Medivir

A research based specialty pharmaceutical company focused on infectious diseases

Q1 2012 Conference Call
10 May
10.00 AM (CET)

Presenting Team

Maris Hartmanis, CEO

Charlotte Edenius, EVP R&D

Bertil Samuelsson, Chief Scientific Advisor

Rein Piir, EVP Corporate Affairs & IR

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Summary of first quarter 2012

Maris Hartmanis, CEO

Strong momentum in our operations

- A phase II interferon free combination trial was initiated with TMC435 and Gilead's GS7977, with and without ribavirin
- Additional phase III trials were initiated with TMC435, including the large and very hard to treat patient group of previous null responders and patients with HCV, genotype 4
- Our internal proprietary, unpartnered, Hepatitis C projects are rapidly moving towards the CD stage
- GSK began the OTC launch of Xerclear® in Europe under the Zoviduo and Zovirax Duo brands
- An application to start phase I trials on Cathepsin K for treatment of skeletal disorders was filed with the European regulatory authority
- Medivir continues to have a solid financial position. Cash and cash equivalents amounted to SEK 485.6 (645.7) m at the end of the period

Post balance sheet events

- The clinical collaboration between our partner Janssen and Bristol-Myers Squibb (BMS) regarding TMC435 and daclatasvir was extended. In addition to interferon and ribavirin-free combination trials on TMC435 in phase II, this collaboration now also covers a phase III program
- The partnership with BMS also involves an evaluation of TMC435 in interferon and ribavirin-free combination trials with BMS's nucleotide inhibitor BMS-986094 (formerly INX-189)
- Medivir's partner Janssen has created a new subsidiary, Janssen Therapeutics EMEA, with a mission to launch TMC435 in Europe, the Middle East and Africa
- Strong final phase II data on TMC435 on hard to treat hepatitis C patients were presented at the EASL meeting

Q1 2012 Group level financial performance
- stable sales development without one-off payments

CONSOLIDATED INCOME STATEMENT	2012	2011	2011
SUMMARY, (SEK m)	Jan-Mar	Jan-Mar	Jan-Dec
Net sales	137.9	121.6	698.6
Cost of goods sold	-97.0	-0.1	-240.6
Gross profit/loss	40.9	121.5	458.0
Selling expenses	-16.7	-2.1	-95.2
Administrative expenses	-15.1	-7.6	-47.2
Research and development costs	-46.7	-57.4	-184.1
Other operating income/expenses	-0.7	-4.3	-19.7
Operating profit/loss	-38.3	50.1	111.9
Net financial income/expense	0.8	2.8	-0.7
Profit/loss after financial items	-37.5	52.9	111.2
Tax	-0.2	0.0	2.5
Net profit/loss	-37.7	52.9	113.8

Q1 2012 financial performance at segment level
- Margins remain at good levels in the first quarter

Net sales split (SEK m)	**2012 Jan-Mar**	**2011 Jan-Mar**	**2011 Jan-Dec**
Outlicensing and partnership agreements			
One-off payments	-	121.3	401.2
Pharmaceutical sales	46.3	0.2	111.2
Parallel imports	91.6	-	185.9
Other services	0.0	0.1	0.3
Total	**137.9**	**121.6**	**698.6**

Pharmaceuticals segment (SEK m)	**2012 Jan-Mar**	**2011 Jan-Mar**	**2011 Jan-Dec**
Net sales	46.3	121.6	512.7
EBITDA	-34.1	51.9	137.6
EBITDA %	-73.7%	42.7%	26.8%

Parallel Import segment (SEK m)	**2012 Jan-Mar**	**2011 Jan-Mar**	**2011 Jan-Dec**
Net sales	91.6	-	185.9
EBITDA	4.2	-	-2.3
EBITDA %	4.6%	-	-1.2%

Strong platform for a leading position in hepatitis C

TMC-435
Phase III program in genotype 1 triple combination
- Naives
- Experienced
- Cirrhotics

TMC-435
All oral IFN free combo with NS5B nucleotides
- GS-7977 (Gilead)
- BMS-986094 (INX-189)

TMC-435
All oral IFN free combo with NS5A inhibitor
- Daclatasavir (BMS)

