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

## Q3-2013 Conference Call 21 November 2013
## Presenting team


**Maris Hartmanis, CEO**
**Charlotte Edenius, EVP Development**
**Richard Bethell, EVP Discovery Research**
**Rein Piir, EVP Corporate Affairs & IR**

# Reflections on Q3 2013

## Maris Hartmanis, CEO

# Medivir´s way forward since the Q2 report

## Commercial focus

- Simeprevir was approved in Japan and Canada
- The approval in Japan triggered a milestone payment of €5m to Medivir
- A new $R_x$ pharmaceutical was added to the Nordic portfolio through a distribution agreement with Ferrer
- Medivir's Nordic $R_x$ portfolio continued to show a stable sales performance

## Progress

- MIV-247 was selected as a candidate drug and entered pre-clinical development for the treatment of neuropathic pain
- Solid phase I data with MIV-711 were presented in our cathepsin K program for bone-related disorders
- New simeprevir results were presented from the COSMOS study, in HCV/HIV co-infected patients and in GT 4 patients
- Our partner Janssen acquired an NS5A replication complex inhibitor from GSK, now named JNJ-56914845. Simeprevir will be evaluated with JNJ-56914845 in upcoming interferon-free trials

## Structure

- We focused the in-house hepatitis C projects to those involving nucleotide-based polymerase inhibitors
- Medivir discontinued its collaboration with Daewoong Pharmaceutical Co. Ltd. regarding the development of MIV-210 (Hepatitis B)
- Evaluation of the future discovery research strategy has started

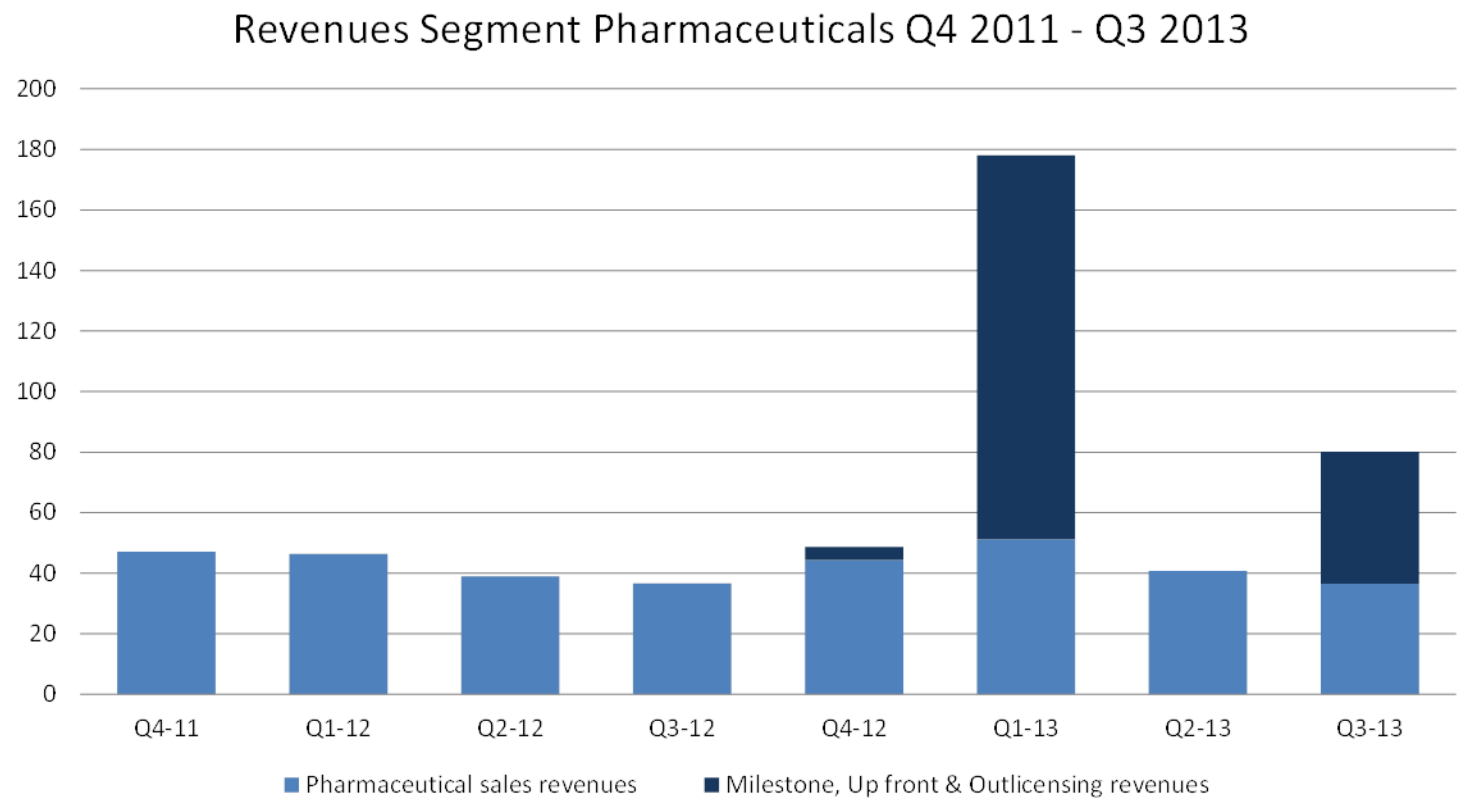
# Consolidated profit performance

| (SEK m) | 2013 July-Sept | 2012 July-Sept | 2013 Jan-Sept | 2012 Jan-Sept |
|---|---|---|---|---|
| Net turnover | 80.2 | 36.6 | 299.0 | 121.8 |
| Gross profit | 64.1 | 22.9 | 247.9 | 77.0 |
| EBITDA | 0.8 | -40.8 | 44.4 | -120.4 |
| EBIT | -10.1 | -48.6 | 4.6 | -147.6 |
| Profit/loss before tax | -9.6 | -53.7 | 4.9 | -152.1 |
| Profit/loss after tax | -10.7 | -56.2 | -3.3 | -163.5 |

