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

Nordea Lunch 17 May

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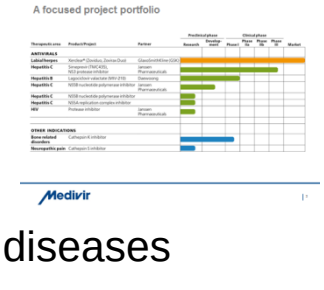
2013 - Setting the framework for becoming
The Emerging European Pharma Company



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

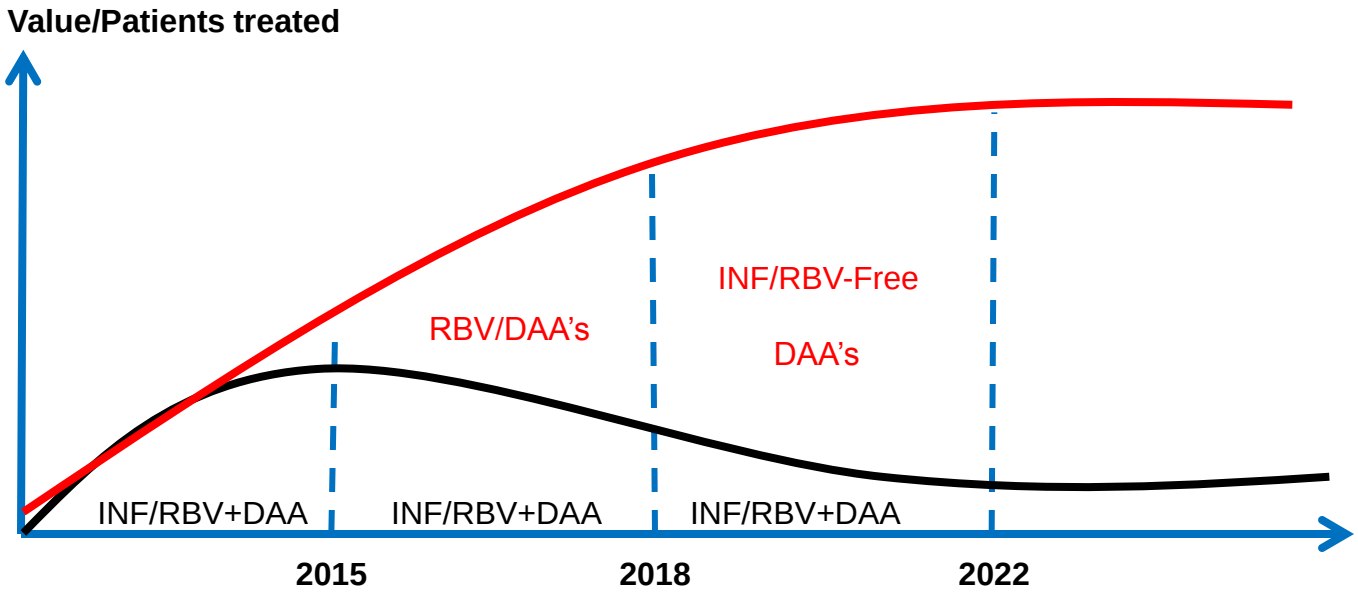
External perspective

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

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

