Medivir

A specialty pharmaceutical company focused on infectious diseases

ABG Lunch Presentation 4 April

Presenting team

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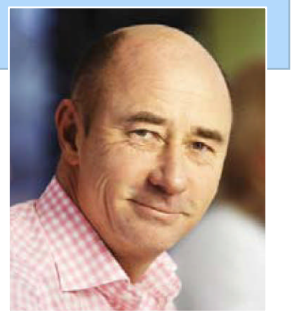


Bertil Samuelsson
CSO

Medivir Vision

Medivir aims to become a profitable specialty pharmaceutical company focused on the development and commercialisation of high-value infectious disease treatments

Hepatitis C in the Nordic countries

Medivir is in a unique position – Nordic commercial rights retained

- To launch one of the first products of a new treatment paradigm for a patient group with a distinct unmet medical need
- To give high priority and focus on pre-launch activities to facilitate broad and rapid market access for TMC435 well in advance of launch
- To capture a significant share of the HCV market due to the highly competitive attributes of TMC435

Unmet medical need – Large market with substantial growth potential

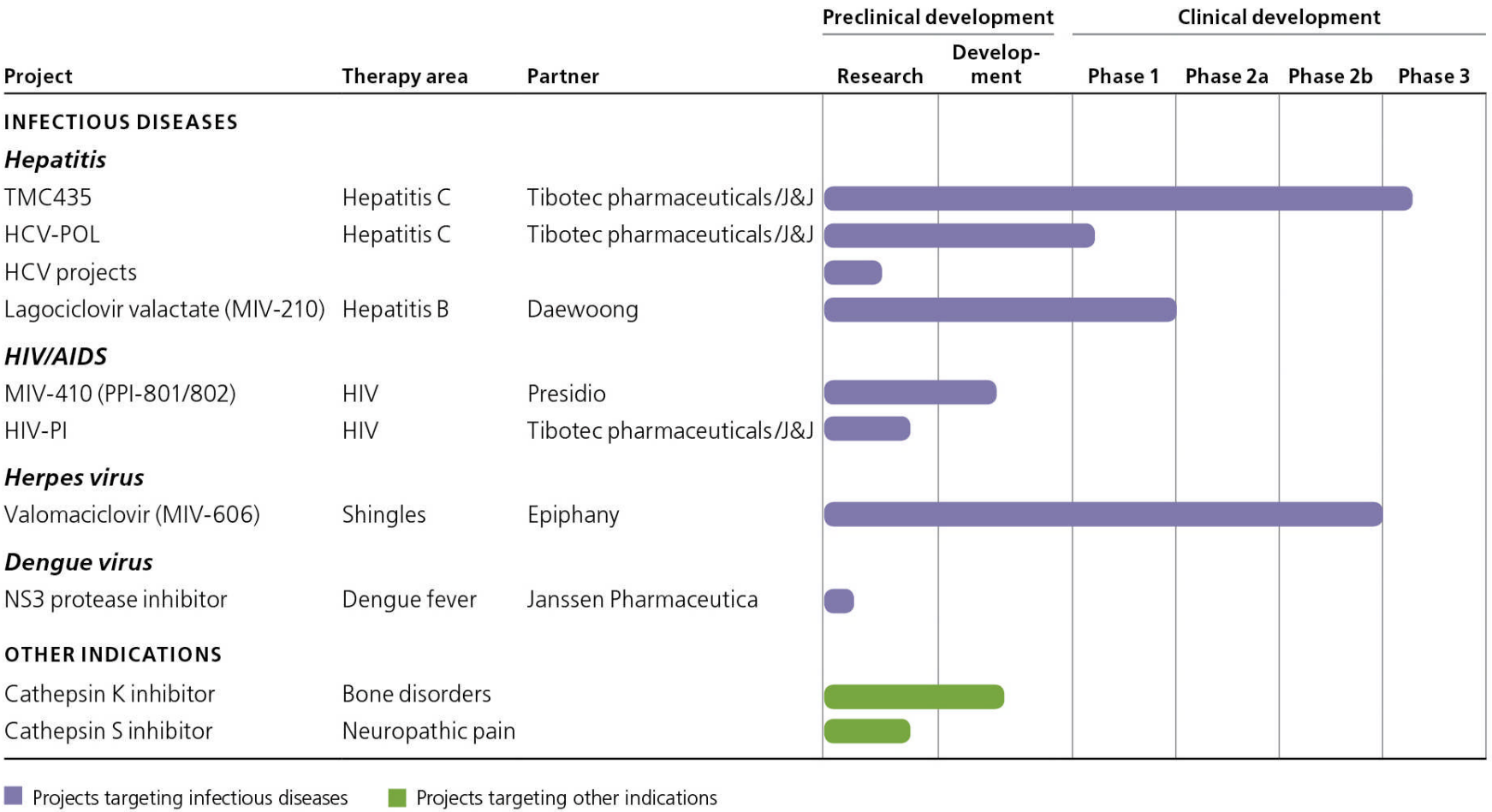
- 115,000 Chronic HCV patients in the Nordic region
- Around 3,000 HCV patients receive treatment today in the Nordic countries The present (2010) market value is SEK 400m
- Poor efficacy and safety profile with current treatment. Less than 50% of patients reach a sustained virologic response
- This medical need will be addressed for the first time with the introduction of protease inhibitors (PI) on the market in 2011/12. TMC435 enter the market as a second generation protease inhibitor.

