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 company

- Research driven pharmaceutical company **focused on infectious disease**, with a strong track record in **partnerships as part of the business model,** located in Sweden

- **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** - our programs including all three validated target classes, two in-house driven.

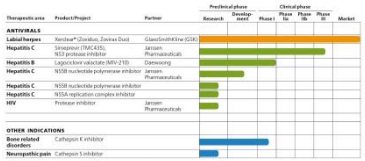
- **Simeprevir (TMC435)** in partnership with Janssen, considered as the best in class PI - **filed globally during 2013**

- **Fifteen marketed products in the Nordics -** generating annual sales of ~85 MUSD with an EBITDA of ~16MUSD

- **Solid financial position**

- **Broad institutional shareholder base -** ~30% outside Nordic region

Medivir - the emerging European pharma company
2013 – setting the framework



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

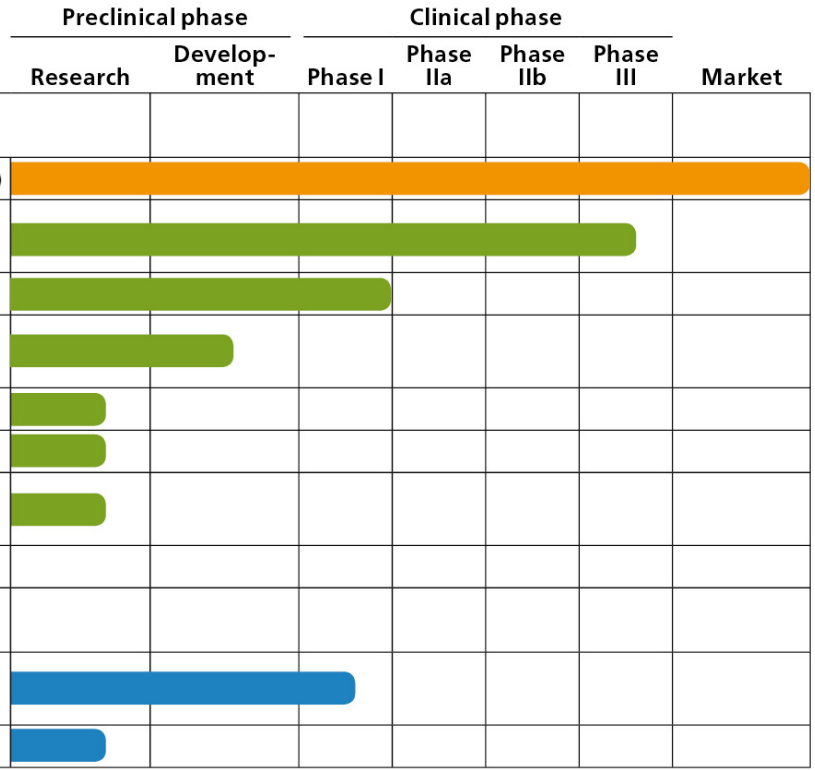
- Expansion of product portfolio, including simeprevir and other in-house developed pharmaceuticals

External perspective

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

A project portfolio focused on infectious diseases -
built on leading expertise in protease and polymerase targets

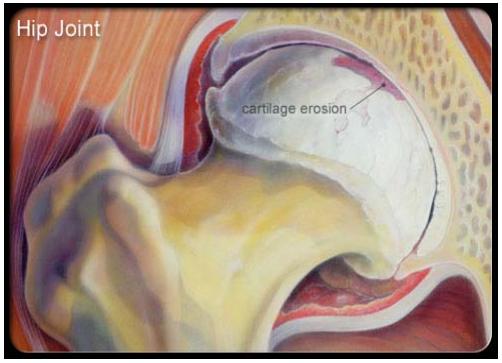
Therapeutic area	Product/Project	Partner
ANTIVIRALS		
Labial herpes	Xerclear® (Zoviduo, Zovirax Duo)	GlaxoSmithKline (GSK)
Hepatitis C	Simeprevir (TMC435), NS3 protease inhibitor	Janssen Pharmaceuticals
Hepatitis B	Lagociclovir valactate (MIV-210)	Daewoong
Hepatitis C	NS5B nucleotide polymerase inhibitor	Janssen Pharmaceuticals
Hepatitis C	NS5B nucleotide polymerase inhibitor	
Hepatitis C	NS5A replication complex inhibitor	
HIV	Protease inhibitor	Janssen Pharmaceuticals
OTHER INDICATIONS		
Bone related disorders	Cathepsin K inhibitor	
Neuropathic pain	Cathepsin S inhibitor	



MIV-711 - A cathepsin K inhibitor in clinical phase I for osteoarthritis and other bone related disorders