NS5B nucleotide
Partnered with
Johnson&Johnson tibotec

Internal NS5B nucleotide
Unpartnered

Internal NS5A project
Unpartnered

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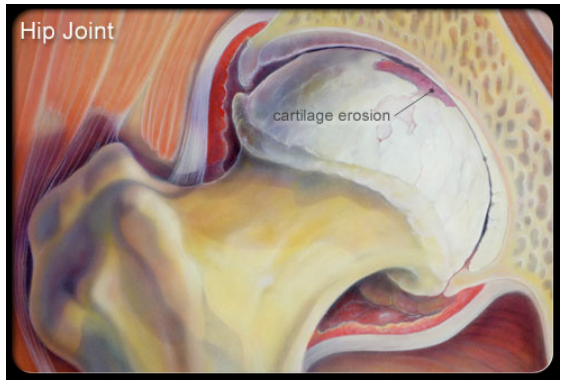
Strongly committed to innovation driven R&D

Charlotte Edenius, EVP R&D

Building on a longstanding protease inhibitor development experience

MIV-711 Cathepsin K inhibitor towards clinical trials

- Osteoarthritis, osteoporosis and metastatic bone disease
- Candidate drug selected, MIV-711
- Anticipated low QD dosage in man
- Regulatory safety documentation finalized and clinical trial application submitted



Cathepsin K inhibitor program to start Phase I in Q2 2012

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

Protease inhibitor – TMC-435

- Investigational, one pill, once daily, oral HCV protease inhibitor
- Potent antiviral activity in patients infected with HCV genotype 1
- Favorable safety profile
- **Currently in Phase III clinical development**

Nucleotide polymerase inhibitor

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

Johnson & Johnson tibotec

Nucleotide polymerase inhibitor

- **Properties similar to the most advanced clinical nucleotides**
- Both purines and pyrimidines with high potencies in the replicon assay
- High triphosphate levels and long triphosphate t1/2 in human hepatocytes
- Aiming for Candidate Drug selection in Q4, 2012

NS5A inhibitor

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

Internal unpartnered projects

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TMC435, 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
PILLAR	**386**	Treatment naive	**81 - 86%**
DRAGON	**92**	Treatment naive (Japan)	**82%**
ASPIRE	**462**	Relapsers	**85%**
		Partial responders	**75%**
		Null responders	**51%**

Robust clinical efficacy data

Efficacious in broad HCV patient populations

- Genotype 1
- Treatment naïve and treatment experienced patients
- Cirrhotic and non-cirrhotic patients