# Net turnover breakdown

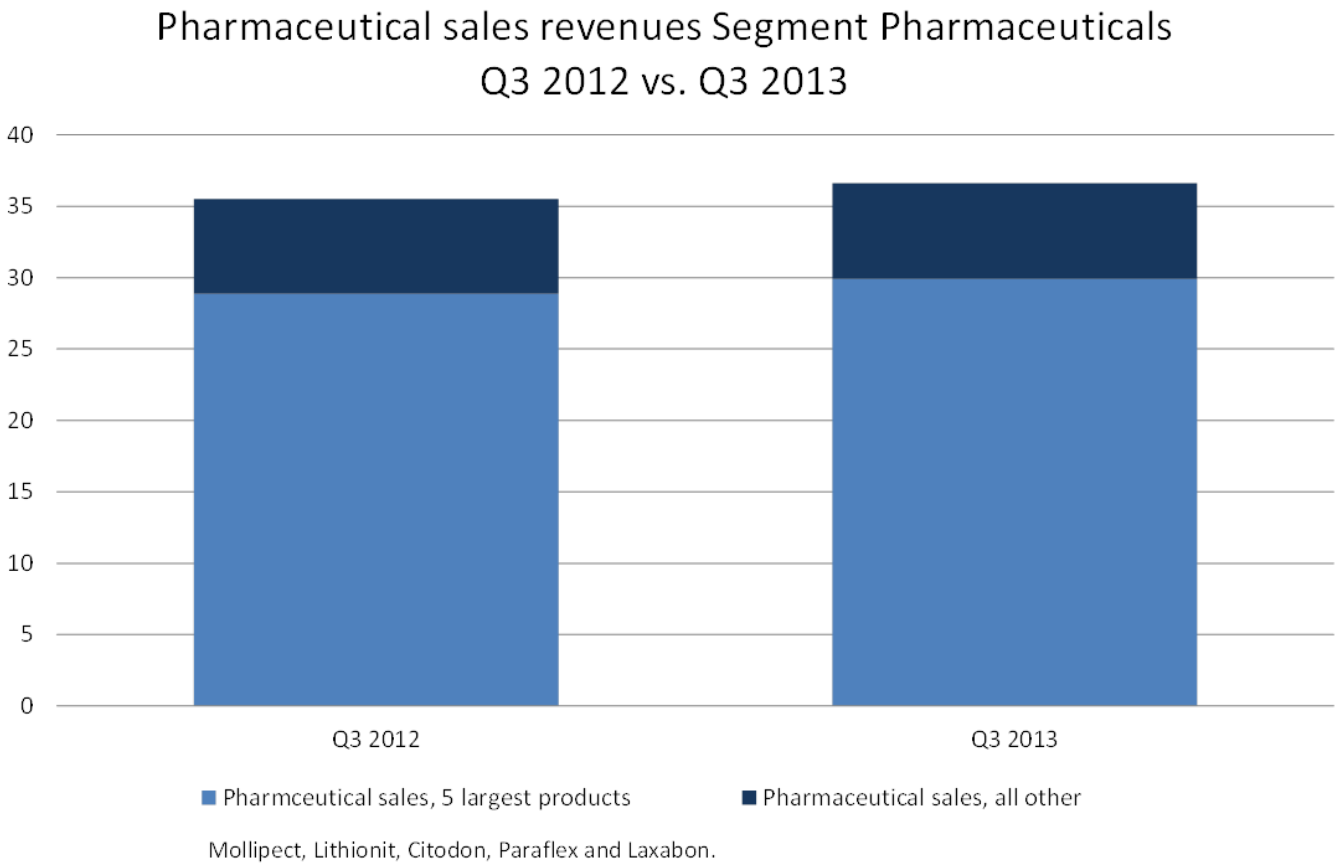
| (SEK m) | 2013 Jul-Sept | 2012 Jul-Sept | 2013 Jan-Sept | 2012 Jan-Sept |
|---|---|---|---|---|
| Outlicensing and partnership agreements/Non-recurrent payments | 43.6 | 0.0 | 170.5 | 0.0 |
| Pharmaceutical sales | 36.6 | 35.4 | 128.5 | 120.6 |
| Other services | 0.0 | 1.2 | 0.0 | 1.2 |
| **Total** | **80.2** | **36.6** | **299.0** | **121.8** |