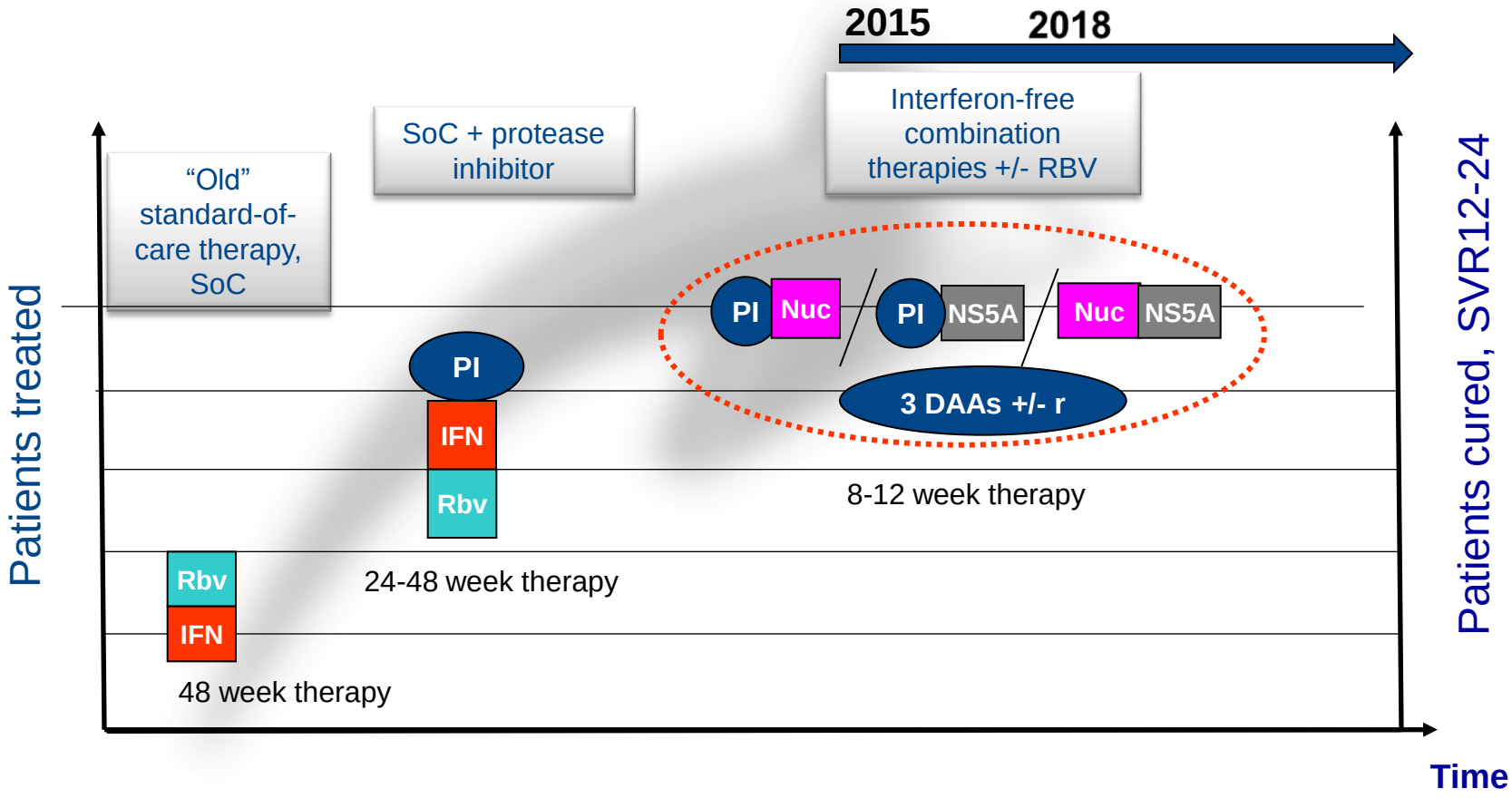
Regional, patient and pricing differences will drive the segments in the future



Vi skall belysa och försöka besvara följande frågor idag

1. Finns det behov av flera interferonfria produkter utöver Gilead, Abbott, BI och BMS?
2. Kommer simeprevir vara med i det kommande interferonfria lanadskapet?
3. Vad är värdet av simeprevir idag?
4. Vilka marknadandelar kommer simeprevir kunna ta?
5. Kommer Janssen att kommunicera mera i framtiden?