Large safety data base with approximately 1800 patients treated today

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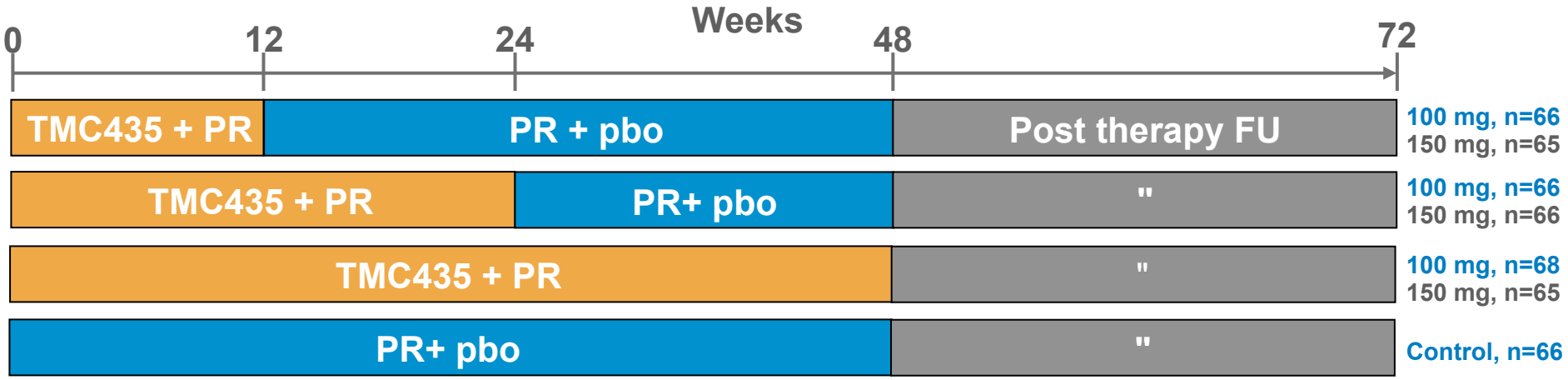
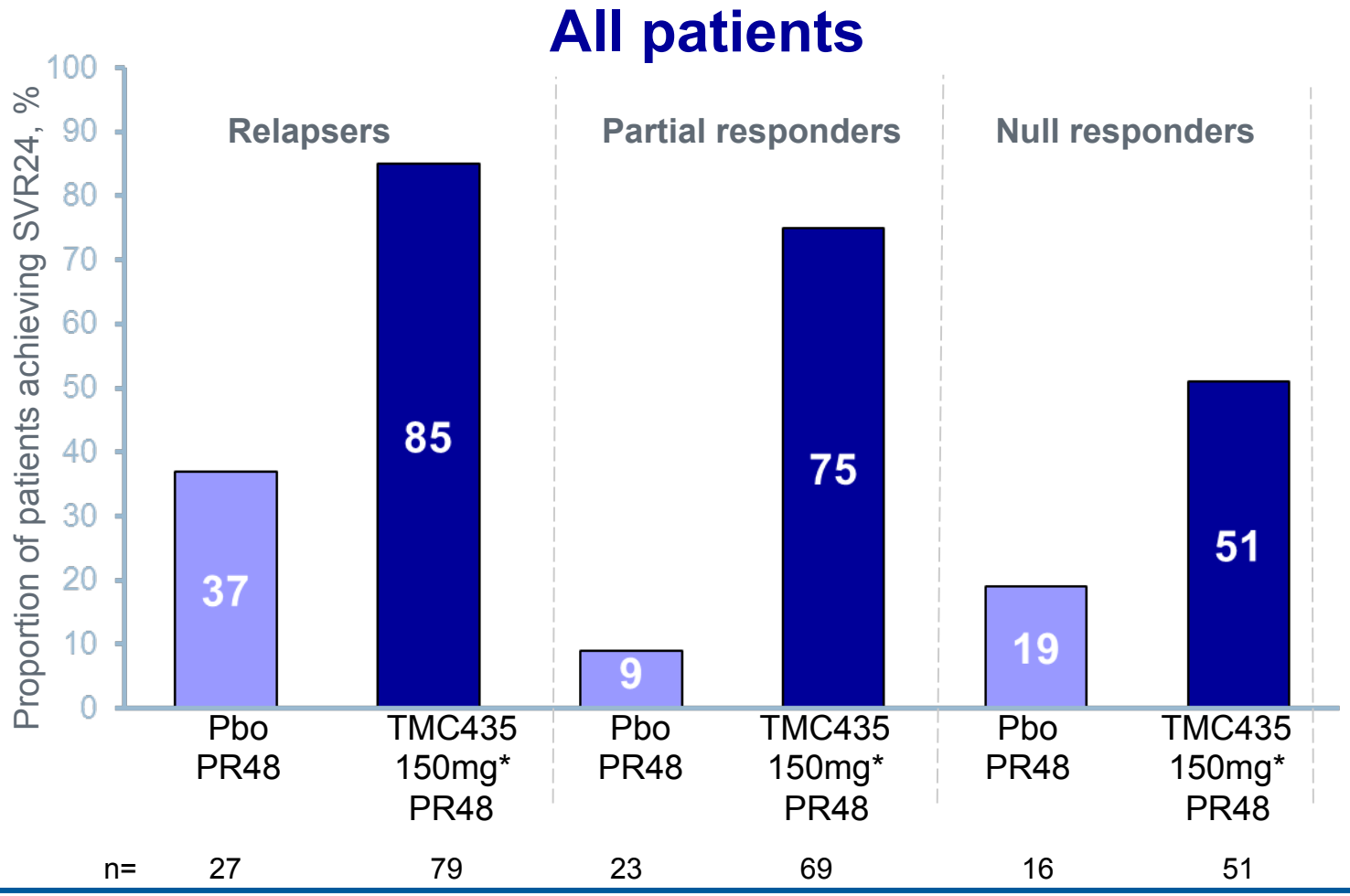
ASPIRE study:

A Phase IIb, randomised, double-blind clinical trial in treatment experienced HCV genotype 1 infected patients (n=462)



- **Primary endpoint:** SVR24

ASPIRE study:
proportion of patients achieving SVR24 by prior response



62 % of patients (287/462) had advanced liver disease (Metavir F2-F4)