Mechanism of action

- 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

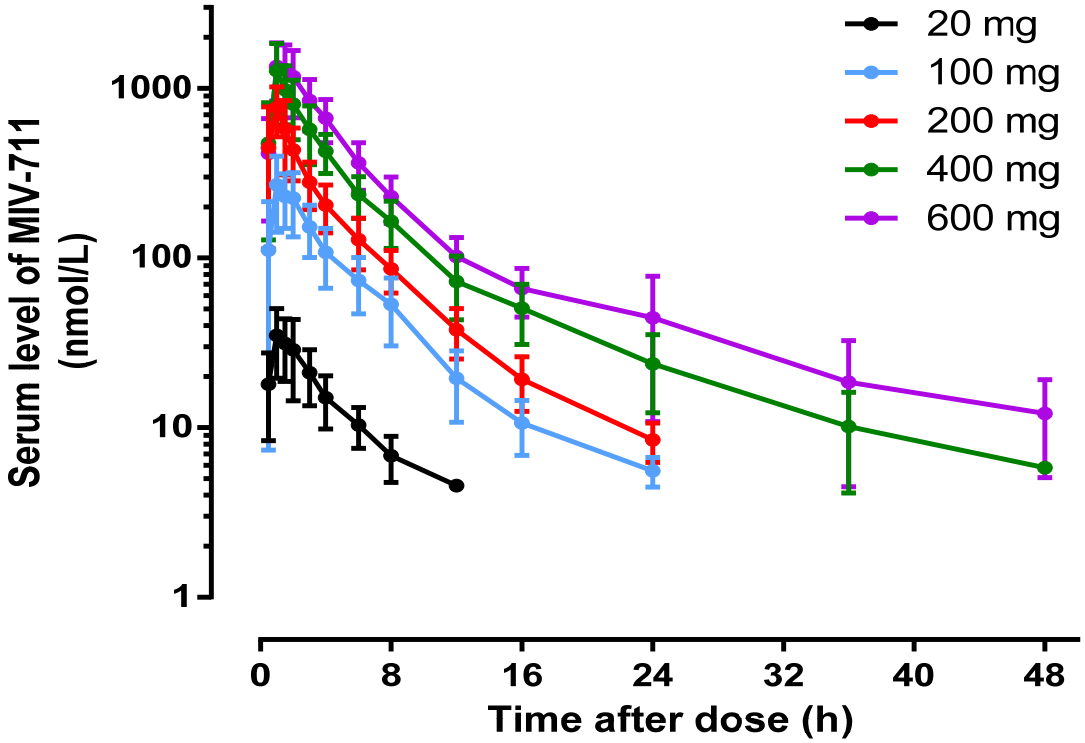


Phase I study recently finished

- Adaptive, placebo controlled, double-blind study in healthy subjects incl. post meno-pausal women
- Ascending single and multiple (7 - 28 days) once daily dosing
- Biomarkers for bone and cartilage turnover (CTX-I, CTX-II etc)
- The top line data will be available around mid-year
- Business development activities aiming for partnership for further clinical development

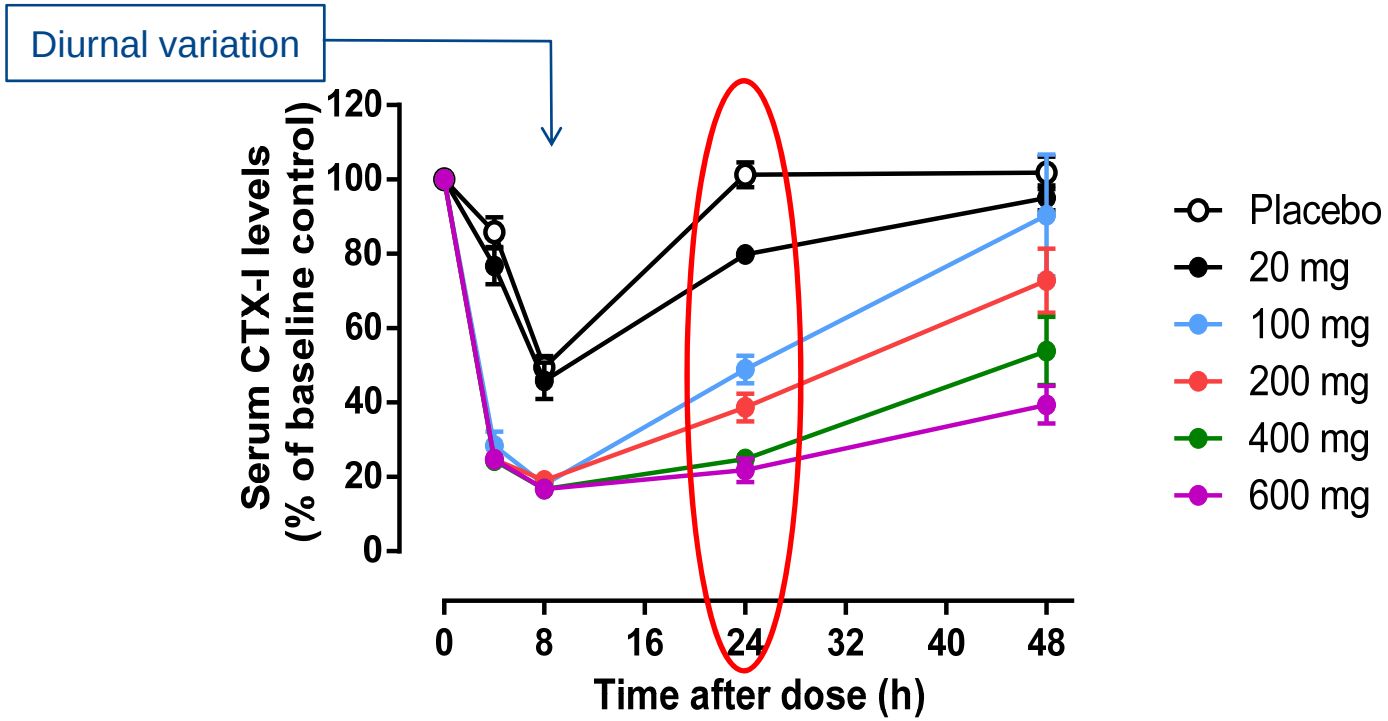
MIV-711 - a phase I clinical candidate efficacious in preclinical models of osteoarthritis and osteoporosis

MIV-711 – Pharmacokinetics after single ascending oral doses in healthy subjects



- **MIV-711 was safe and well tolerated at all doses tested (up to 600 mg)**
- **Exposure increased in a dose proportional manner**

MIV-711 – Effect on a bone resorption marker after single ascending oral doses in healthy subjects



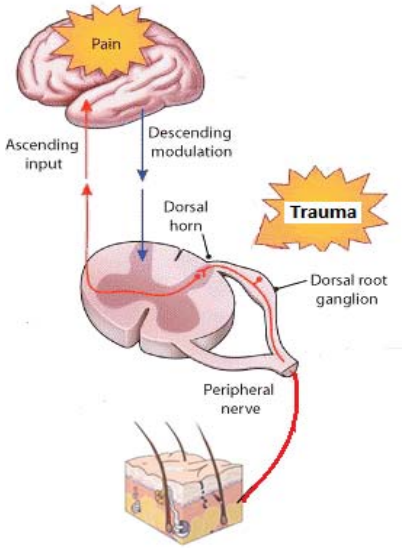
Serum levels of the bone resorption biomarker CTX-I were reduced by up to 79% at 24 h after dose - reversible effect

