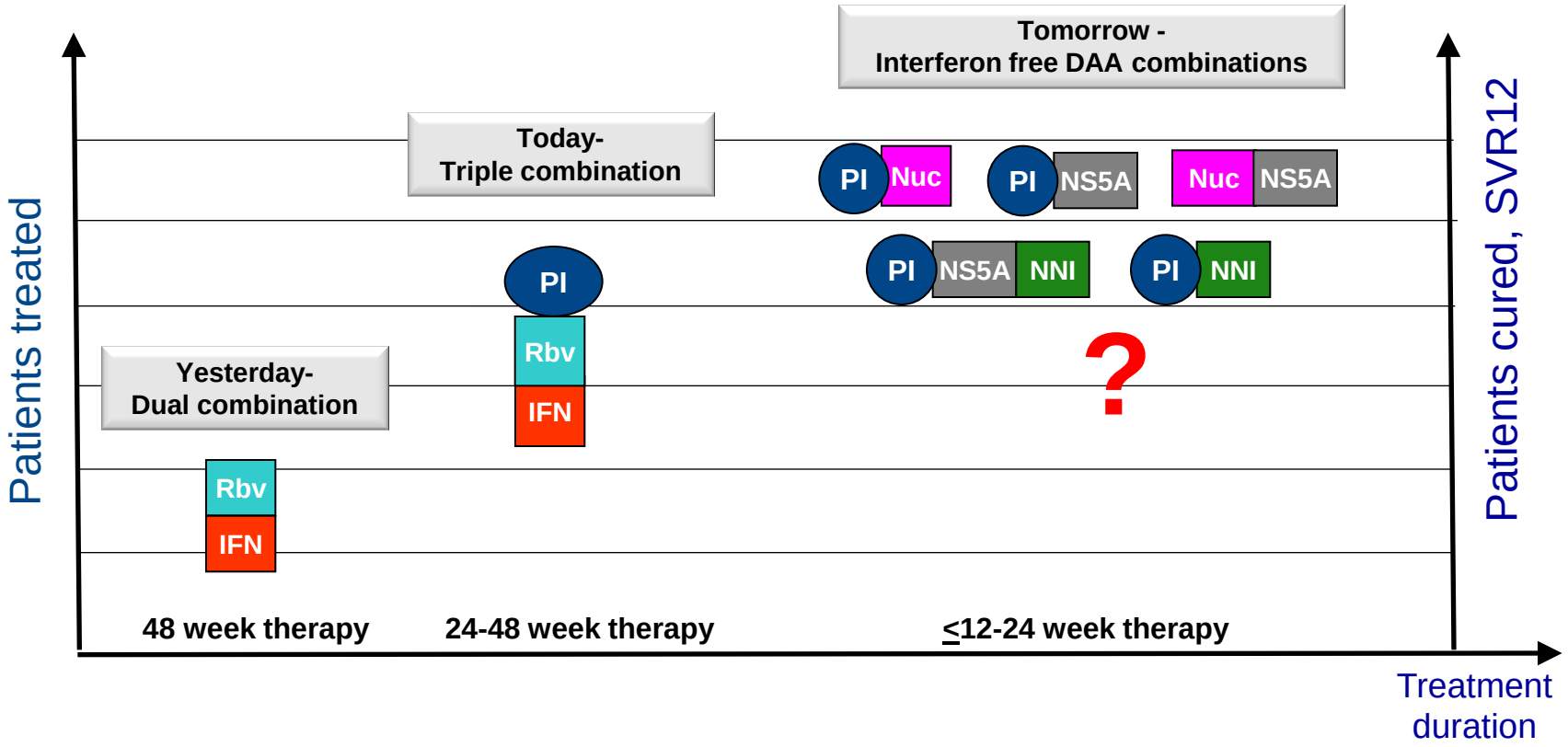
Evolution of HCV therapy in HCV G1 infection



Simeprevir

✓a safe and tolerable 2nd generation protease inhibitor based on phase III

✓well positioned for triple as well as future interferon free combination therapies