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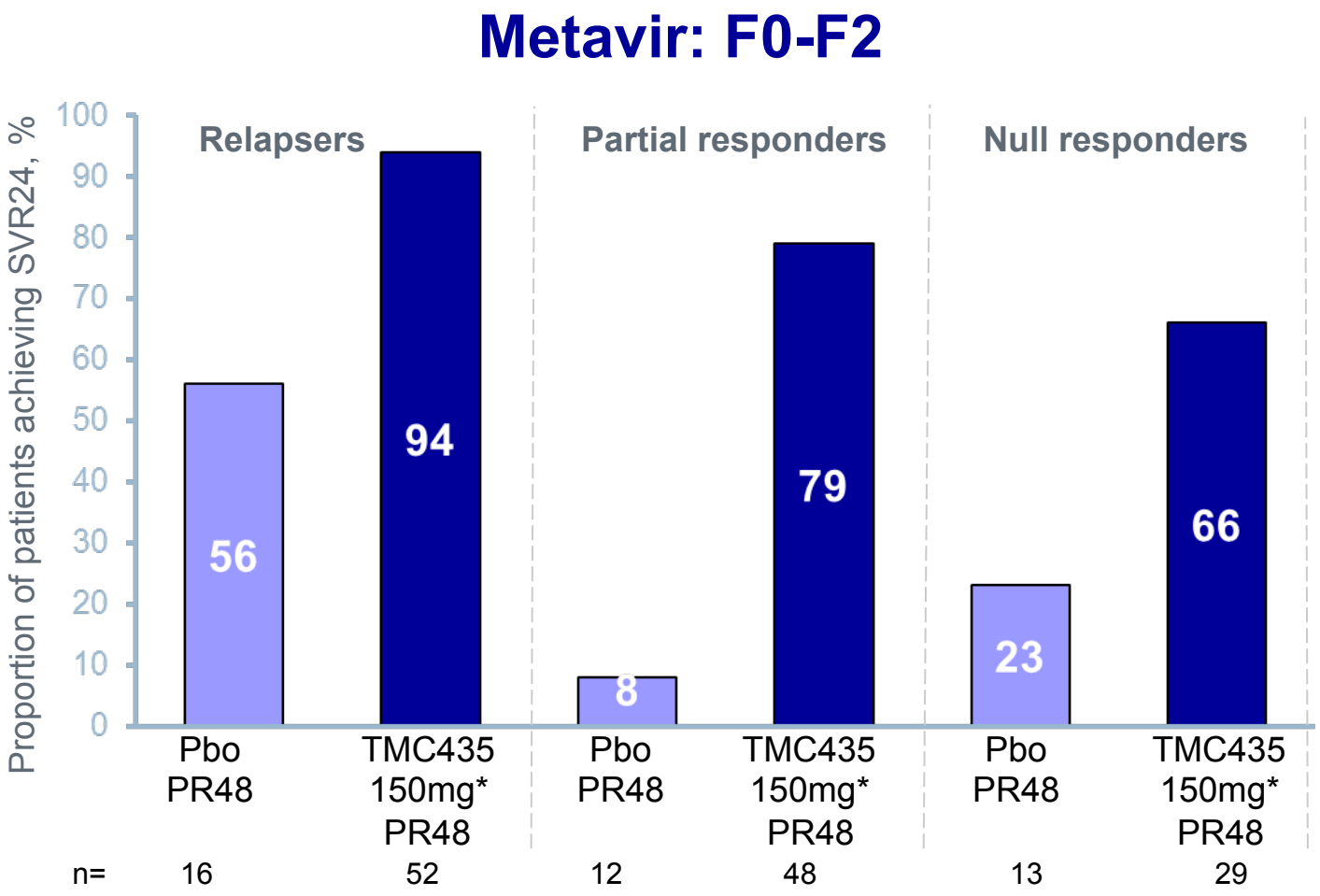
*Dose groups (treatment duration) combined;