Cathepsin S inhibitor for neuropathic pain (NP)

Principle for 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



Medical need and market

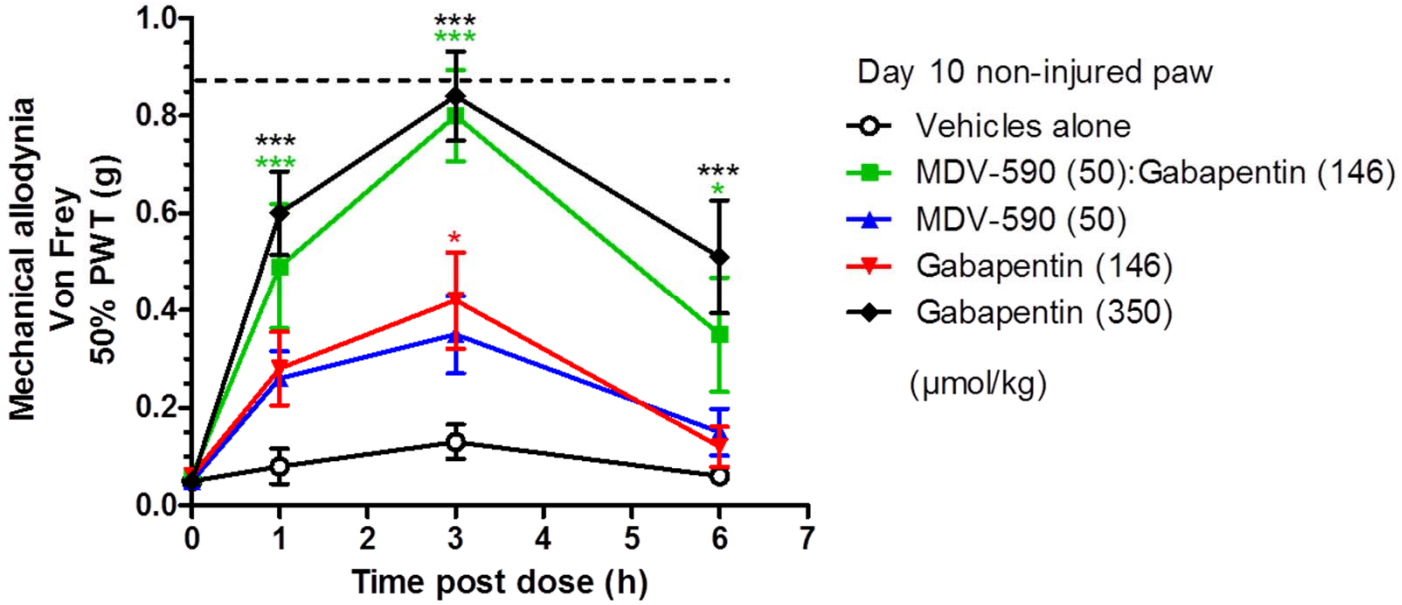
- Current treatments incl. anticonvulsants and antidepressants
  - Pain persists in 75% patients with at best a 50% reduction in overall pain
  - Significant side effects e.g. dizziness, somnolence
- 25M people in the 7 MM suffer from NP

Mechanism of action

- Inhibition of Cathepsin S prevents inflammatory damage to the sensory system in the spinal cord by blocking fractalkine release
- Potent, selective and orally bioavailable inhibitors available

Cathepsin S inhibitor – efficacious as monotherapy and synergistic with gabapentin in a model of neuropathic pain

Combining minimal effective doses of a Cathepsin S inhibitor (MDV-590) and gabapentin in a neuropathic pain model



Expected candidate drug selection around mid year for preIND safety and toxicology studies

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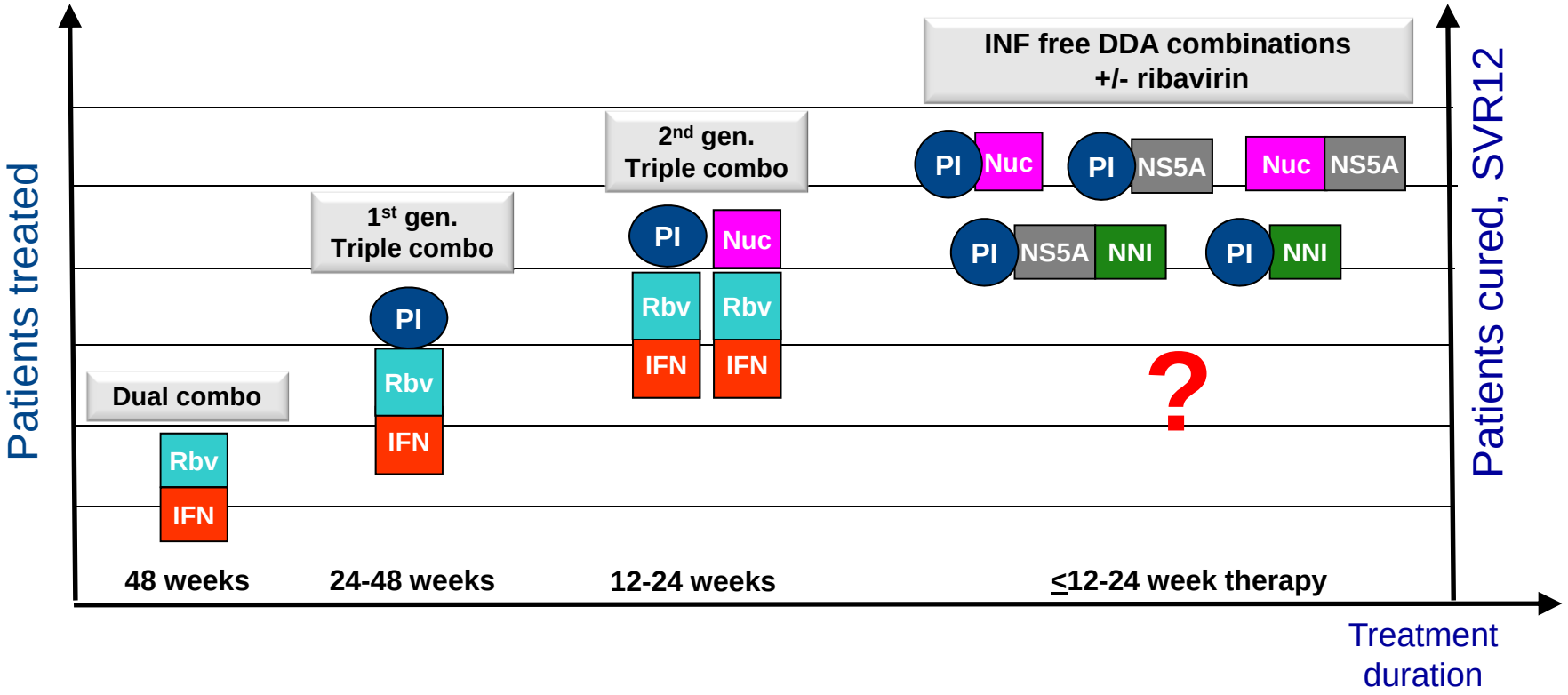
Simeprevir (TMC435) soon to reach the market in a rapidly evolving treatment landscape