Treatment evolution – Main market driver

- Patient warehousing of HCV patients with G1 is acknowledged – Approx 10-20% of these patients are in an acute phase and need treatment immediately
- Share of PI treated naïve patients will increase over time as PI's gain recognition

Our pipeline

Strong Pipeline with Multiple Paths to Value Creation



Our hepatitis C franchise

Partnered and in-house product portfolio

Hepatitis C - A Blockbuster Potential Market

The Hepatitis C Market

- Globally ~180 million (3-4% of world population) infected with hepatitis C virus, of which 80% develop chronic disease
- The difficult to treat genotype 1 (G1a/b) account for ~70% of the HCV population
  - Sustained viral response (SVR) in G1 patients is very low, 42-48% on PegIFNα/RBV, SoC
- Approximately 12 million HCV infected in the US, Europe and Japan
  - Prevalence in JPN ~1.9 million with ~55% being diagnosed (~25% worldwide)
  - Health care burden in the US ~ 5 BUSD / year

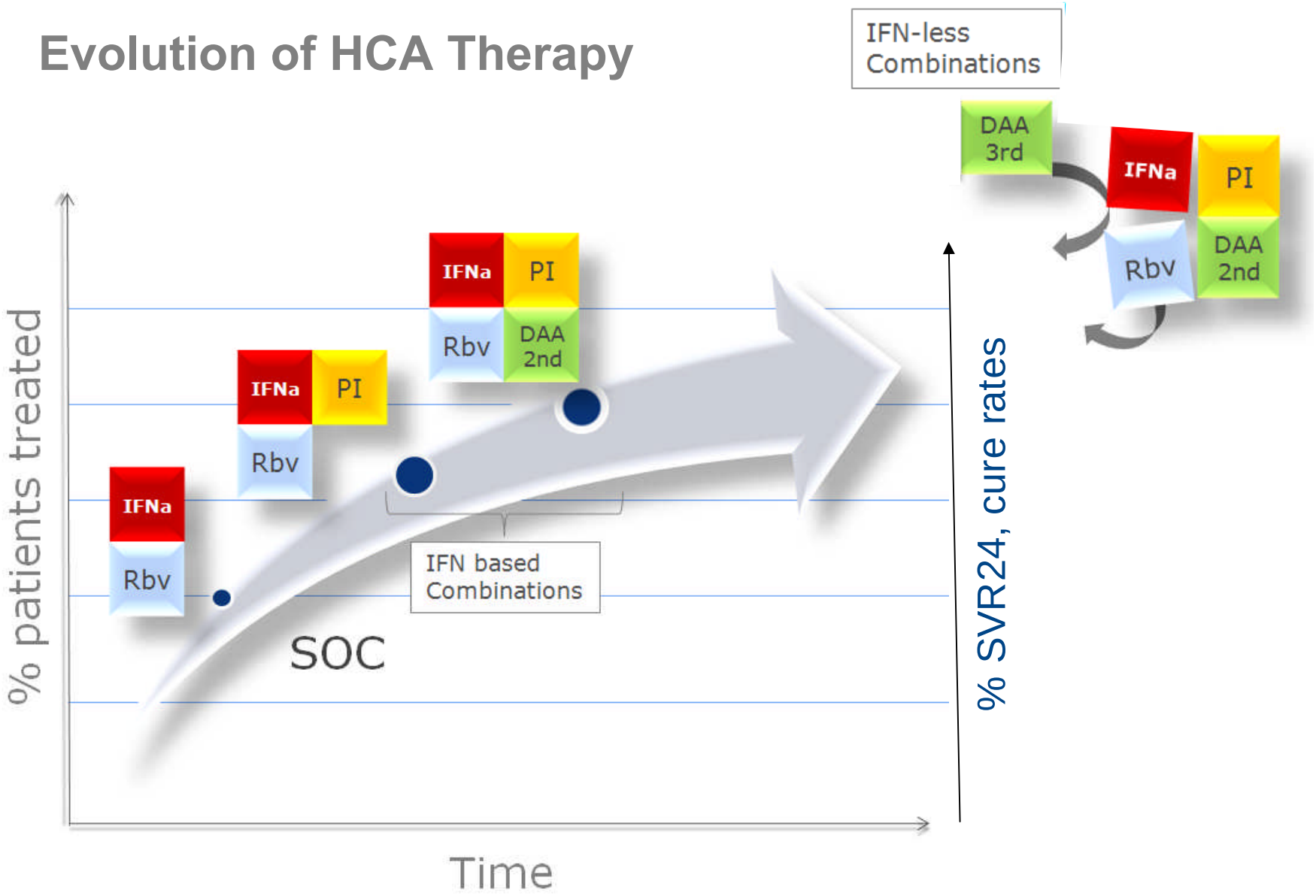
Market Value

- Estimated market value of over USD 10 billion in 2015 and increasing
- Treatment-experienced patients, currently ~ 0.5 million, comprise ~half of the market value