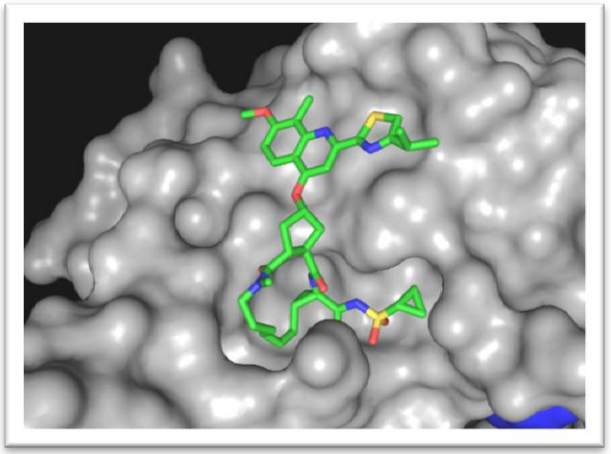
What did the protease inhibitors achieve?

- First generation PIs (telaprevir and boceprevir)
  - ✓Increased cure rates (from ~45-50 to 75-79%)
  - ✓Shorter treatment durations (from 48 weeks to 24 week in up to 60% of patients)
  - ✓Added safety & tolerability issues (rash, pruritus, anemia etc)

- What is urgently needed from next generation PIs?
  - ✓Improved safety and tolerability
  - ✓Improved efficacy and safety in difficult to treat patients (non-responders and patients with severe liver disease)
  - ✓Shorter treatment duration

Simeprevir (TMC435)

- One-pill, once-daily, oral HCV protease inhibitor indicated for the treatment of chronic HCV infection
- Multi-genotypic; antiviral activity against genotypes 1, 2, 4, 5, and 6
- Phase II studies demonstrated:
  - ✓ Safety and tolerability profile comparable to placebo
  - ✓ Increased SVR vs placebo in GT1, treatment-naïve and treatment-experienced patients and difficult to treat patients
  - ✓ Shorter overall treatment duration



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

Study	Total no. of patients	Patient population	SVR24 (%)	SVR24 P/R control (%)	Delta
Pillar	**386**	**Treatment naive**	**83**	65	18
Dragon	**92**	**Treatment naive (JPN)**	**82**	46	36
Aspire	**462**	**Treatment experienced**	**73**	23	50

Prior response to PegINF/RBV	SVR24 (%)	SVR24 P/R control (%)
Relapser	**85**	37
Partial responders	**76**	9
Null responders	**51**	19

Safe and efficacious with excellent tolerability, one pill once daily

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

Pivotal phase III studies:

- **QUEST 1** treatment-naïve
- **Quest 2** treatment-naïve
- **PROMISE** prior relapsed
- **Japan** naïve & experienced (four studies)

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

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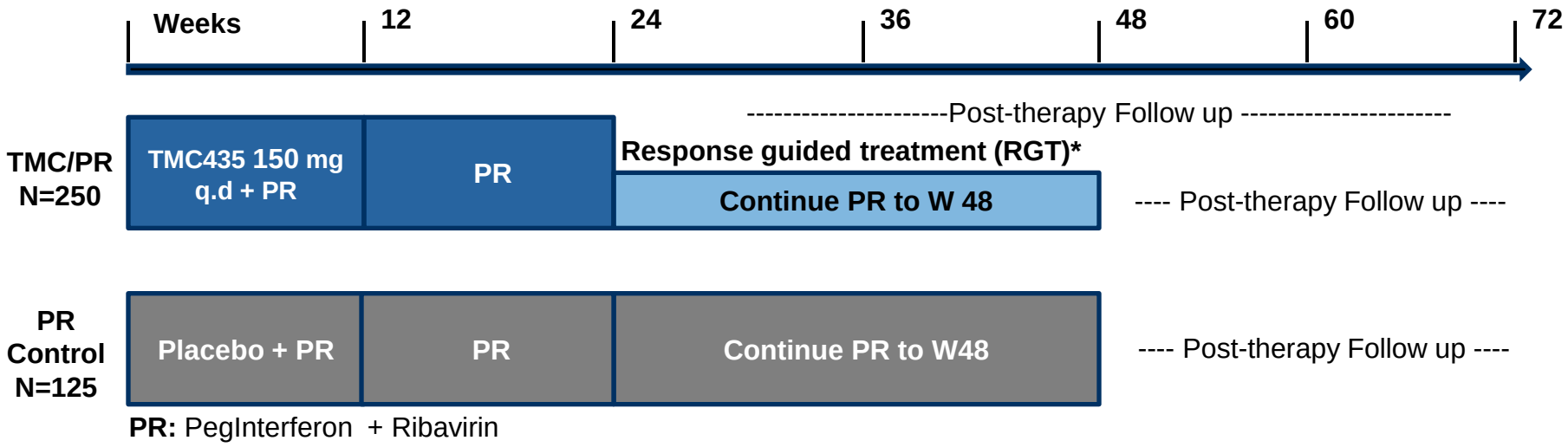
For additional information, please see www.clinicaltrials.gov