# Quarterly sales trend in Pharmaceuticals, SEK m*

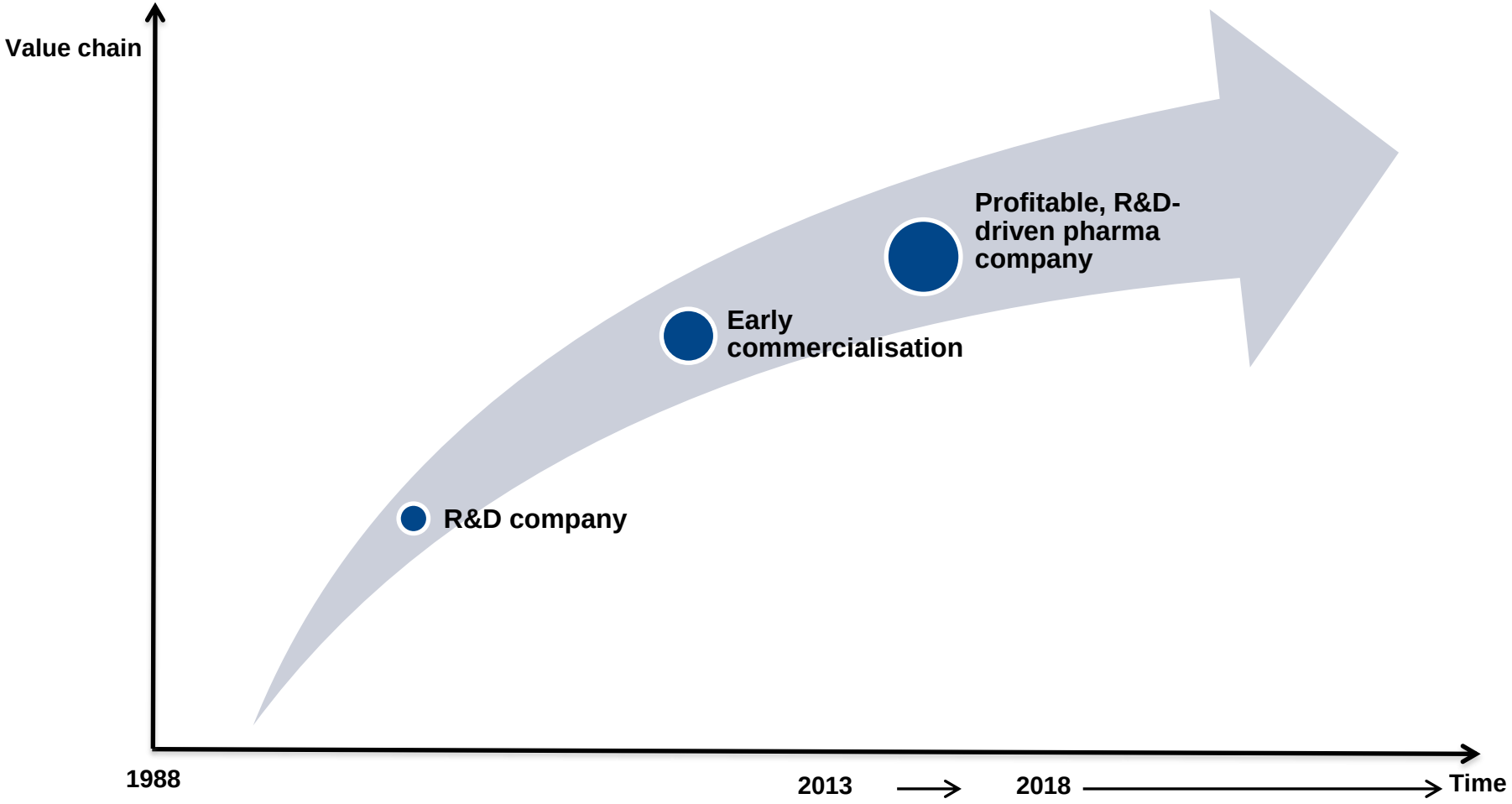



*The BioPhausia corporate group is included from May 31, 2011.