ASPIRE study:
proportion of patients achieving SVR24 by prior response



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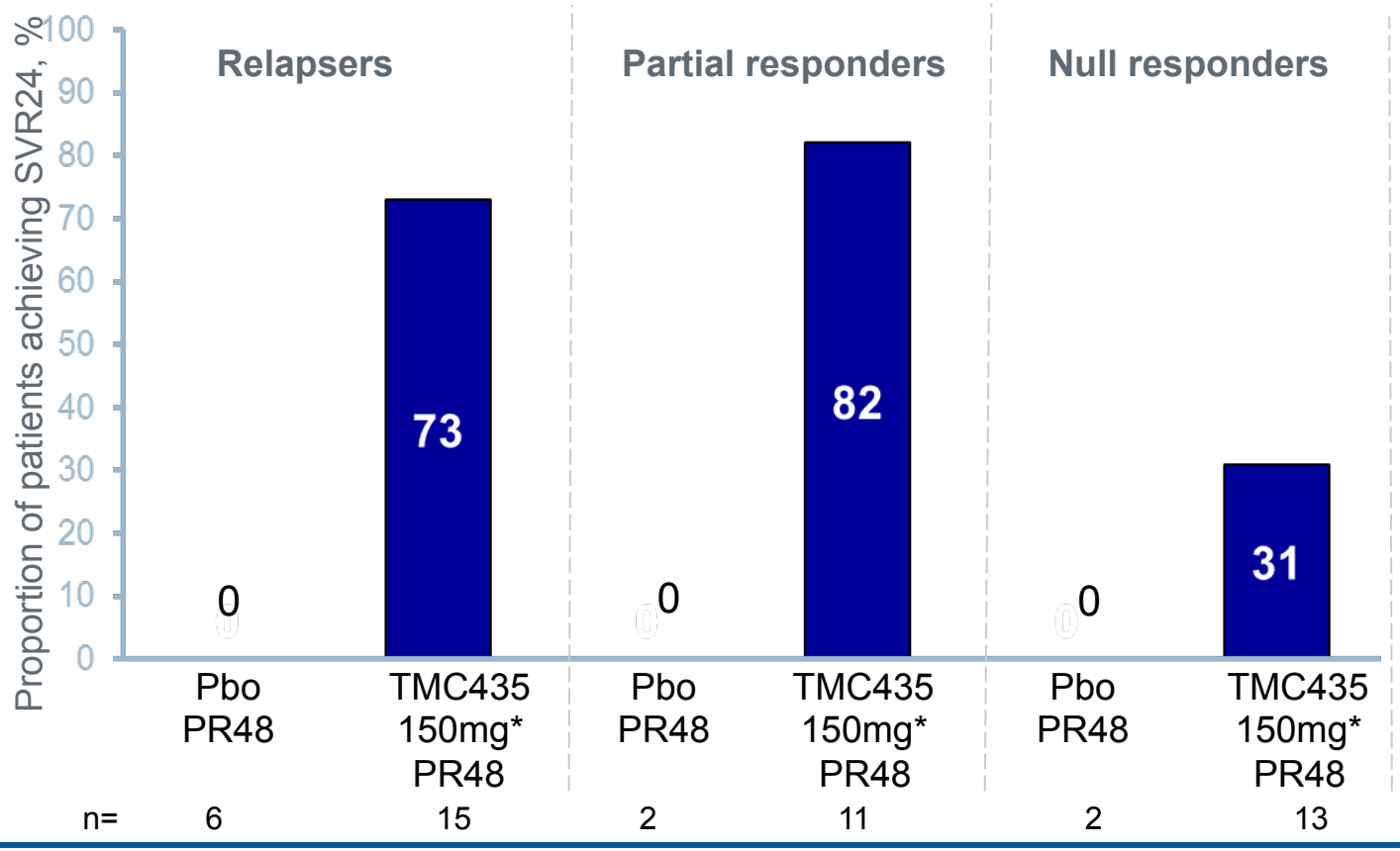
*Dose groups (treatment duration) combined;

ASPIRE study:
proportion of patients achieving SVR24 by prior response

Cirrhotics (F4)



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*Dose groups (treatment duration) combined;

ASPIRE study: adverse events

Note: mean PegIFN/RBV exposure longer for patients in TMC435 groups (41 weeks) compared with placebo group (28 weeks)

	TMC435 150 mg* n=199	Pbo PR48 n=66
AEs leading to TMC435/Pbo discontinuation, %	9	5
Serious adverse events, %	10	6
Grade 3-4 AEs	36	26
AEs most frequently reported inTMC435 groups (>25% of patients), %		
Headache	40	36
Fatigue	41	44
Influenza-like illness	24	20
Pruritus	35	17
Neutropenia	28	17
AEs of interest (regardless of severity or causality), %		
Hepatobiliary disorders	10	5
Rash (any type) †	30	18
Rash (any type), Grade 3	0.5	0
Photosensitivity AEs	6	2

Once-daily TMC435 was well tolerated in this population

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*Dose groups combined; †Combines all types of reported rash; AE, adverse event; Pbo, placebo; PR, peginterferon α-2a + ribavirin

TMC 435 – triple combination summary

- Potent → low dose (150mg), one tablet once daily, 12 weeks duration
- 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
- As demonstrated in three large phase IIb trials highly efficacious in;
  - G1a and G1b
  - treatment naïve and treatment experienced
  - cirrhotic and non-cirrhotic patients,
  - regardless of IP-10 level or *IL28B* genotype
- Long patent life, IP extending to 2026 and 2028

TMC-435: Best-in-class properties in triple combination standard of care treatment (to be filed H1 2013)

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TMC435, broad clinical development program in HCV genotype 1 & 4 infected patients

Phase III

QUEST 1 treatment-naïve patients; n=375

QUEST 2 treatment-naïve patients; n=375

PROMISE (C3007) prior relapsed patients; n=375

Japan phase III program naïve and experienced patients; n=417 (four studies)

C3001 *prior partial and null responders vs telepravir; n=744*

C3011 *naïve and experienced patients; n=100 open label in* ***G4*** *patients*

IFN free combinations

TMC435 and GS-7977, a nucleotide NS5B inhibitor.
12/24 weeks, +/- ribavirin, null responders; +/- cirrhotics, n=180