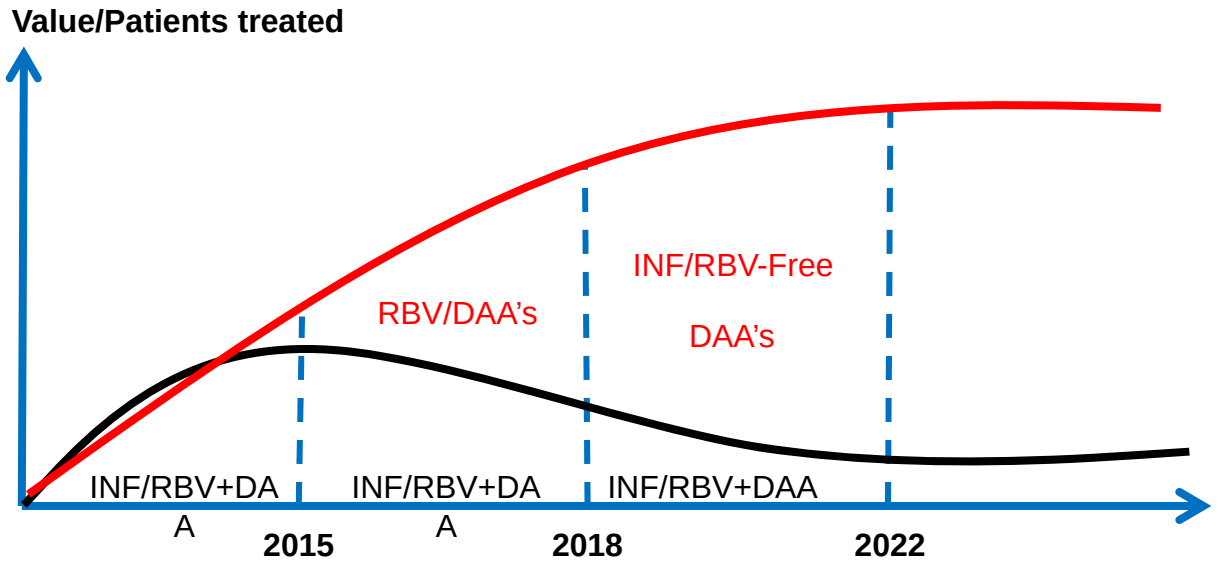
Evolution of HCV therapy in HCV G1 infection



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

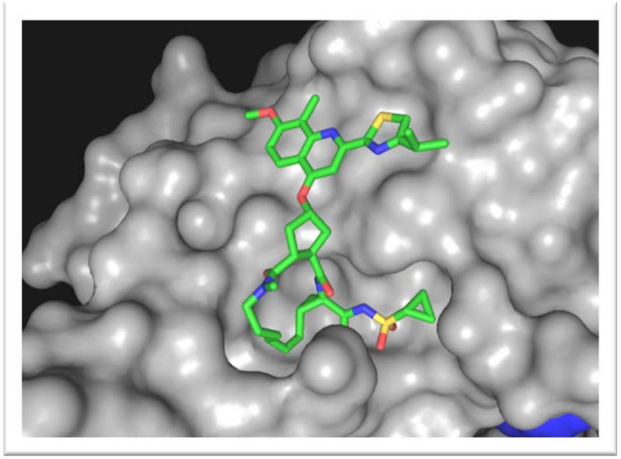
Long term goal – eradication of hepatitis C

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



Regional, patient and pricing differences will drive the segments in the future

Simeprevir - Next generation Protease Inhibitor (PI)