Evolution of HCV therapy in G1 infection



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

IFN-free combos in GT1 patients

- The consensus view today

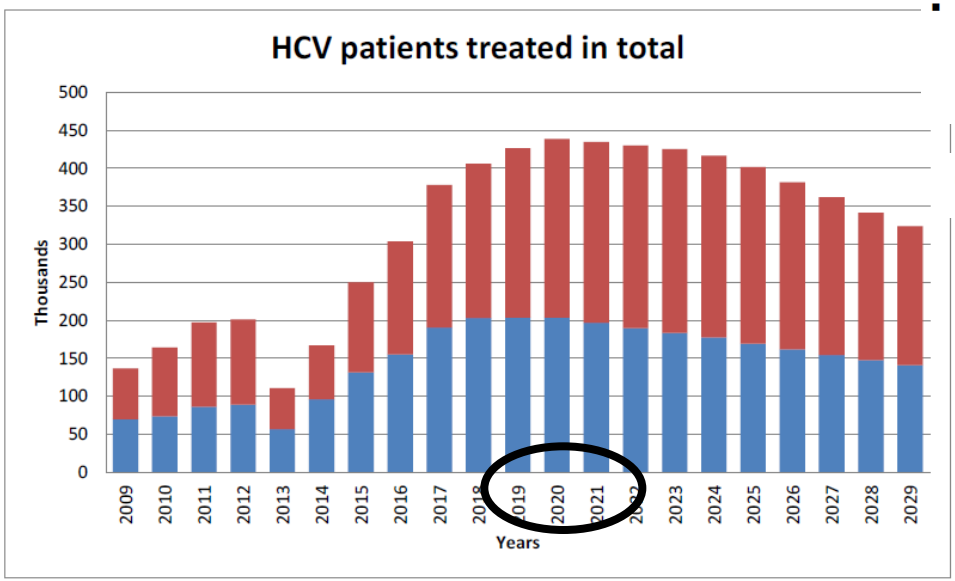
  - Interferon-free treatments work, full stop!
    - Viral cure has been reported in over 1300 patients receiving IFN-free treatments (multiple GTs).
  - Nucleotides are expected to be the cornerstone of future IFN-free combos
    - Evidence now that 2 DAAs could be sufficient in nucleotide containing combos, i.e. IFN and RBV free combos
    - Only two nucleotides currently in clinical development;
      - ✓ sofosbuvir (Gilead) – progressed by Gilead for in-house combos
      - ✓ VX-135 (Vertex) - non-exclusive co-development with JNJ, GSK and BMS for clinical phase 2 studies
        - Mericitabine (Roche) 1st generation, nucleoside
  - IFN-free combos lacking a nucleotide backbone will require 3 DAAs or 2 DAAs + RBV to cure GT1a and other difficult-to-cure patient groups
  - RBV-free combos will rapidly become the next differentiating factor among IFN-free treatments
    - Simeprevir and sofosbuvir for 12 weeks in prior null responders, majority GT1a patients, achieved a SVR8 cure rate of 97% (COSMOS)
  - Treatment duration of 8-12 weeks will be sufficient for large patient groups

IFN-free combinations will dominate the GT1 market, starting from 2015

Patient estimates 2013

We project ~400K WW treatments in 2018, but this may be conservative

- Main reasons currently HCV is untreated: patient compliance/intolerance, contraindications that don't allow for interferon use 3) active IVDU or alcoholism
- We assume about 240K at peak treated ROW including EU & Japan



Source: Deutsche Bank

- #3: SOF pricing (GILD has suggested 50-80K)
  - we estimate gross $65K US & $45K ex-US.
  - Our net pricing is 48K in US & 34K ex-US
- SOF (65K) + Riba (8K) is roughly $73K in GT 2/3

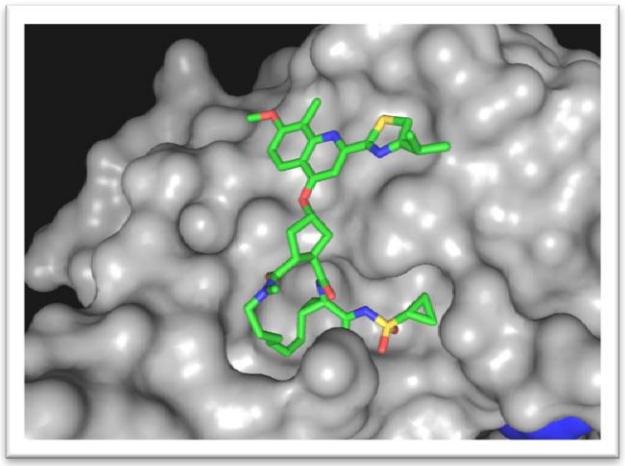
Summary of current view

The HCV market is substantial and will remain so for the near and medium term future, i.e. up to 2030