On-going

TMC435 and daclatasvir
(BMS-790052), an NS5A inhibitor.
12/24 weeks, +/- ribavirin in G1 null responder and interferon intolerant patients

Planned to start H1-2012

TMC435 and BMS-986094 (INX-189)
Clinical evaluation will start with a DDI study

Regulatory filings in first half of 2013 in US, EU and Japan

Hepatitis C – TMC435 treatment evolution
INF-free combinations

Bertil Samuelsson, CSA

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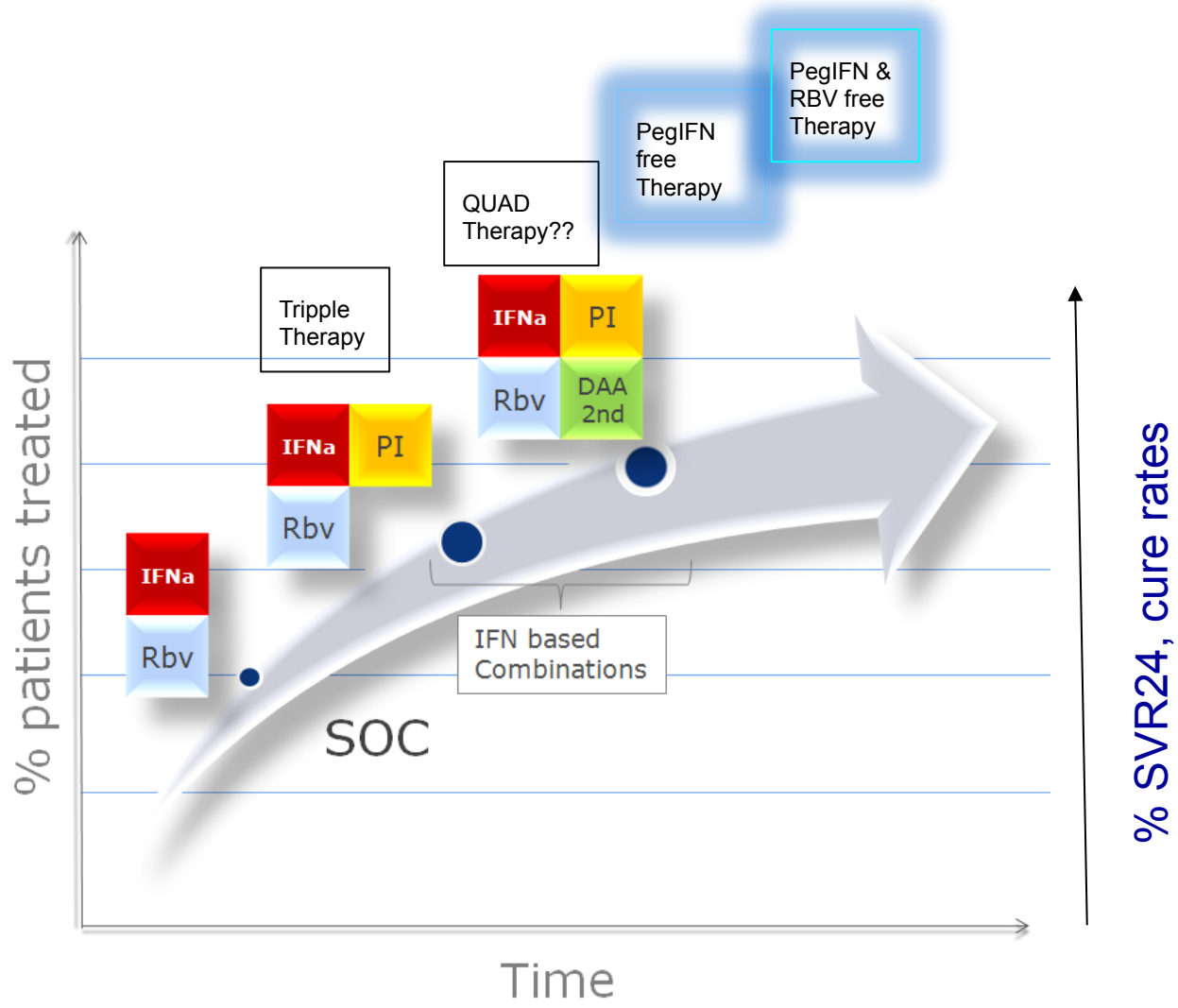
Evolution of HCV therapy in genotype 1 infection



Evolution of HCV therapy

DAA combinations, INF-free or INF /RBV-free, are being evaluated in phase II clinical trials

Lessons learned from 1-3 DAA combinations (+/- ribavirin)