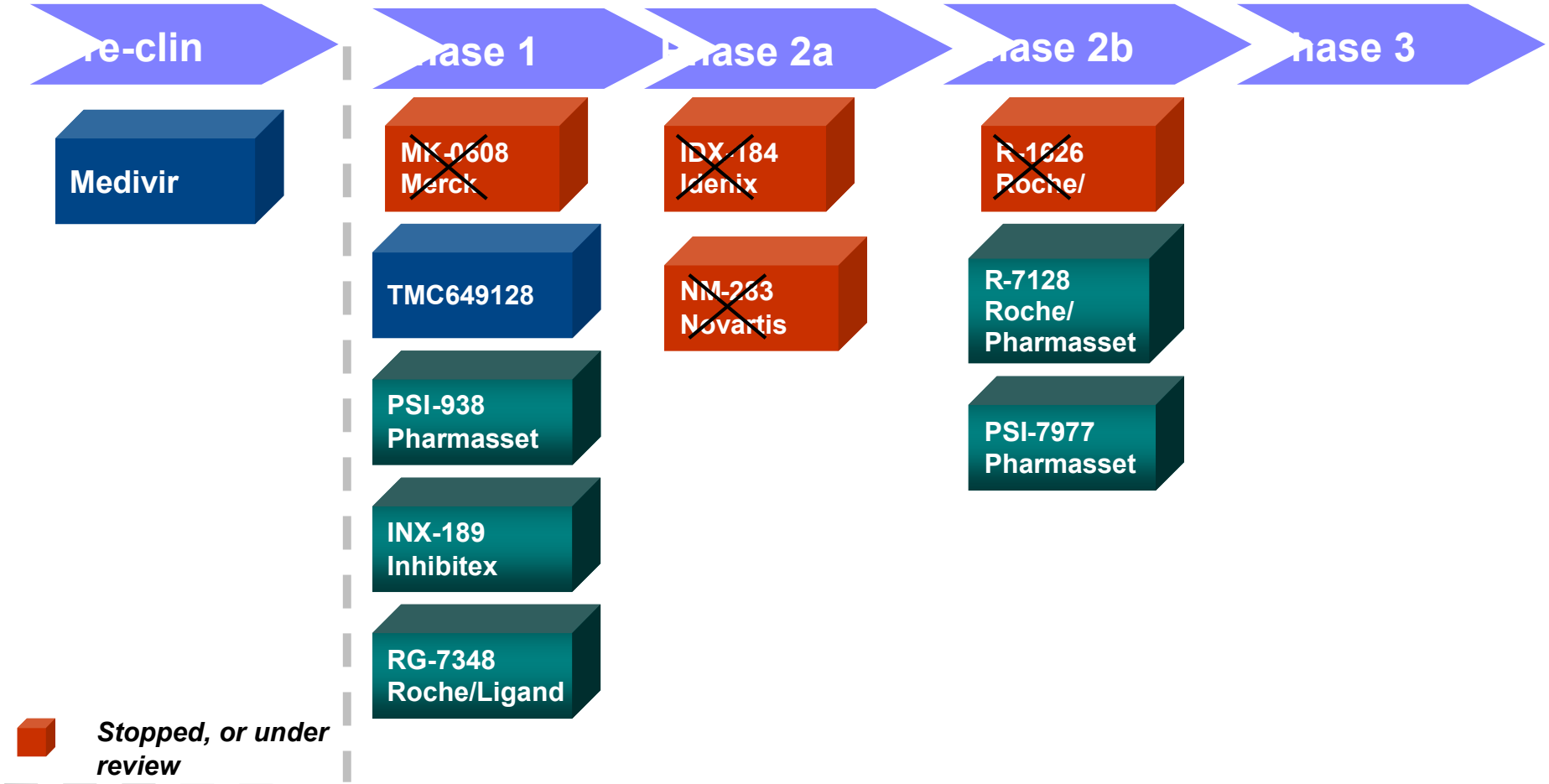
TMC 435 potential

- Analysts estimate TMC435 annual peak sales of 2-4 BUSD

Evolution of HCA Therapy



HCV Nucleosides & Nucleotides – Competitive landscape



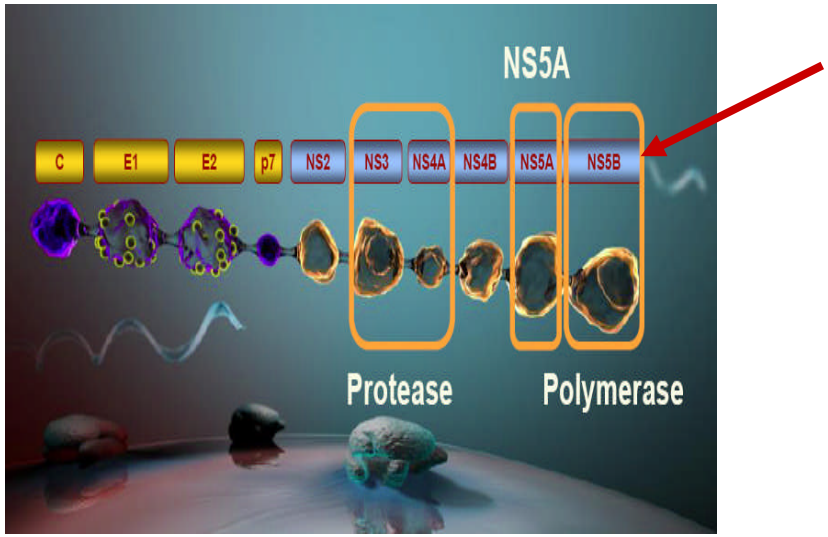
HCV Clinical Pipeline

TMC649 (HCV Pol) – a major commercial opportunity

- EUR 147 million deal value
  - EUR 95 million outstanding
  - Royalties on global sales
- Medivir retain Nordic market rights
  - Prevalence of chronic HCV infected ~115,000
  - Current treatment rates ~ 3,000