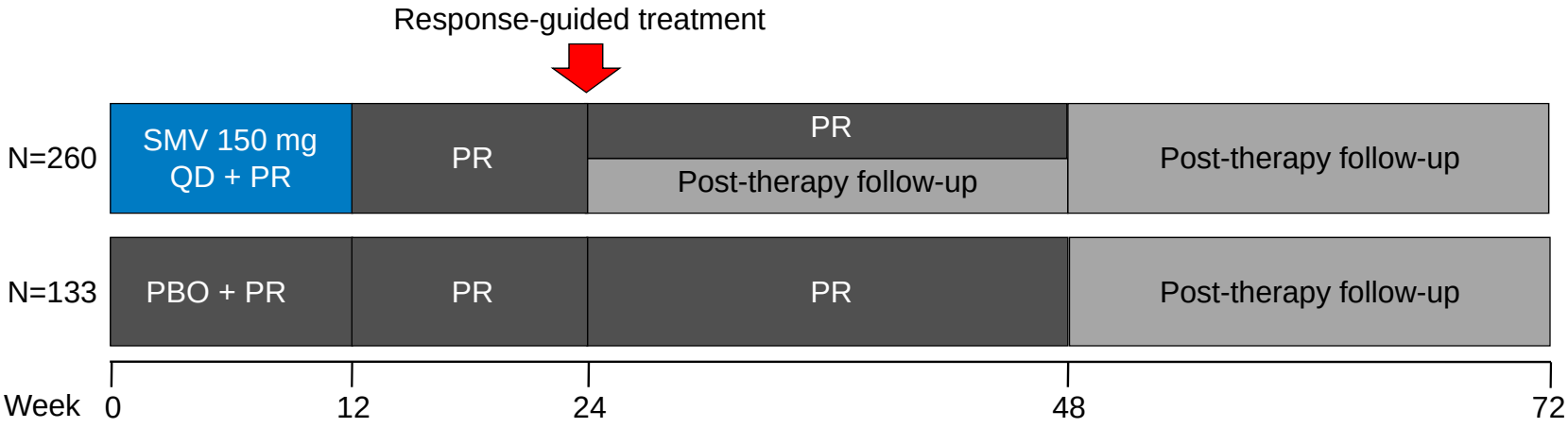


- One-pill, once-daily, investigational HCV NS3/4A protease inhibitor

- Multigenotypic: Antiviral activity in patients infected with HCV gt 1, 2, 4, 5, and 6
- Three large pivotal phase III studies of SMV 150 mg QD plus PegIFN/RBV completed in treatment-naïve and prior relapser patients
- Safe and well tolerated with high SVR12 rates (cure rates)
- Simeprevir is currently being studied in a number of IFN-free regimens

Regulatory filings for simeprevir triple combination submitted in Japan, US and EU

Simeprevir
- Phase III study design in HCV GT1 infected patients



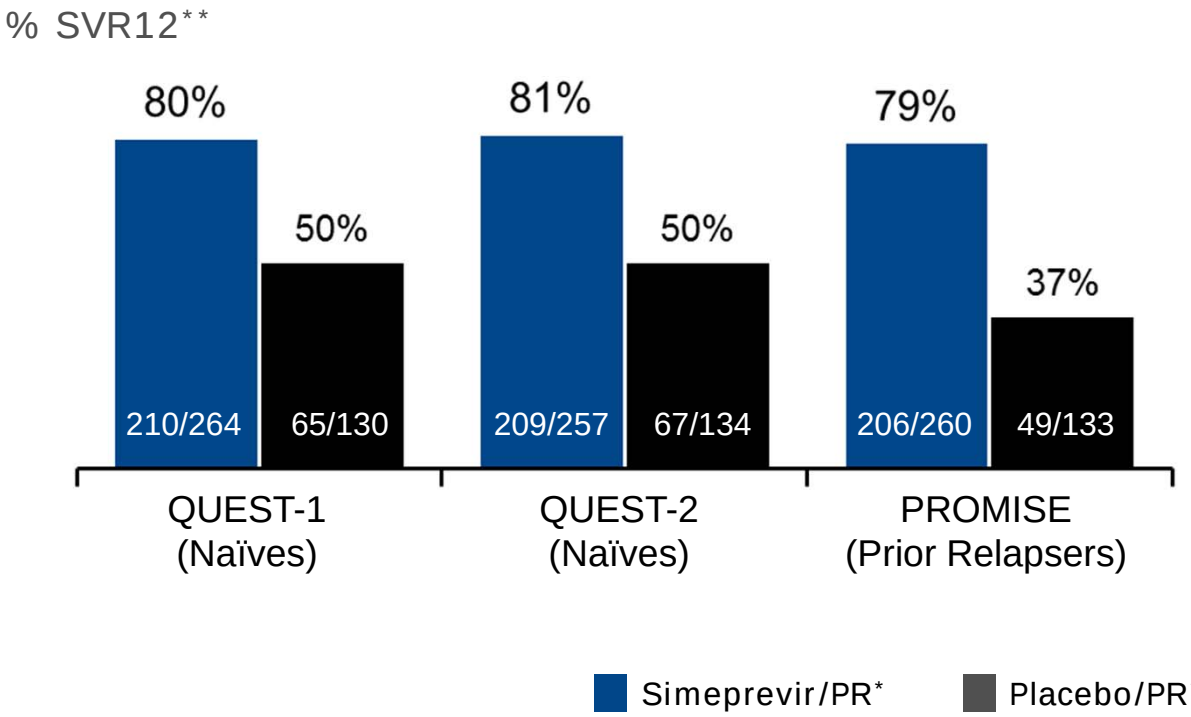
- Patients were stratified by HCV G1 subtype and *IL28B* genotype
- **Primary endpoint: SVR12 -** HCV RNA < 25 IU/mL 12 weeks after planned end of treatment

QUEST-1: n=394, naive (30% F3-F4*)
QUEST-2: n=391, naive, (22% F3-F4*)
PROMISE: n=393, prior relapsers, (31% F3-F4*)

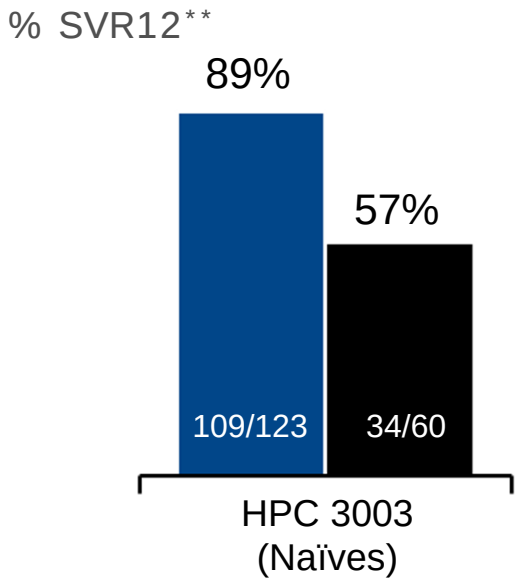
PR, PegIFNα-2a + ribavirin; SMV, simeprevir
*METAVIR score