# Segment Pharmaceuticals



# The transformation of Medivir



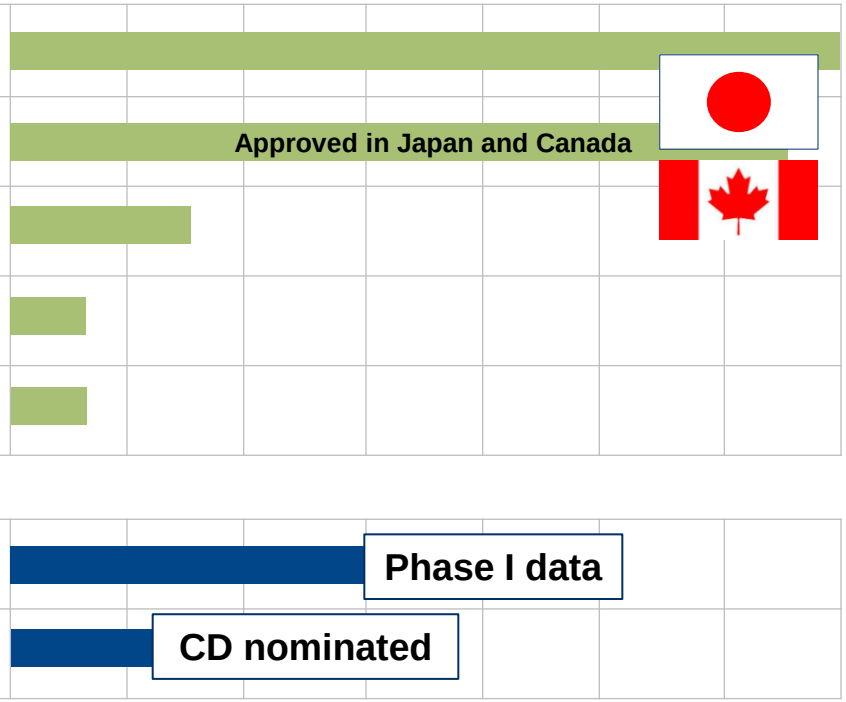

**We are on a journey to transform Medivir into a pharma company with long-term sustainable profit and growth**

# Key R&D highlights from Q3 2013

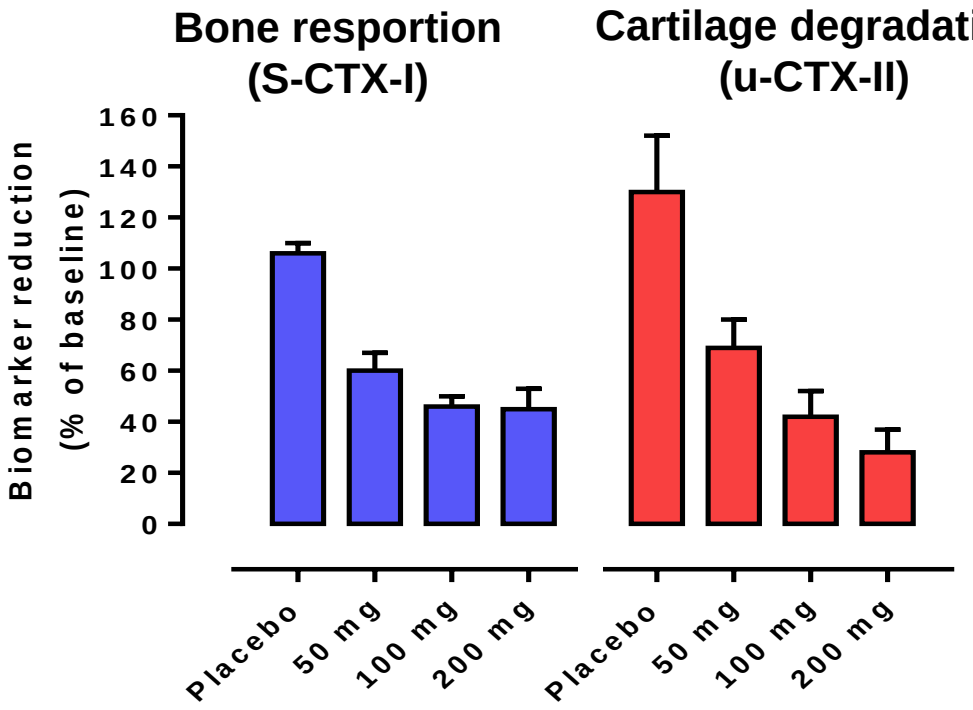
## Charlotte Edenius, EVP Development

# Our R&D pipeline is the engine of Medivir

| 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 |
|---|---|---|---|---|---|---|---|---|---|
| **Antivirals** | | | | | | | | | |
| **Labial herpes** | Xerclear (Zoviduo, Zovirax Duo) | GlaxoSmithKline (GSK) | | | | | | | |
| **Hepatitis C** | Simeprevir (TMC435), NS3 protease inhibitor | Janssen Pharmaceuticals | | | | | | | |
| **Hepatitis C** | NS5B nucleotide-based polymerase inhibitor | Janssen Pharmaceuticals | | | | | | | |
| **Hepatitis C** | NS5B nucleotide-based polymerase inhibitor | Unpartnered | | | | | | | |
| **HIV** | Protease inhibitor | Janssen Pharmaceuticals | | | | | | | |
| **Other indications** | | | | | | | | | |
| **Bone related disorders** | Cathepsin K inhibitor | Unpartnered | | | | | | | |
| **Neuropathic pain** | Cathepsin S inhibitor | Unpartnered | | | | | | | |



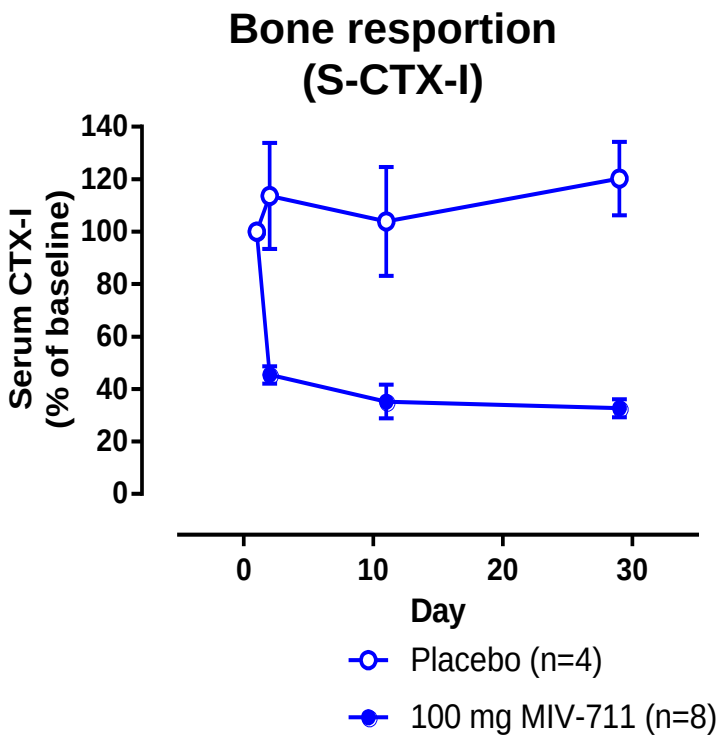
# MIV-711 Phase I: potent effects on cartilage and bone turnover of once daily MIV-711 over 7 days

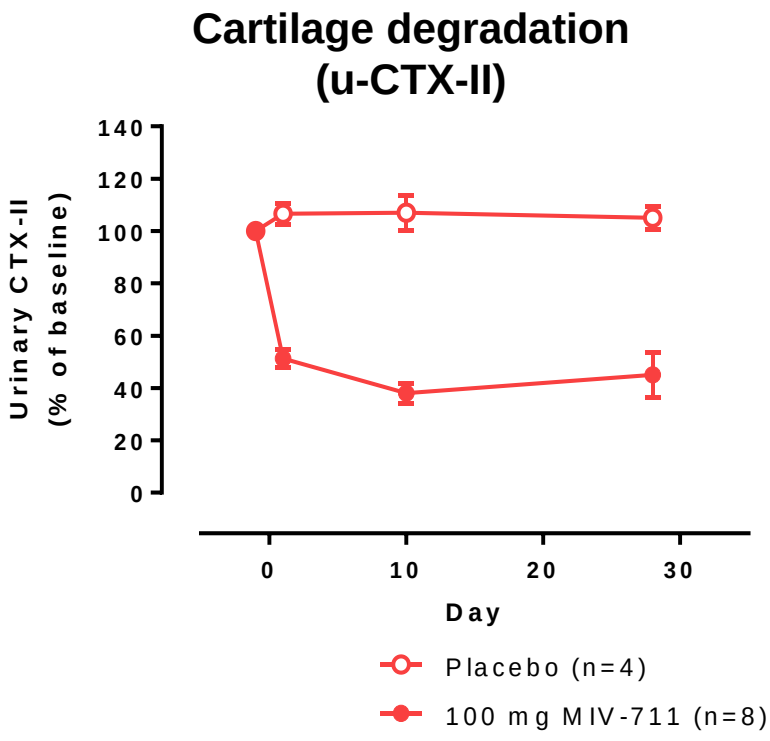



Mean ± SEM
n = 6-7

***MIV-711 showed dose-dependent reduction in markers of both cartilage degradation and bone resorption***

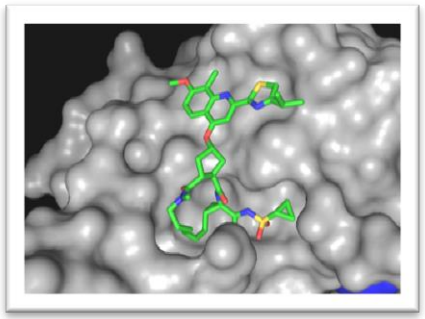
# MIV-711 Phase I: reduced cartilage and bone turnover in post-menopausal women