Simeprevir - Phase III Study designs in HCV GT1 infected patients

Response guided, double-blind, placebo controlled

2:1 randomization



PR: PegInterferon + Ribavirin

Studies:

QUEST-1: n=394, naive (METAVIR score F3-F4: 30%)

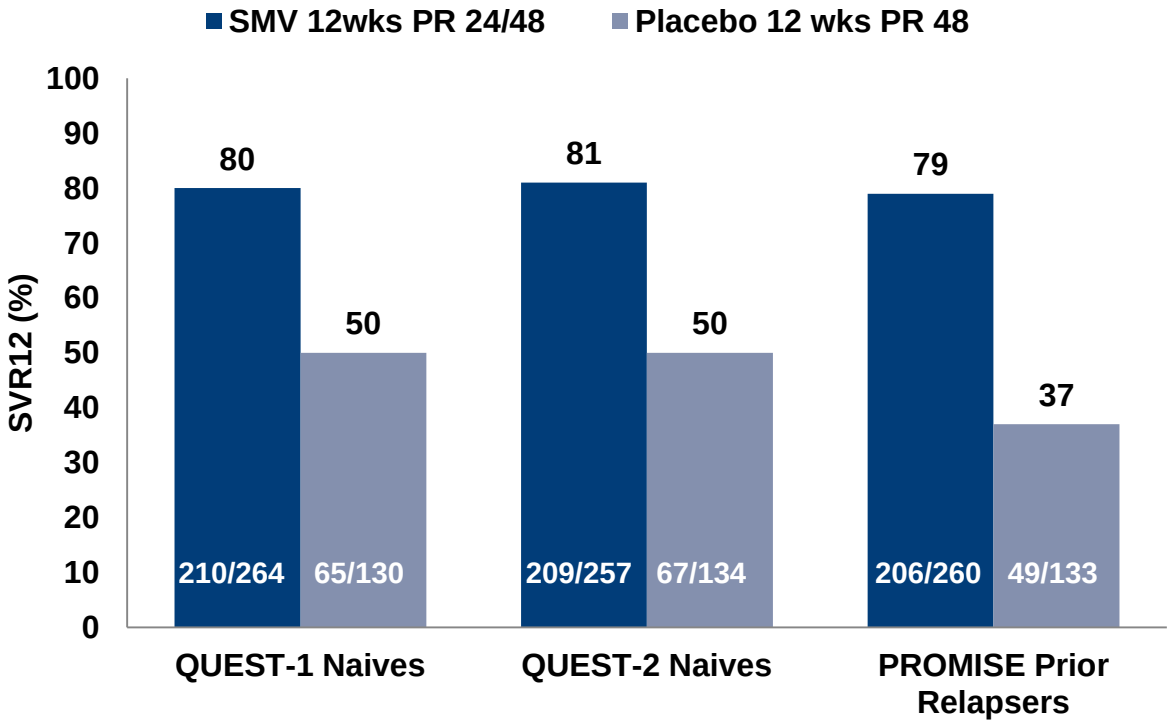
QUEST-2: n=391, naive, (METAVIR score F3-F4: 22%)