The market peak is now estimated to occur around 2020-22

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

Simeprevir



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

- Antiviral activity against HCV GT 1, 2, 4, 5, and 6
- Safe and well tolerated in clinical trials, with high SVR rates. To date, more than 2000 patients have been treated with simeprevir in clinical trials
- Three large pivotal phase III studies of SMV 150 mg QD plus PegIFN/RBV completed (QUEST-1 and QUEST-2 in treatment-naïve and PROMISE in prior relapsers)
- Simeprevir is currently being studied in a number of IFN-free regimens, including the COSMOS study

Simeprevir - clinical development programs 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 treatment experienced patients
- **12 weeks full stop** open-label, single-arm study in treatment naïve patients

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

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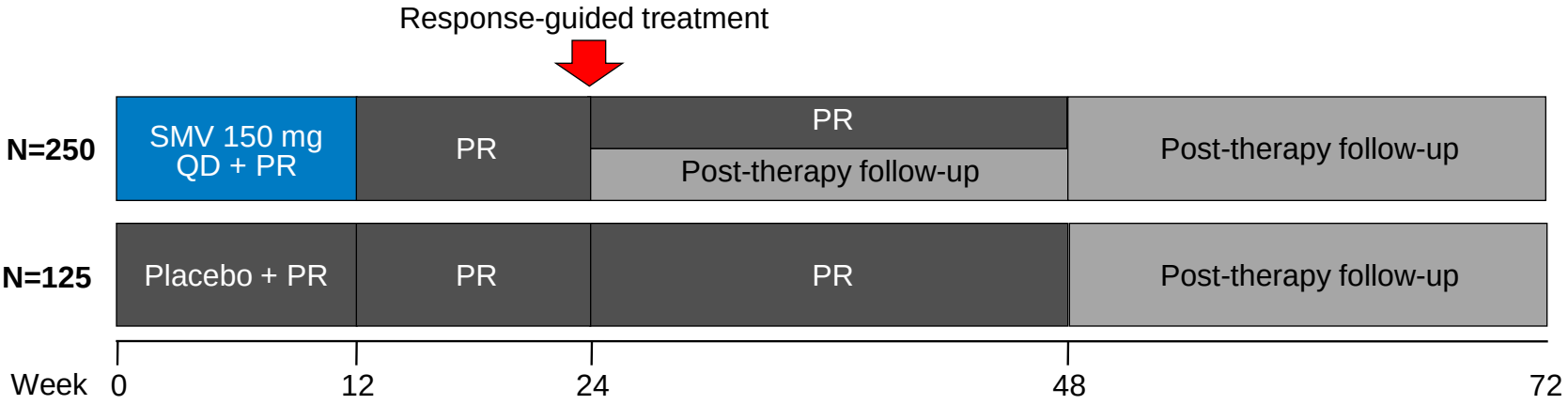
For additional information, please see www.clinicaltrials.gov

Simeprevir - Phase III Study designs in HCV GT1 infected patients (QUEST-1, QUEST-2 and PROMISE)

- Randomized, double-blind, placebo controlled design
- Patients were stratified by HCV subtype and IL28B genotype



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%)

Top line data Dec-12

Reported at EASL 2013

Summary: SVR12 data from QUEST-1 and QUEST-2

Patients with SVR12 %	QUEST-1		QUEST-2	
	SMV + PR	Placebo + PR	SMV + PR	Placebo + PR
All patients	**80**	50	**81**	50
SVR12 with 24 wks treatment (% pat meeting RGT criteria)	**91 (85)**	N/A	**86 (91)**	N/A
CC / CT / TT	**94 / 76 / 65**	78 / 42 / 24	**96 / 80 / 58**	81 / 41 / 19
GT1a & other / GT1b	**71 / 90**	49 / 52	**80 / 82**	46 / 53
F0-F2	**83**	60	**85**	51
F3-F4	**70**	28	**66**	47

Robust data from two large placebo-controlled studies including a large proportion of patients with advanced liver fibrosis (F3-F4)

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Most common adverse events in QUEST-1 and QUEST-2 during the first 12 weeks of treatment

Patients, %	QUEST-1		QUEST-2	
	SMV/PR (N=257)	PBO/PR (N=134)	SMV/PR (N=257)	PBO/PR (N=134)
Most common AEs (≥25% in SMV arm)				
Fatigue	40	38	35	39
Pruritus	21	11	19	15
Headache	31	37	37	34
Pyrexia			30	36
Influenza-like illness			26	26
AEs of interest				
Rash (any type)	27	25	24	11
Anemia	16	11	14	16