***Clinical data support further development of MIV-711 for osteoarthritis and other skeletal disorders***

# Simeprevir: a next generation HCV protease inhibitor



- Approved in Japan and Canada with a broad label
- Under review in US and EU
  - Unanimous recommendation for approval at Oct. 24 FDA AdCom
- Activities underway to expand commercial opportunity of triple regimen
- An important cornerstone in coming IFN  free treatment options
  - Currently studied in a large number of IFN and ribavirin free combinations

***Simeprevir – High cure rates in broad patient populations and a favorable safety profile***

# Additional phase III studies of simeprevir triple therapy to enhance commercial profile

## 12 week treatment duration

- **12 weeks full stop triple combination study,** open-label, single-arm study in treatment naïve GT1 patients
  - Recruitment ongoing

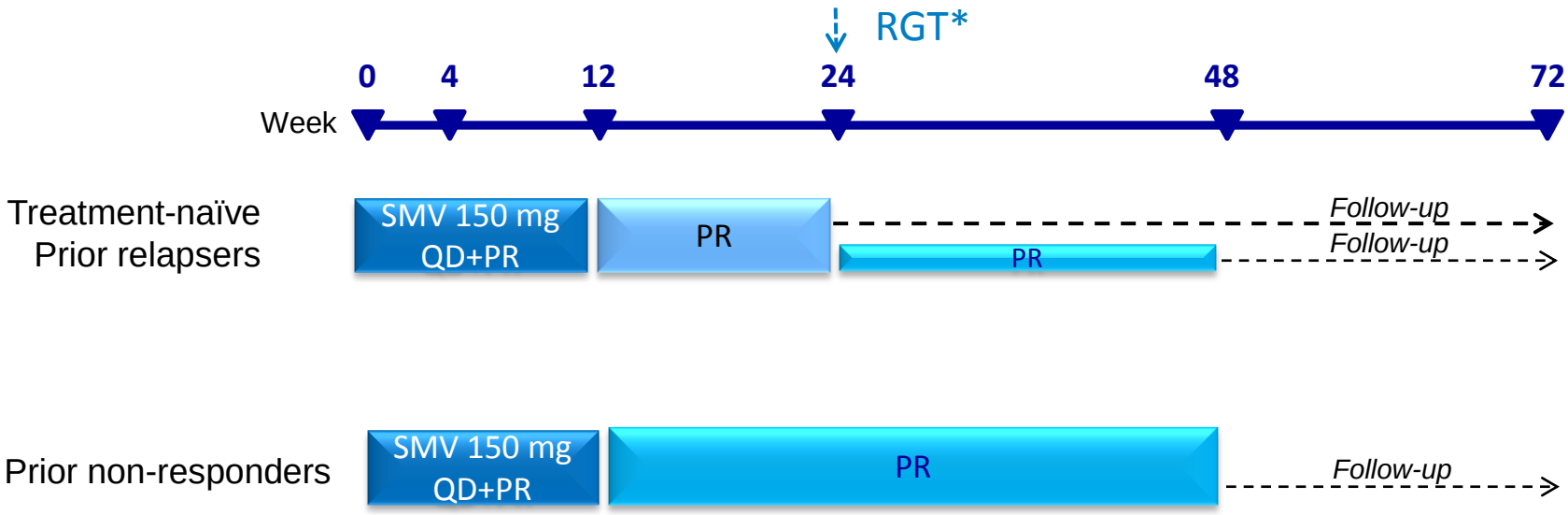
## Regional expansion - China

- A pivotal study of Efficacy, Safety & Tolerability and Pharmacokinetics in treatment naive GT1 HCV patients *(fully enrolled; n=444)*

## Patient population expansion

- **Genotype 4 HCV infected patients**
  - Interim results presented at EACS, Brussels, Oct 2013
- **HIV/HCV co-infected patients**
  - Primary SVR12 results at EACS, Brussels, Oct 2013

# RESTORE: HCV genotype 4 infected patients
# Study design




At time of interim analysis SVR could only be assessed in patients who met RGT and reached study visit W28 (SVR4) and W36 (SVR12)

***HCV genotype 4 accounts for approximately 20% of all cases of chronic HCV worldwide[1]***

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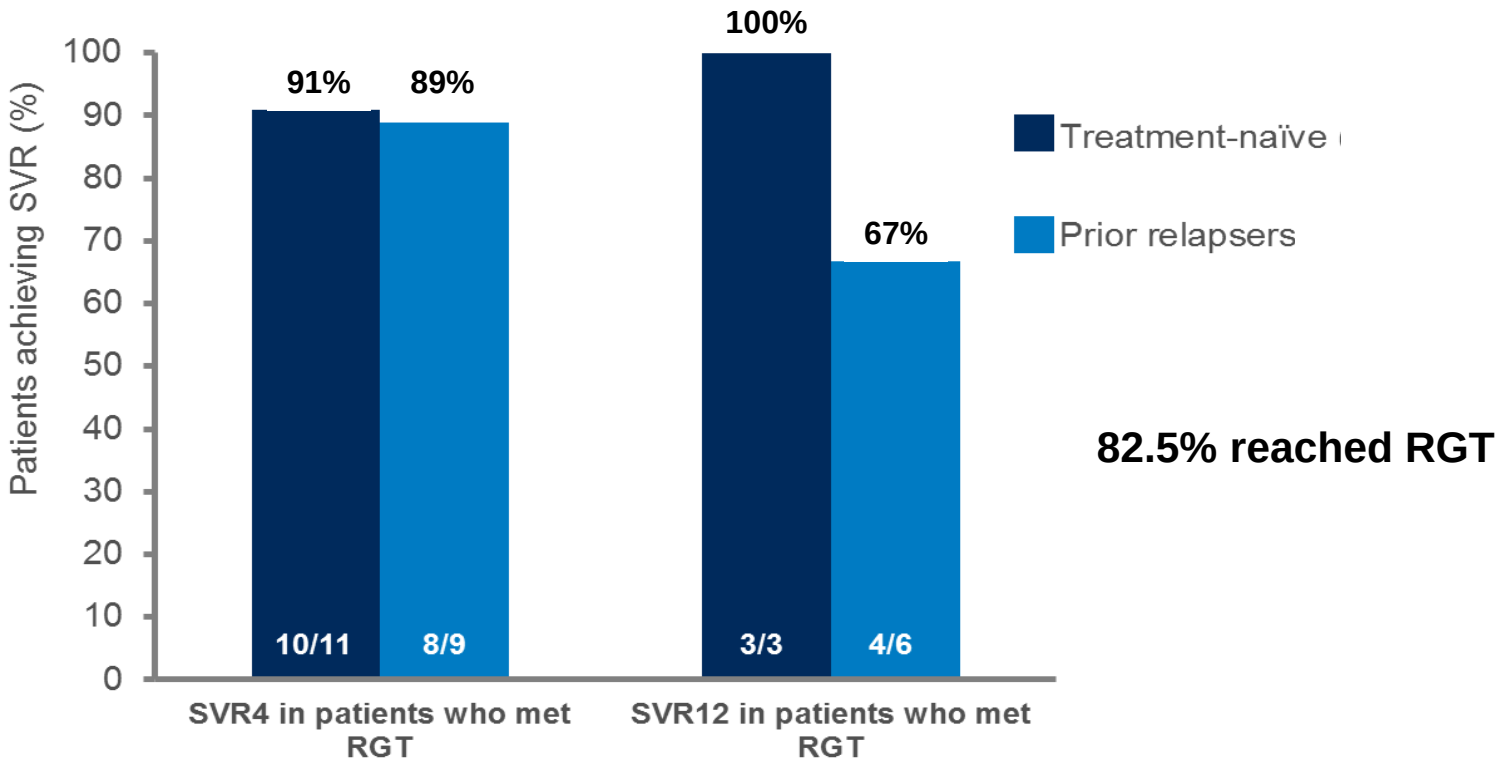
1. Khattab MA, et al. J Hepatol 2011;54:1250-62