PROMISE: n=393, prior relapsers, (METAVIR score F3-F4: 31%)

*HCV RNA < 25 IU/mL (detectable or undetectable) at Week 4 and undetectable (< 25 IU/mL undetectable) at Week 12

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

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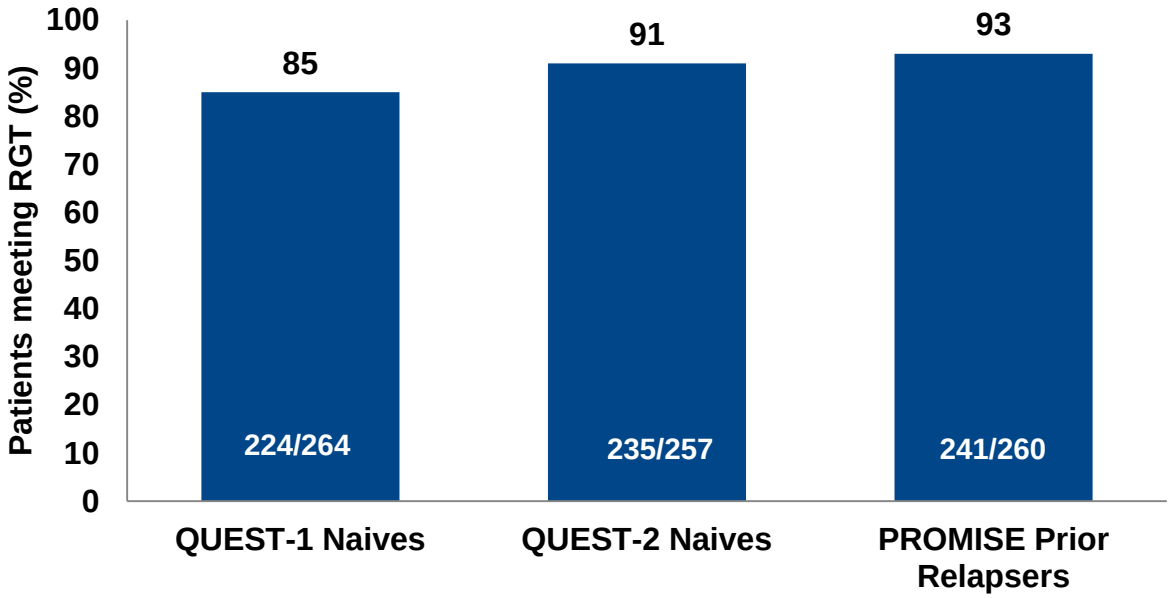
Simeprevir - Phase III Triple therapy

Efficacy – Response Guided Treatment (RGT)



Markedly shortened treatment durations:

85 - 93 % of the patients were able to stop all treatment at week 24

Simeprevir - Phase III triple therapy

Results – Safety and Tolerability

- Overall simeprevir was safe and well tolerated
  - ✓ Incidence of adverse events, including rash and anemia, were similar to those observed in the placebo control group
- Mild and reversible increases in bilirubin were observed in simeprevir dose groups
- Discontinuations due to AEs were consistently lower in the simeprevir treatment arms as compared to control

Overall incidence of adverse events was similar to placebo control

Simeprevir - Phase III triple therapy

Summary

- **Robust efficacy** - high cure rates in all trials (SVR12 in 79, 80 and 81%)*
- **Excellent safety and tolerability** - incidence of adverse events, including rash and anemia, similar to placebo

Phase III data support simeprevir as a new treatment for G1 HCV, with advantages vs marketed 1st generation PIs is:

Safer – similar AE profile as placebo (vs known issues with 1st generation PIs)

Shorter – 85-93 % could stop all treatment at week 24 (vs ≤ 60%)

Simpler – 1 pill, once daily (vs. 2-3 times daily)