Simeprevir: Summary of phase III results

Global Program



Japanese Program



Simeprevir was significantly superior to placebo in all studies

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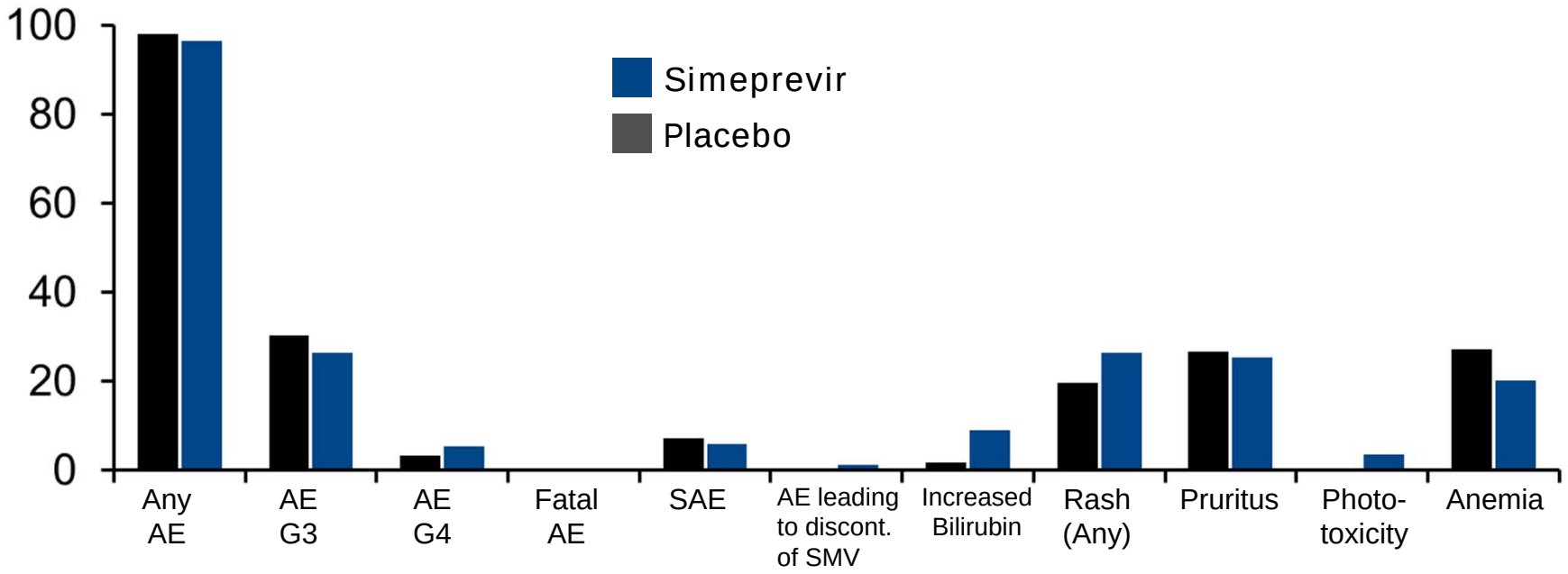
* PR: Pegylated Interferon + Ribavirin.

** SVR12: Sustained Virologic Response 12 weeks after EOT.

Data presented at EASL, Amsterdam, 2013 and DDW2013, Orlando, Fl, and on file.

Simeprevir: Safety profile comparable to placebo



Data from QUEST-2 - comparable results seen in all Phase III studies

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Simeprevir - Phase III summary

79-81% overall SVR12 rates[1]:

- Naive and relapser patients in three large global studies
- *89% SVR12 rates in Japan program[2]*

83-91% SVR12 rates with 24 weeks treatment

- 85-91% of patients stopped all treatment at 24 weeks

Excellent safety and tolerability

- Overall incidence of adverse events similar to placebo, including rash and anemia
- *Safety and tolerability confirmed in Japanese studies[2]*

Regulatory applications filed in JPN, US and EU aiming for a broad label

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[1] All three trials included hard-to-cure patients with advanced liver fibrosis/cirrhosis (METAVIR score F3-F4)
[2] To be presented at upcoming scientific meetings

Simeprevir – a broad clinical development program in HCV G1 & 4 infected patients

Pivotal phase III studies:

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

Regulatory files submitted in US (March-13) and in EU (April-13)

Regulatory file submitted February 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
- **RESTORE: HCV genotype 4 infected** naïve or treatment experienced patients
- **C212: HIV-HCV** co-infected treatment naïve and experienced patients
- **12 weeks full stop,** open-label, single-arm study in treatment naïve patients