- Proof-Of-Concept achieved
- Cirrhotic patients are either not being evaluated or display poor cure rates. These patients are the most difficult to treat and make up a substantial portion on the currently available patient pool
- SVR36 might be needed to capture real-life relapse rates in an IFN-free setting
- Very small patient groups in experimental trial designs

Ribavirin will not be part of future HCV combinations

- Ribavirin has severe side effects and safety issues
- *Can cause severe adverse events in patients, e.g. hemolytic anemia, teratogenicity, cough, dyspnea, rash, pruritus, insomnia and anorexia. It is a powerful mutagenic agent and is contraindicated in pregnant women and patients with hemoglobinopathies*

Phase III INF-free or INF /RBV-free trials have not yet started in HCV G1 patients

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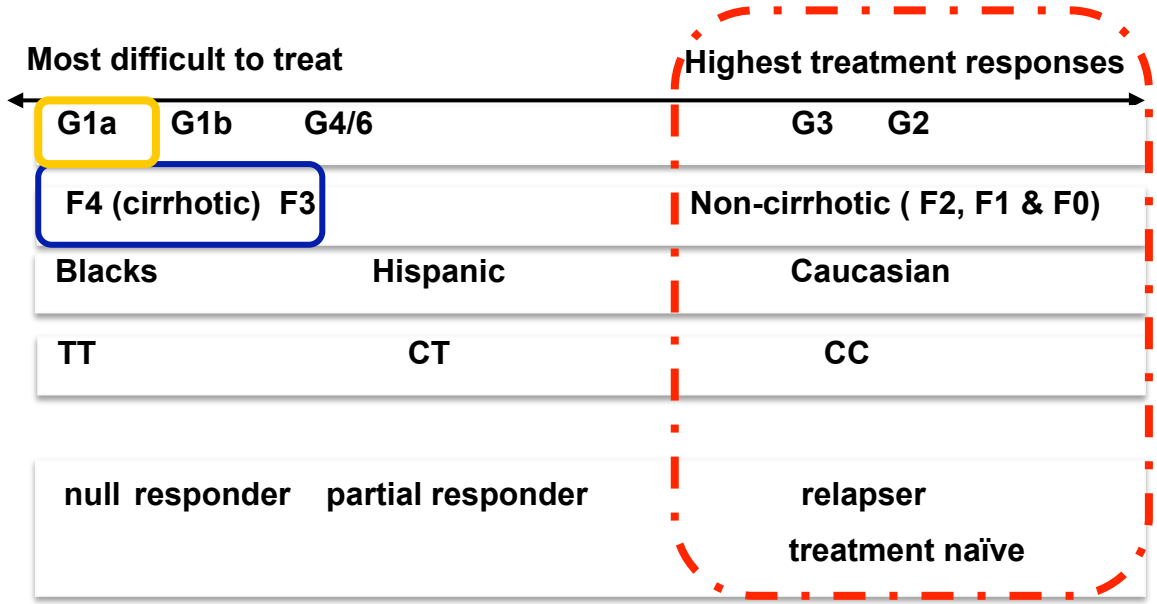
Evolution of HCV therapy

Goals - next generation standard of care treatments

- Combination of only two potent DAAs
  - Potential to meet cost and reimbursement challenges of the future
- Compelling efficacy, strong safety and minimal side effects
- 12 weeks treatment duration
- Fixed dose combination, once daily

Patient responses to treatment – a complex picture

- Genotype/subtype
- Liver disease, F4-F0
- Population
- IL28B at baseline
- Patient characteristics
  - Treatment experienced
  - Treatment naïves



Treatment experienced patients (Metavir score)	% F4	% F3
TMC435 ASPIRE	18	19

TM435 deliver high cure rates also in the most difficult to treat, including cirrhotic patients (as shown in three large phase IIb trials)

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IFN-free combinations - proof-of-concept achieved

One DAA + ribavirin

- **GS-7977 + RBV** — Cirrhotic patients: NO
  - SVR4 11%, 12 weeks in G1 null responders (n=9) ELECTRON trial
  - SVR4 88%, 12 weeks, G1 treatment naïves (n=25), ELECTRON trial

- **GS-7977 + RBV** — Cirrhotic patients: Yes
  - SVR4 53% (10/19), 12 weeks, G1 treatment naïves (including 20% cirrhotic patients) (n=19), QUANTUM trial

One nucleotide DAA + RBV - likely suboptimal combination

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IFN + RBV-free combinations – first proof-of-concept achieved