# HCV genotype 4 infected patients
## Results & conclusions from interim analysis




**82.5% reached RGT**

***The interim analysis suggests good efficacy and safety of simeprevir also in patients with HCV genotype 4 infection***

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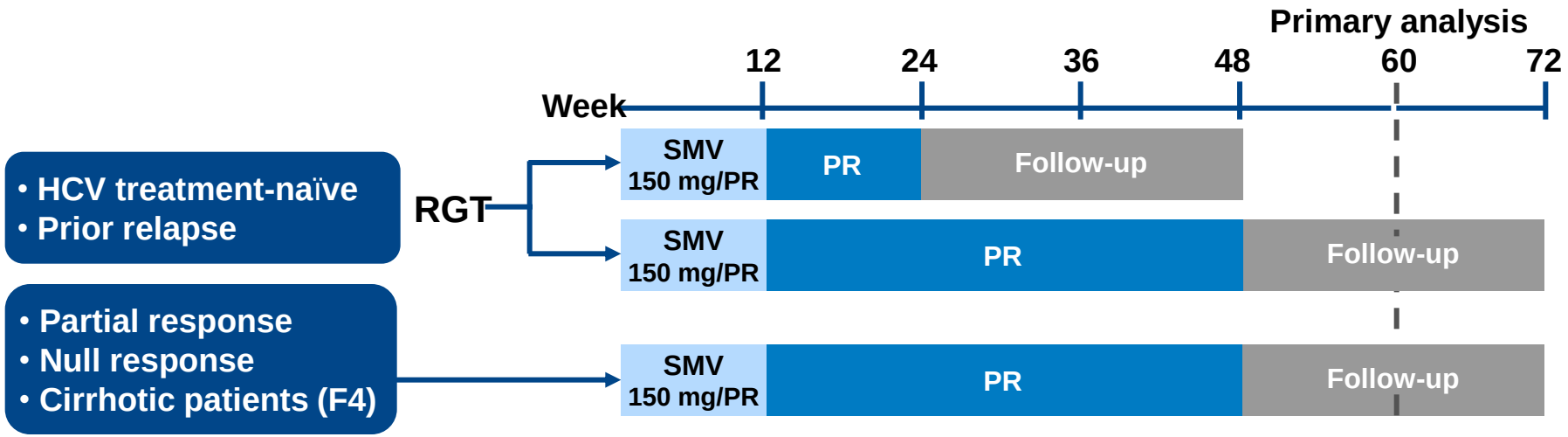
# HCV/HIV co-infected patients
## Study design




- N=106
- Primary endpoints: SVR12, safety and tolerability

***In the US 25 % of HIV patients are coinfected with HCV***

SMV, simeprevir
PR, peginterferon-α2a + ribavirin;
RGT, response-guided treatment;
SVR12, sustained virologic response 12 weeks' after end of treatment

# HCV/HIV co-infected patients
## Results & conclusions

- SMV QD + PR for 12 weeks led to high rates of SVR12 regardless of prior HCV treatment response
  - **Treatment-naïve** **79%**
  - **Prior relapsers** **87%**
  - **Prior partial responders** **70%**
  - **Prior null responders** **57%**
- SVR12 rates were high, regardless of baseline METAVIR fibrosis score
  - **64% SVR12 in F3-4 patients**
- **87% SVR12 with 24 weeks** therapy (89% of eligible patients)
- Well tolerated with a safety profile similar to that observed in mono-infected patients