Regulatory applications filed in JPN, US and EU aiming for a broad label

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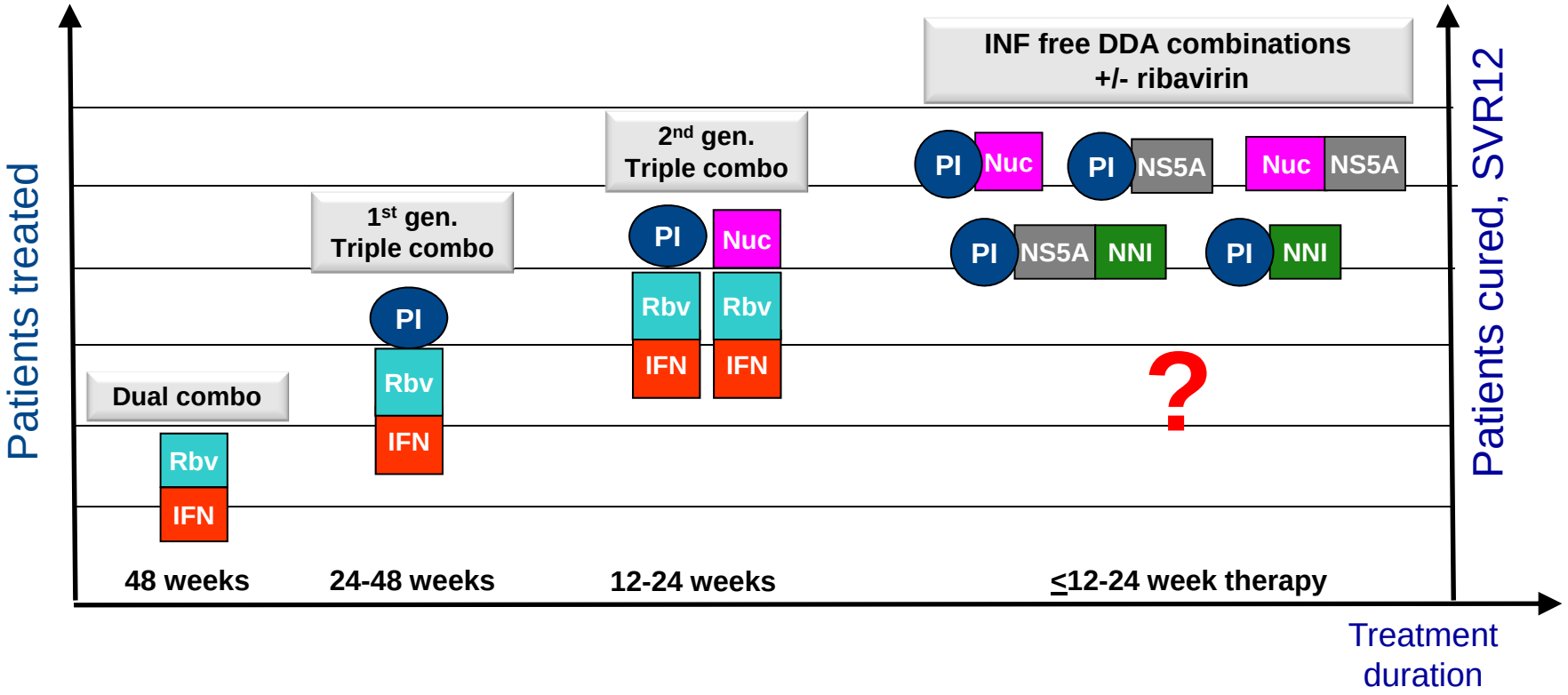
For additional information, please see www.clinicaltrials.gov

Simeprevir

- All oral interferon free combination update

Evolution of HCV therapy in HCV G1 infection



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

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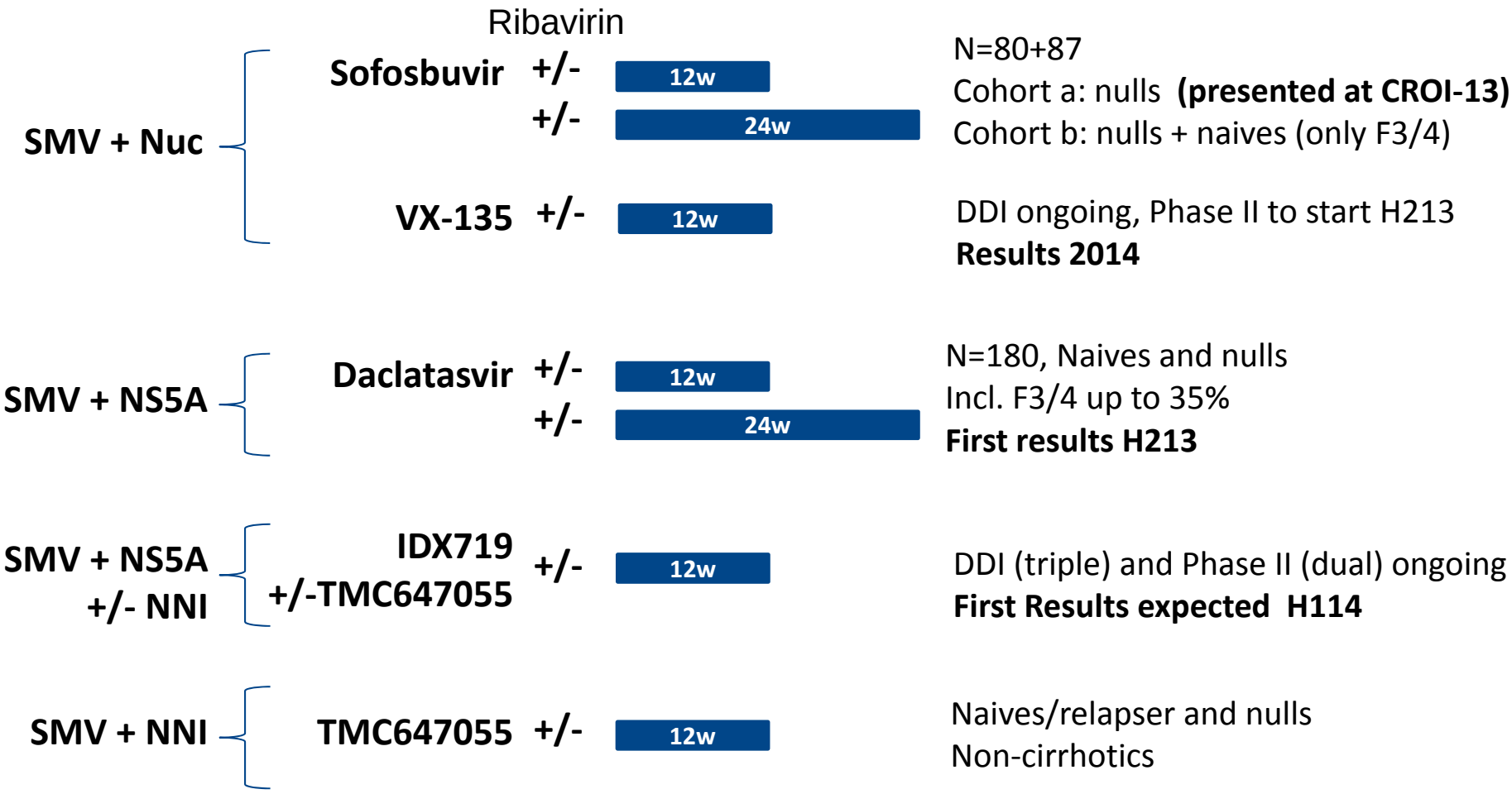
Simeprevir (SMV) – a PI in interferon-free combinations