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

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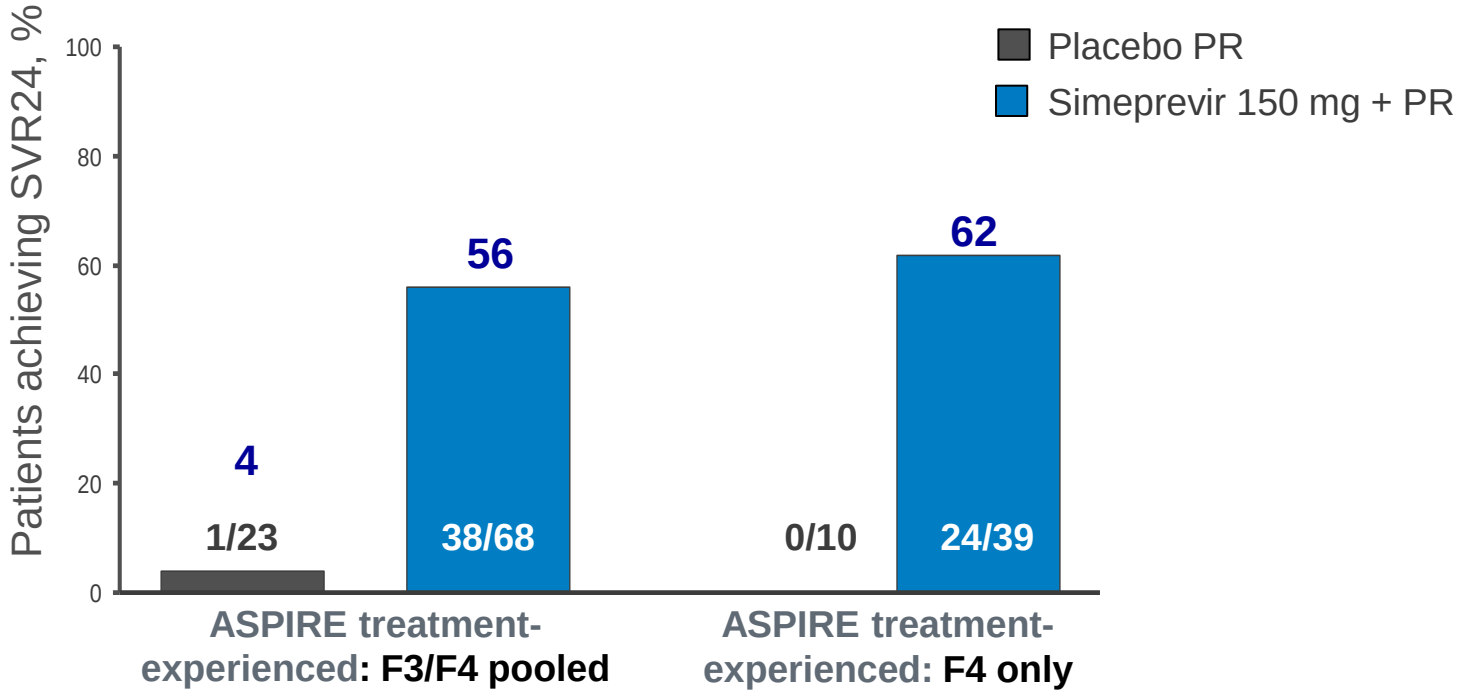
* All three trials included difficult-to-treat patients with advanced liver fibrosis/cirrhosis (METAVIR score F3-F4)

ASPIRE
– a phase II study in treatment-experienced G1 HCV patients



High SVR rates in patients with advanced liver disease (F3 and F4)