Overall incidence of adverse events was similar to placebo control

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Simeprevir - clinical development programs in HCV G1 & 4 infected patients

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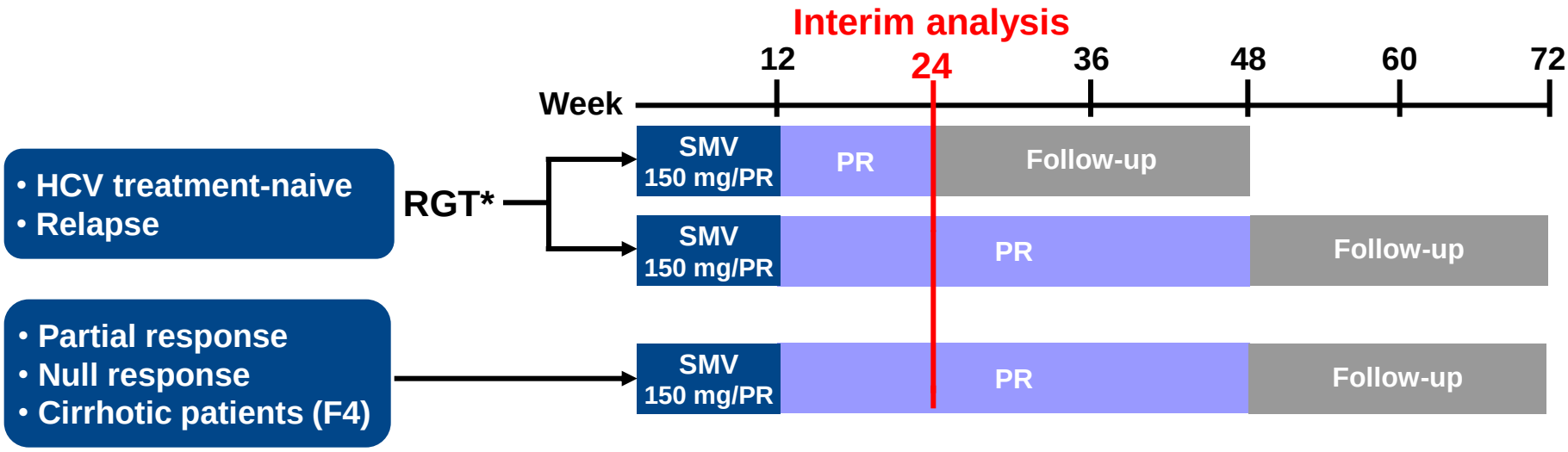
C212 HCV-HIV Co-infected

Study design



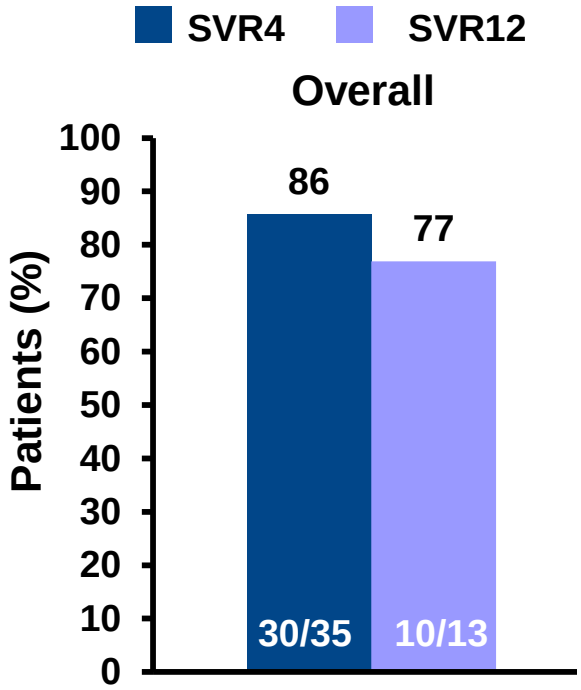
Interim analysis:

- **All patients included in the analysis had completed 24 weeks of treatment or had discontinued prior to that point**