***Simeprevir was safe and efficacious in a broad population of HCV-HIV co-infected patients***

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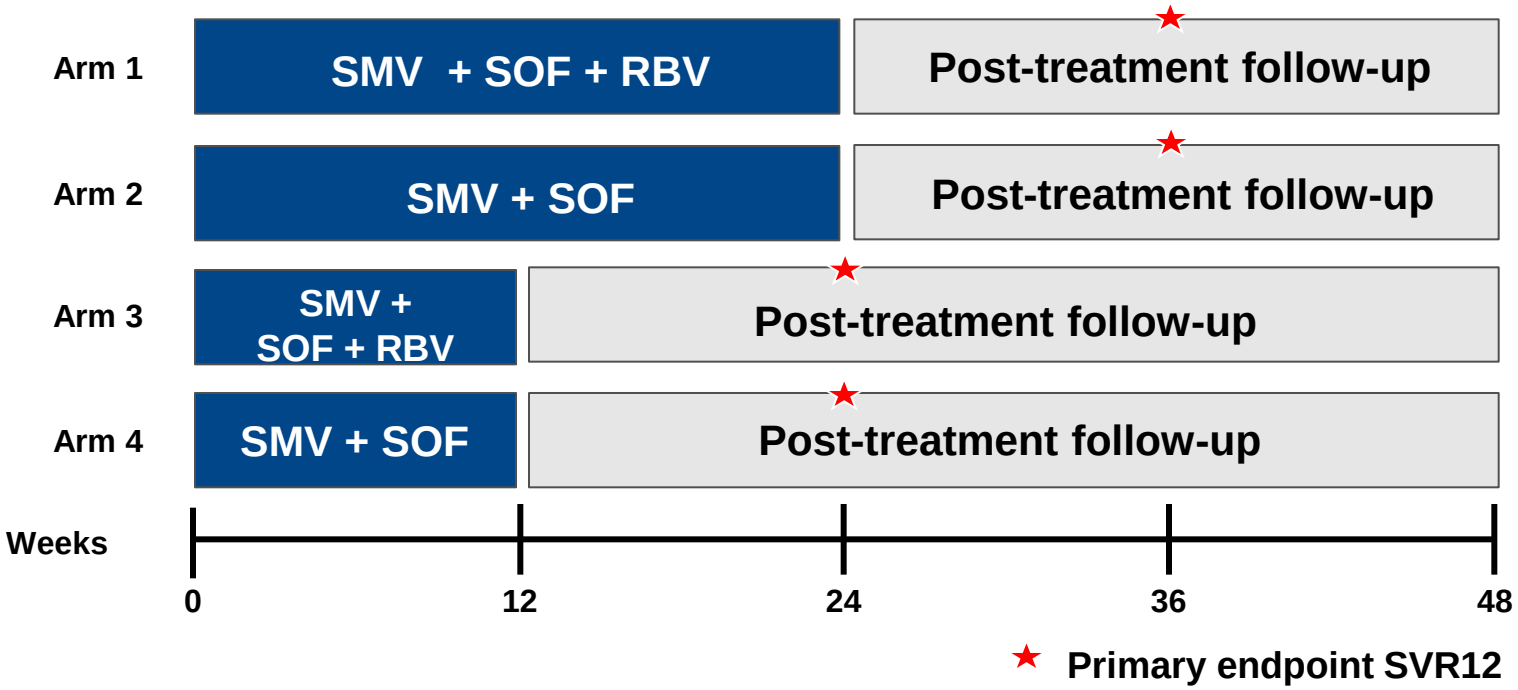
# Simeprevir

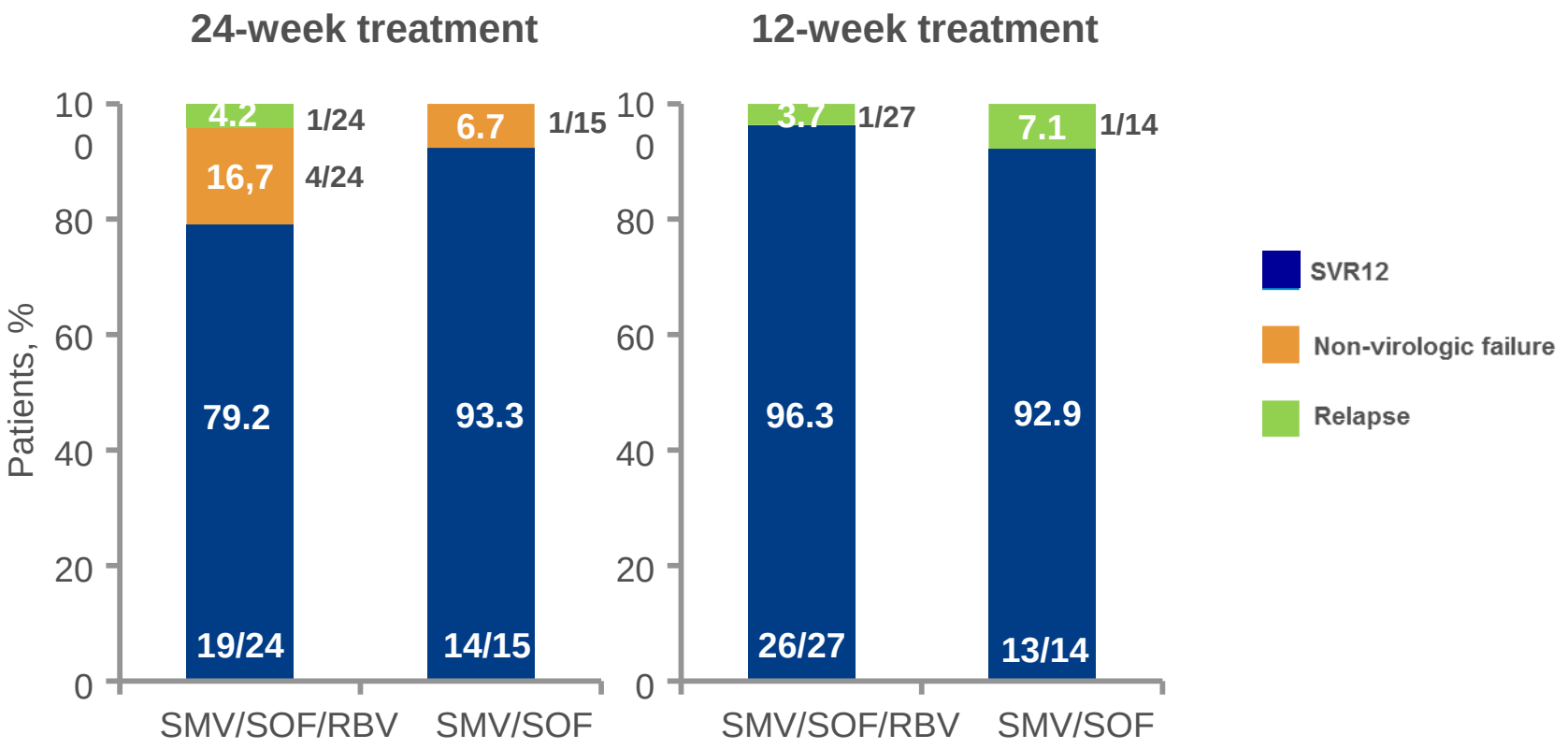
## - All oral interferon-free combination update