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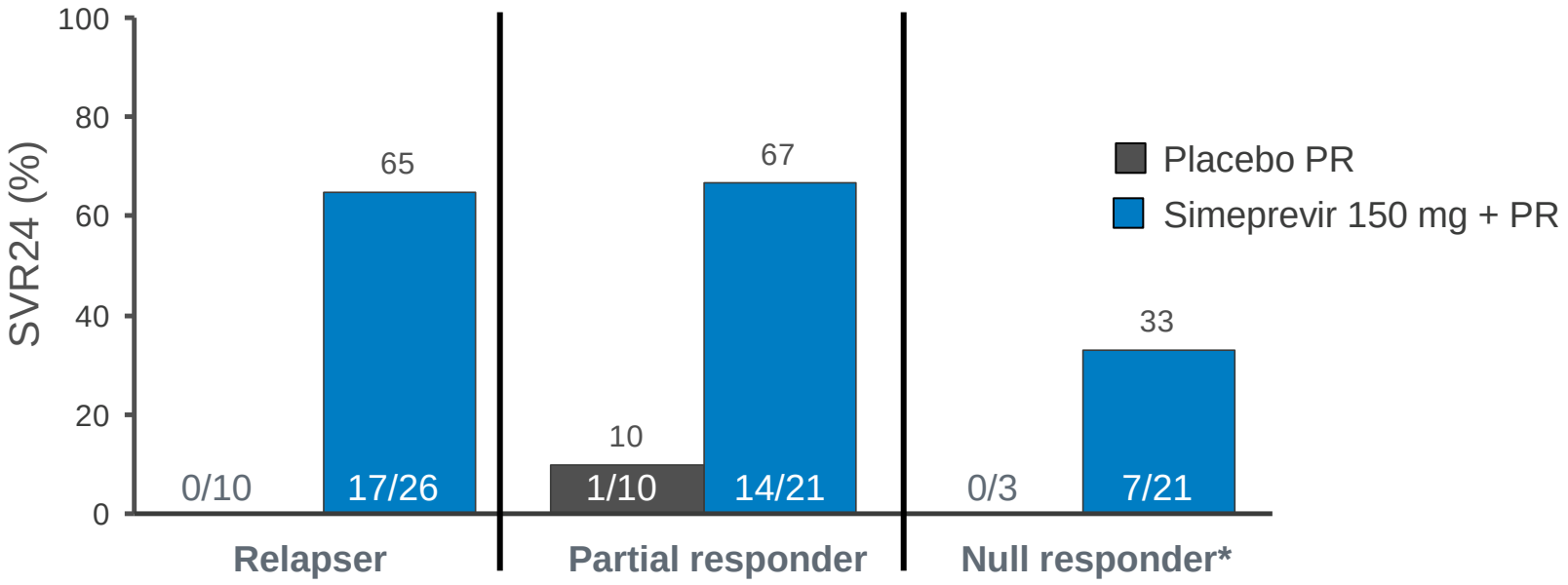
*Treatment arms within ASPIRE with different durations pooled

PR, pegylated interferon α-2a + ribavirin; SVR24, HCV RNA <25 IU/mL undetectable 24 weeks after planned end of treatment