Two DAAs only

- **BMS daclatasvir + asunaprevir** Cirrhotic patients NO
  - 90% SVR12, 24 weeks, G1b null responders (Japan), patients, n= 21
  - 64% SVR12, 24 weeks, G1b IFN ineligible or intolerant (Japan), patients, n=22
- **BMS daclatasvir + asunaprevir** Cirrhotic patients NO
  - 36% SVR12, 24 weeks, G1 null responders (64% RVR), n=11
- **BMS daclatasvir + GS-7977** Cirrhotic patients NO
  - 100% SVR4 (SVR12 considered as cure rate), 24 weeks , (n=29), G1 treatment naïve patients

IFN-free combinations - proof-of-concept achieved

Two DAAs + ribavirin

- **BI-201335 + BI-207127 + RBV** — Cirrhotic patients: Yes
  - SVR12 68%, 28 weeks, G1 treatment naïve patients (including 10% cirrhotic patients) (SOUND-C2)
    - ✓ Note. Markedly lower SVR rate (39%) in RBV-free arm and in G1a patients and in non-CC IL28B genotype.
- **ABT-450 + ritonavir + ABT-333 + ribavirin** — Cirrhotic patients: NO
  - SVR12 93%(n=14); 95%(n=19), 12 weeks, G1 treatment naïve non-cirrhotic patients
  - SVR12 47%, (n=17), 12 weeks, non-responders (6 null - & 11 partial resp.), non-cirrhotic patients
- **ABT-450 + ritonavir + ABT-072 + ribavirin** — Cirrhotic patients: NO
  - 82% SVR36, 12 weeks, G1 treatment naïve non-cirrhotic patients, IL28B CC genotype

A protease inhibitor present in all these combinations

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TMC435 – interferon free combinations

Two DAAs +/- ribavirin

- **TMC435 and GS-7977** (nucleotide NS5B inhibitor) — Cirrhotic patients: Yes
  - genotype 1 prior null responders, non-cirrhotic and cirrhotic patients, n=180
  - 12 and 24 weeks treatment durations, +/- RBV
  - *On-going*

- **TMC435 and daclatasvir** (NS5A inhibitor) — Cirrhotic patients: Yes
  - genotype 1 null responder and interferon intolerant patients
  - 12 and 24 weeks treatment durations, +/- RBV
  - *Planned to start H1-2012*

- **TMC435 and BMS-986094** (former INX-189; a nucleotide NS5B inhibitor)
  - *Clinical evaluation will start with a DDI study*

TMC435, a best in class PI, developed in IFN-free therapies

TMC435 IFN–free combinations

- TMC435 tripple therapy is today the only therapy that has shown to deliver high cure rates for the most difficult-to-treat cirrhotic patients in both treatment naïve and treatment experienced patients

- In the TMC435 treatment experienced ASPIRE trial the subgroups Null Responders, Partial Responders and Relapser patients achieved viral cure rates (SVR24) of 31%, 82% and 73% respectively *vs* 0% in all the INF/RBV control groups

- The new IFN-free combinations have so far only evaluated small groups of more easy-to-treat non-fibrotic patients. In cases where fibrotic patients have been included the SVR rates drops dramatically

- The current TMC435 triple therapy offer an HCV cure for cirrhotic patients and future INF-free TMC435 combinations will also offer a cure for cirrhotic patients as well as for the treatment naïve patient and non-cirrhotic treatment experienced patient populations.

Expected key news flow highlights

- ✓ Q1-12 DAA phase II combination study with TMC435 and GS-7977 started
- ✓ Q1-12 OTC launch of Xerclear® (ZoviDuo) in Europe by GSK
- ✓ Q1-12 Start of Phase III trials with TMC435 + standard of care in prior null and partial responder patients vs telaprevir.
- ✓ Q2-12 Expanded agreement signed on TMC435 and daclatasvir (BMS-790052) collaboration
- ✓ Q2-12 TMC435 and BMS-986094 (formerly INX-189), two direct-acting antivirals in combination, will be evaluated in clinical trials
- ✓ Q2-12 EASL – ASPIRE full SVR24 data
- ✓ Q2-12 Janssen creates new division to launch TMC435 in EMEA
- Q2-12 Start of DAA phase II combination study with TMC435 and daclatasvir
- Q2-12 Start of Phase I clinical trials with MIV-711 (cathepsin K inhibitor)
- Q4-12 Potential CD selection in our internal Nucleotide NS5B inhibitor program
- Q4-12 EoT-data from Cohort 1 with TMC435 and GS7977 DAA phase II study
- Q4-12 Potential CD selection in Cathepsin S (Neuropathic pain) program
- Q4-12 Goal to start phase 1 trials with Medivir/Janssen Nucleotide NS5B inhibitor
- Q4-12 Top line results from phase III trials with TMC435 (Quest 1+2 and Promise)