# COSMOS study
# – interim results presented at AASLD Nov 2013




- Cohort 1: n=80, nulls, F0-F2 - *SVR12 data available*
- Cohort 2: n=87, naives and nulls, F3-F4 - *SVR4 data available*
- SMV 150 mg QD + SOF 400 mg QD +/- RBV

# Cohort 1: Prior null responders (METAVIR F0-F2) SVR12
## ITT population




***High efficacy in prior null responder HCV patients also without ribavirin***

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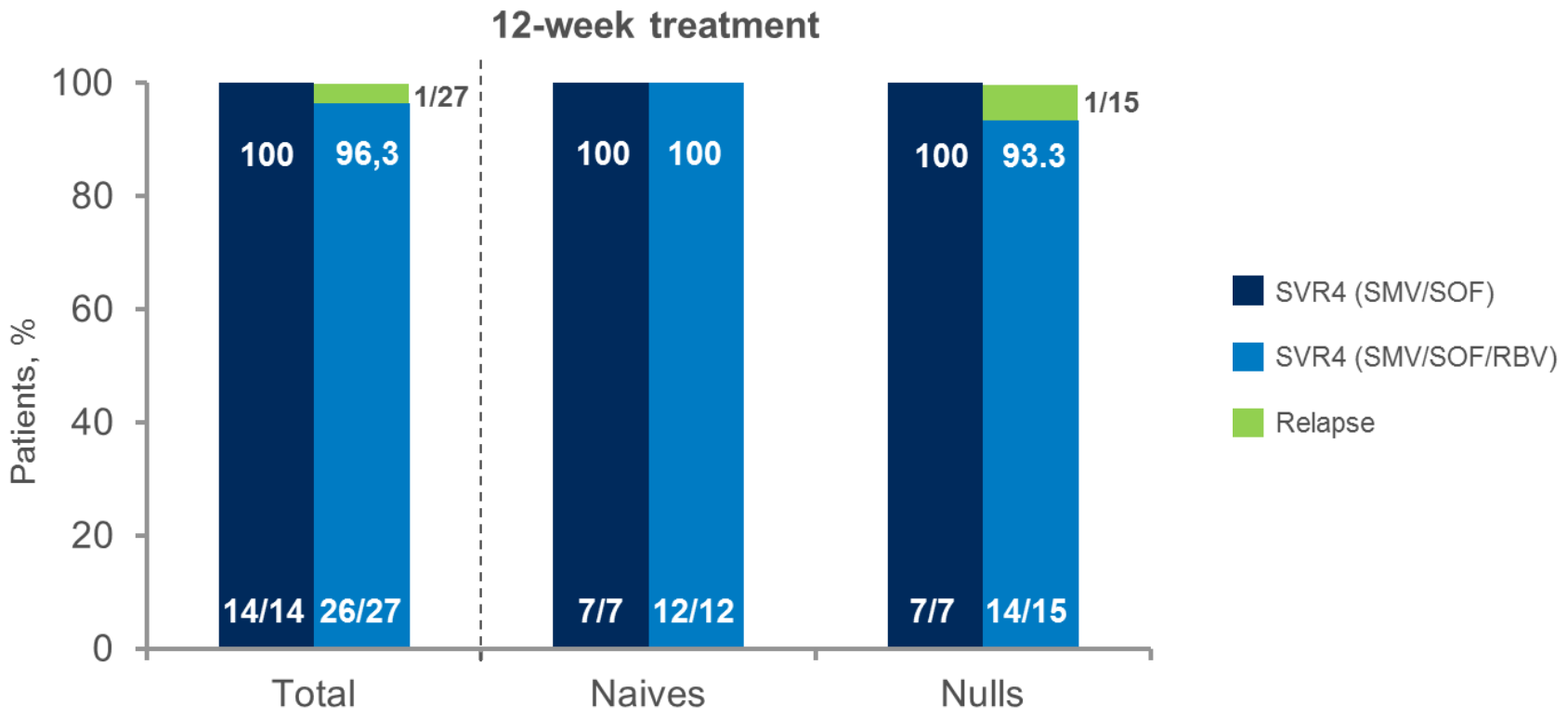
ITT, intent-to-treat
SMV: simeprevir; SOF: sofosbuvir; RBV: ribavirin
Sustained Virological Response 12 weeks (SVR12) after end of treatment.

# Cohort 2: Naïve and prior null responders (METAVIR F3-F4) SVR4* interim analysis, ITT population




**SVR4 data was only available for 12-week arms at time of interim analysis cut-off*

***High efficacy in hardest to cure HCV patients also without ribavirin***

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ITT, intent-to-treat
SMV: simeprevir; SOF: sofosbuvir; RBV: ribavirin
Sustained Virological Response 4 weeks (SVR4) after end of treatment.

# Data driven approach to exploring different interferon free simeprevir combinations (with or w/o ribavirin)

| Simeprevir given in combination with a: | Investigational compound | Study information |
|---|---|---|
| **Nucleotide** | Sofosbuvir | **COSMOS**: Cohort A: nulls ;<br>Cohort B: nulls + naives (F3&4) |
| | VX-135 | DDI finished, Next step to start Phase II |
| **NS5A inhibitor** | Daclatasvir | Naives and nulls, F0-F4 |
| | Samatasvir | HELIX-1: Phase II on-going (Gt1b and 4) |
| **NS5A inhibitor + NNI** | TMC647055 + Samatasvir | HELIX-2 to start before YE-13 |
| | TMC647055 + **JNJ-56914845** | Phase II, in planning phase |
| **+ NNI** | TMC647055 | Naives/relapser and nulls |

NNI: non-nucleoside poymerase inhibitor

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# Q / A

www.medivir.com

**Ticker: MVIR**
**Exchange: OMX / NASDAQ**

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