ASPIRE
– a phase II study in treatment-experienced G1 HCV patients

SVR24 by prior response to PegIFN/RBV in F3/F4 patients



*** 31% (4/13) null responders with cirrhosis (F4) achieved SVR24**

Simeprevir was safe and well tolerated also in this patient population

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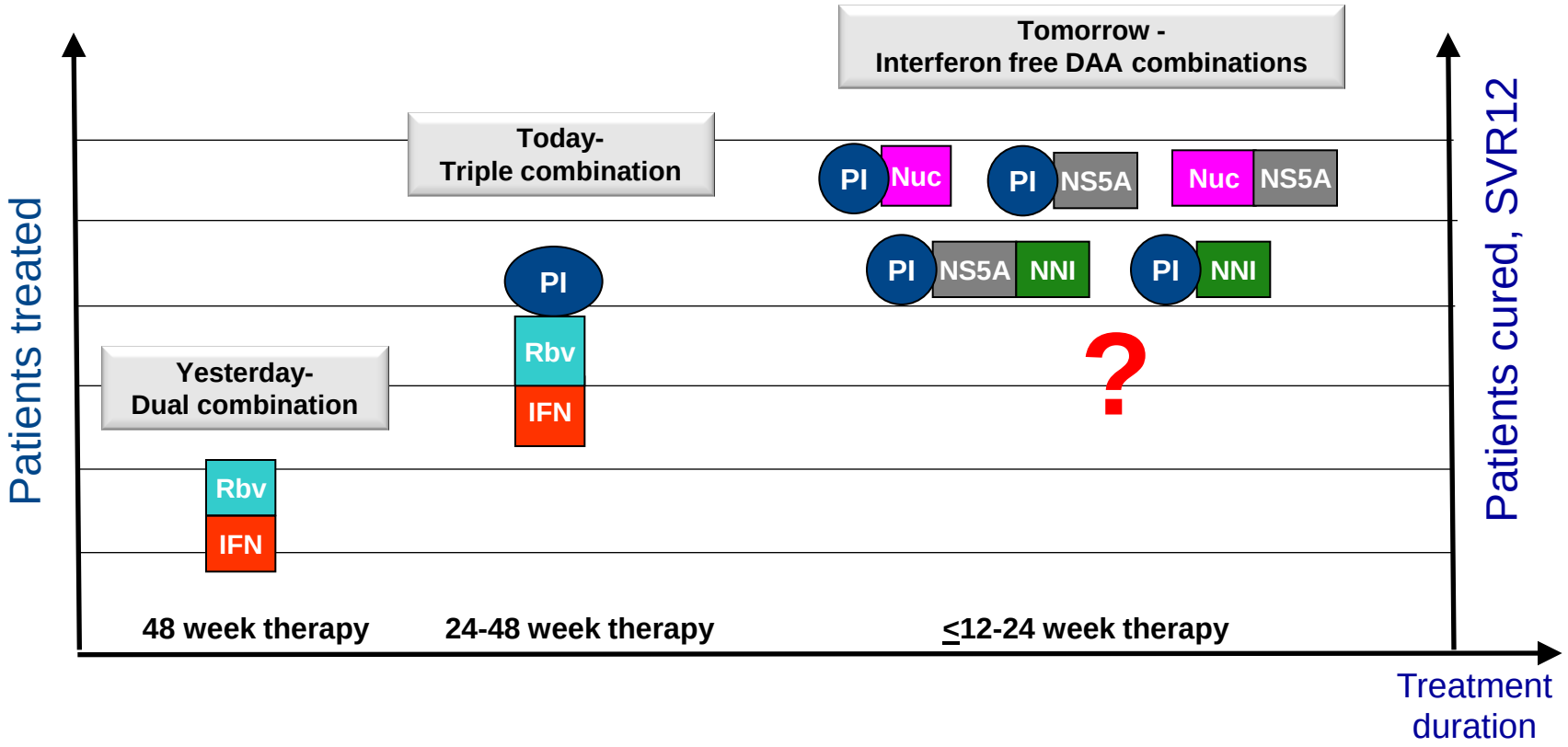
*Treatment arms across ASPIRE with different durations combined
PR, pegylated interferon α-2a + ribavirin ; SVR24, HCV RNA <25 IU/mL undetectable 24 weeks after planned end of treatment