- **No. of patients:** **Week 24: N=100**
  Week 28: N=71
  Week 36: N=27

C212: HCV-HIV Co-infected

Preliminary SVR4 and SVR12 rates in patients treated with SMV/PR



- 82% GT1a,
- 21% (METAVIR F3/4)
- 93 out of 106 patients on ARV therapy
- 88% met RGT criteria and stopped all treatment at W24
- Simeprevir was safe and well tolerated
- No HIV breakthroughs

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

Simeprevir - Phase III summary and regulatory status

79-81% overall SVR12 rates[1]:

- Naive and relapser patients in three large global studies (QUEST-1 & -2, and PROMISE)
- *SVR12 rates confirmed in Japan program*[2]

86-91% SVR12 rates with 24 weeks treatment in QUEST-1 and -2

- 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 for approval of simeprevir in:

- **Japan** for hepatitis C genotype 1, treatment naïve, prior non-responders or relapsed
- **US** for hepatitis C genotype 1
- **EU** for hepatitis C genotype 1 or 4,

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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

IFN and RBV containing triple combinations in pipeline

Compounds	Company	Patient groups	Filing dates	comments
SMV + INF/RBV	JNJ	GT1,4, naïve, relapsers and non-resp. HIV/HCV co-infected Non-cirrhotic + cirrhotic	Feb-April, 2013	Three phase 3 trials in naïves and relapsers completed
SOF + INF/RBV	GLD	GT1,4,5,6; naive Non-cirrhotic & cirrhotic	April-May, 2013	No study in JPN. One single arm, open label study
Faldaprevir + INF/RBV	BI	GT1, naive + experienced Non-cirrhotic + cirrhotic	Q3, 2013	
DCV + INF/RBV	BMS	GT 1 & 4, naive	Q3, 2014	

- **SMV triple combo;**
  - **is comparable to SOF triple with regards to both efficacy and safety**
  - **will have considerable broader indications (anticipated upon approval)**
  - **has substantially broader territory (filed in JPN, ahead in China)**

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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 ongoing Phase II to start H2 2013
Simeprevir	**+**	**IDX719** (NS5A inhibitor) **+/- TMC647055/r**	**+/-**	12w	DDI study ongoing Phase II to start H2 2013

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

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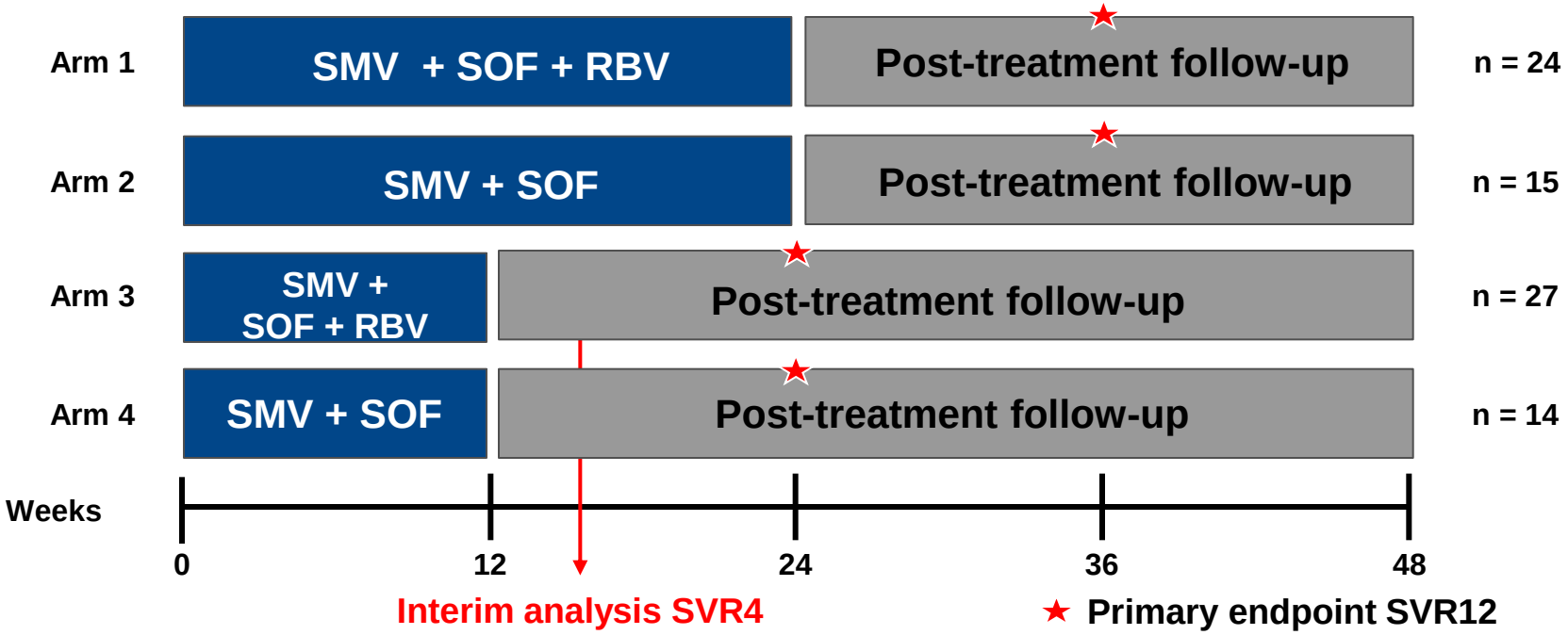
For additional information, please see www.clinicaltrials.gov