N=80+87
Cohort a: nulls **(presented at CROI-13)**
Cohort b: nulls + naives (only F3/4)

DDI ongoing, Phase II to start H213
Results 2014

N=180, Naives and nulls
Incl. F3/4 up to 35%
First results H213

DDI (triple) and Phase II (dual) ongoing
First Results expected H114

Naives/relapser and nulls
Non-cirrhotics

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

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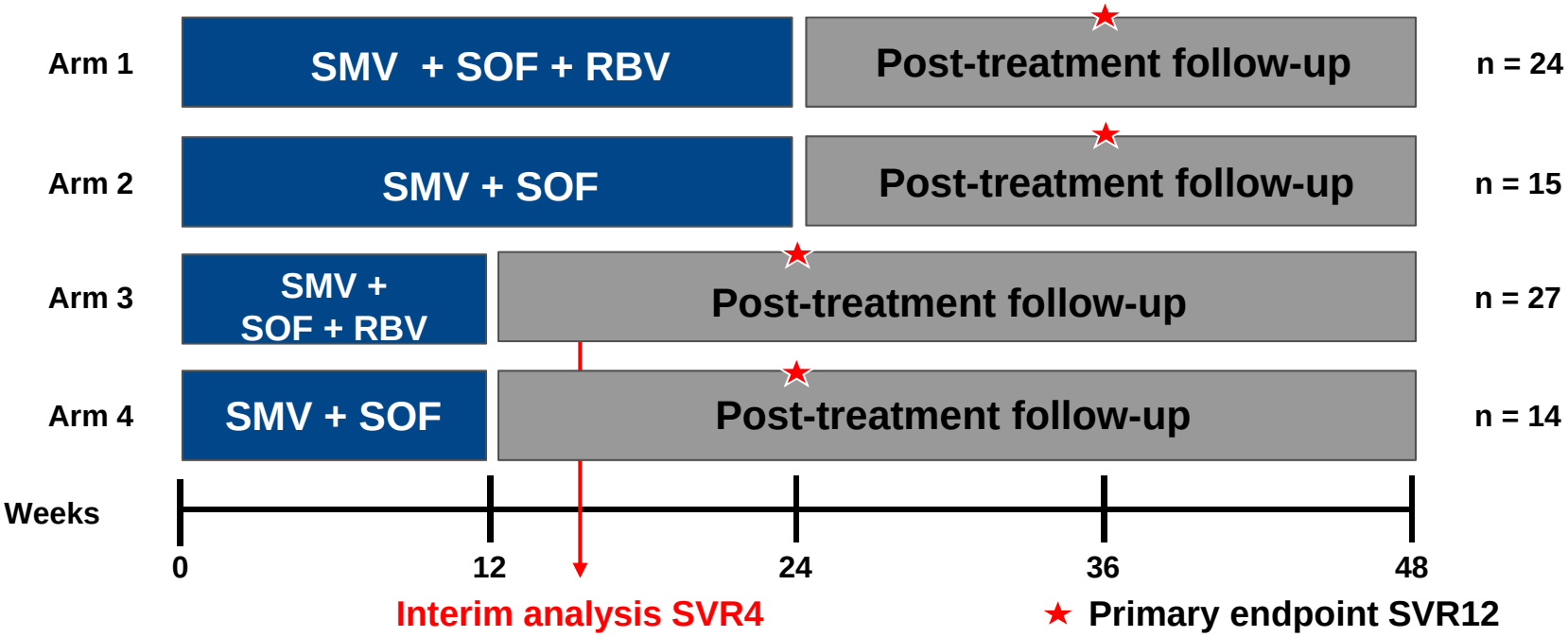
For additional information, please see www.clinicaltrials.gov

COSMOS - Simeprevir plus sofosbuvir with or without ribavirin in HCV genotype 1 null responders*



- **Cohort 1: n=80, nulls, F0-F2**
- **Cohort 2: n=87, naives and nulls, F3-F4**
- **SMV 150 mg QD + SOF 400 mg QD with/without RBV**
- **Interim analysis of Cohort 1 conducted when all patients in 12 week treatment arms reached SVR4 time point or discontinued early**

*The **COSMOS** study**: CO**mbination of **SiM**eprevir and s**O**fosbuvir in HCV infected patie**ntS**

COSMOS study – Efficacy results (interim analysis)

Response rates	12 weeks treatment	
	SMV + SOF+ RBV (n=27)	SMV + SOF (n=14)
RVR[1], n/N (%)	23/27 (85)	8/14 (57)
Undetectable end of treatment, n/N (%)	27/27 (100)	14/14 (100)
Relapse, n	1	1
SVR4, n/N (%)	**26/27 (96)**	**13/14 (93)**
SVR8, n/N (%)	**26/27 (96)**	**13/14 (93)**

- **Simeprevir + sofosbuvir was safe and well tolerated**
- **Enrollment of Cohort 2 is complete, nulls and naïves, all with advanced fibrosis (METAVIR F3-F4)**

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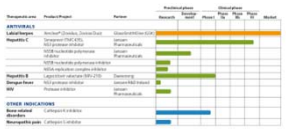
[1]RVR is based on patients with available data at Week 4 (2 patients discontinued before Week 4)
EOT, end of treatment; RVR, rapid virologic response; SMV, simeprevir; SOF, sofosbuvir; SVR, sustained virologic response

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 – participate in eradicating hepatitis C

- Simeprevir, partnered with Janssen Pharmaceuticals
  - Regulatory files have been submitted in EU, US and Japan
  - Many interferon-free combination treatments opportunities
- In-house HCV programs will offer combination opportunities

BioPhausia – a Medivir sales company

Commercial presence in the Nordic region creates stability

- 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

Solid financial position

- Present liquid assets are solid and will take us to the time point were we are profitable

www.medivir.com

Ticker: MVIR
Exchange: OMX / NASDAQ

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