Evolution of HCV therapy in HCV G1 infection



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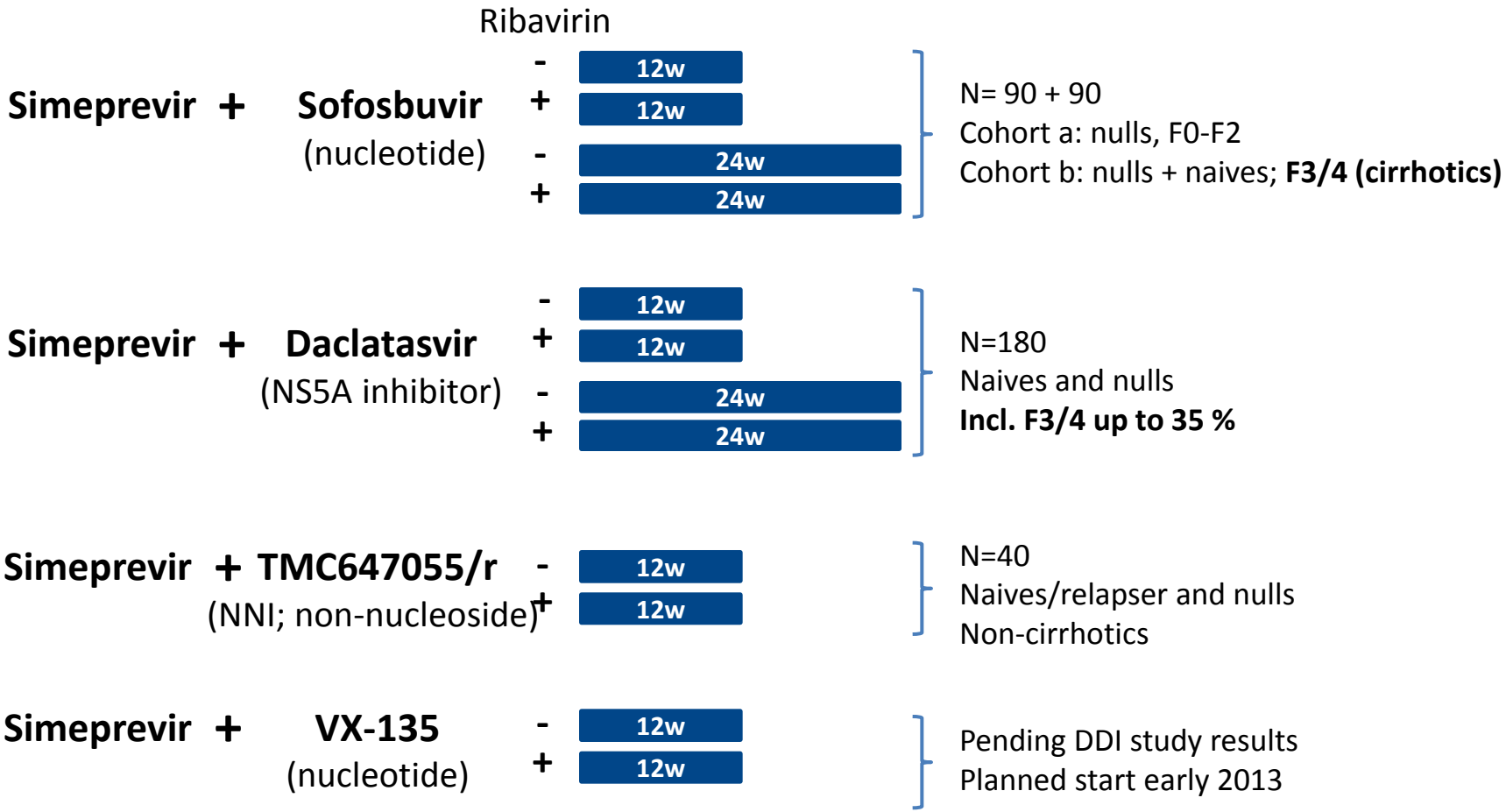
✓well positioned for triple as well as future interferon free combination therapies

Simeprevir (TMC435) – interferon free combinations



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

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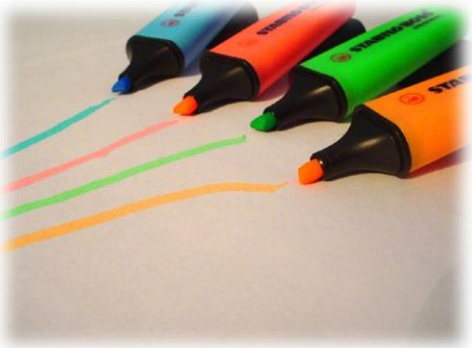
For additional information, please see www.clinicaltrials.gov

Strong news flow - highlights



- ✓ Q3-12 Start of Phase Ib clinical trials with MIV-711, a cathepsin K inhibitor
- ✓ 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 Potential CD selection in Cathepsin S (neuropathic pain) program
- Q1-13 EoT and partial SVR data from Cohort 1 with simeprevir and GS7977 phase II study
- 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

www.medivir.com

Ticker: MVIR
Exchange: OMX / NASDAQ

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