COSMOS - Once-daily regimen of 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**
- **Interim analysis of Cohort 1 conducted when all patients in 12 week treatment arms reached SVR4 time point or discontinued early**

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*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)**

Of the patients in the **12 week arms** who achieved SVR8

– **24/24** who reached post-treatment Week 12 had achieved **SVR12**

[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

COSMOS study - Summary & Conclusions

- SMV + SOF for 12 weeks yielded high SVR rates in prior null responders with mild to moderate fibrosis (METAVIR F0-F2)
  - ✓ **SVR8 rate of 96% with RBV and 93% without RBV**

- SMV + SOF was safe and well tolerated
  - ✓ Anemia was seen only in RBV arms
  - ✓ Bilirubin increases only occurred in RBV containing arms

Enrollment of Cohort 2 is complete and include prior null responders and treatment-naïve patients all with advanced fibrosis (METAVIR F3-F4)

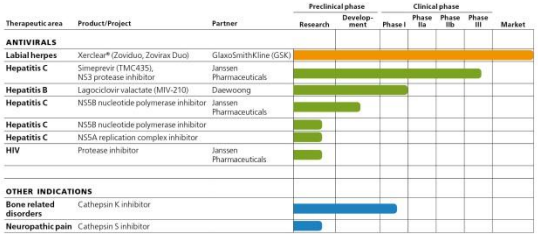
Interferon-free combinations in HCV null responders

- 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 **

Daclatasvir + asunaprevir	BMS	**64- 91%** SVR12 (GT 1b)	24 weeks duration
ABT-450/r + ABT-267 + RBV	Abbott	**89%** SVR12	
ABT-450/r + ABT-267 + ABT-333 + RBV		**93%** SVR12	
Sofosbuvir + ledipasvir + RBV *		**95%** SVR4 (20/21 patients) (**50% F3-4)	
Sofosbuvir + ledipasvir *		**95%** SVR4 (18/19 patients) (**50% F3-4)	
DCV + SOF (24 weeks)*		**100%** SVR12 (EASL)	
Simeprevir + Sofosbuvir +RBV	Medivir/J&J	**97%** SVR8 (26/27 patients)	
Simeprevir + Sofosbuvir		**93%** SVR8 (13/14 patients)	

* (relapsers, partial responders & null responders)

News flow - highlights



- ✓ H1-13 EoT and partial SVR data from Cohort 1 with simeprevir and sofosbuvir phase II study
- ✓ H1-13 Filing of simeprevir in Japan, the US and EU
- ✓ H1-13 FDA granted simeprevir “Priority Review”
- 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 Step two in GSK launch strategy for Xerclear® (ZoviDuo), launch in major European OTC markets
- H2-13 Start of Phase II with simeprevir and IDX719
- H2- 13 Start of Phase II with simeprevir and VX-135
- H2-13 Start of Phase II with simeprevir, TMC647055 and IDX719
- 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

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