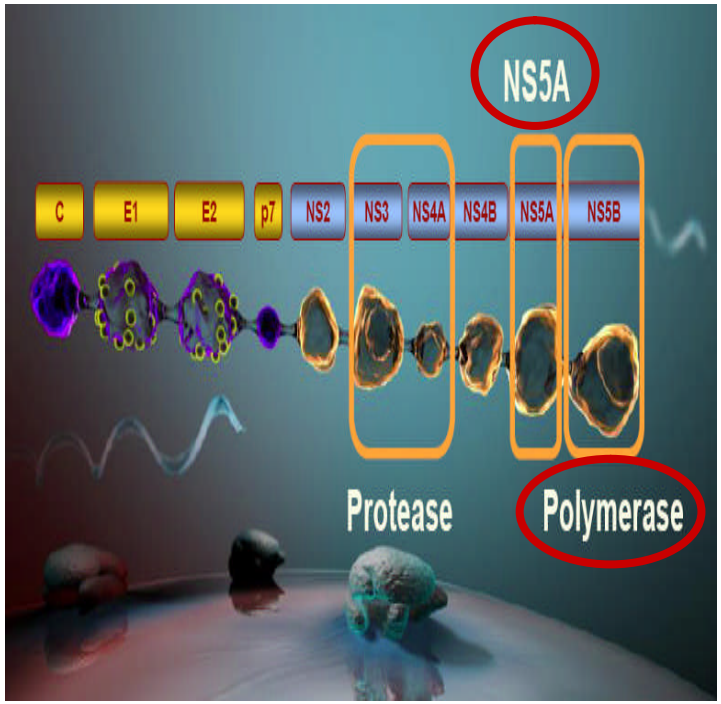
TMC649 (HCV Pol) – summary status

- Nucleoside/tide NS5B inhibitor
- An ideal DAA agent for future TMC435 combination regimens
- High barrier to resistance and broad genotype coverage
- Long patent life
  - IP extending to 2027 and 2029
- Phase 1 trials ongoing



HCV Preclinical In-House Programs

- An internal NS5B nucleoside/tide program
- A NS5A program in LO phase



TMC435 – The Leading Next Generation Protease Inhibitor

- Strong safety profile: no adverse events over SoC in the Phase 2b PILLAR and ASPIRE studies
- Excellent anti-viral efficacy shown in Phase 2b PILLAR and ASPIRE studies
- Convenient: one pill and once daily, no food interactions

HCV Clinical Pipeline

TMC435 – summary status

- Potent HCV NS3/4A protease inhibitor
- TMC435, the backbone of future DAA combination therapies
  - Combination studies to be communicated
- Long patent life
  - IP extending to 2026 and 2028
- Global Phase 3 trials ongoing
- Regulatory filings expected in 2013

Decision Resources, Report March 2011

TMC-435 has the potential to emerge as the future gold-standard therapy in our Drug Comparator Model because of its superior clinical profile over the current therapies we evaluated.

TMC435 – the commercial opportunity

- EUR 80.5 million deal value
  - EUR 30 million still outstanding
  - Royalties on sales worldwide
  - Medivir retain all rights to the Nordic market

Hepatitis C PI – the Competitive Landscape

Phase 1a	Phase 1b	Phase 2a	Phase 2b	Phase 3	Registration
VPY-376	ACH-1625	ABT-450	Danoprevir R-7227**?**	**TMC435**	Telaprevir VX-950
PHX1766			BMS-650032		Boceprevir SCH-503034
IDX320			GS-9256		
MK-5172			Vaniprevir **?** MK-7009		
			BI201335 **?**		
			Narlaprevir**?**		

HCV PI's in combination with DAAs and SoC

- Combinations of DAA agents:
  - Telaprevir in phase 2a in combination with VX-222 (NNRTI) +/- SoC
  - Danoprevir in phase 2a in combination with R7128 (NI) +/- SoC
  - BMS-650032 in phase 2a in combination with BMS-790052 (NS5A inh) +/- SoC
  - GS-9256 in combination with GS-9190 (NNRTI) +/- Ribavarin

Note: nanoprevir and ABT-450 require ritonavir-boosting

TMC435 Late Stage Clinical Trial Programme

Follow Up Phase

Phase 2b studies

PILLAR (C205) – 386
genotype-1 infected
treatment-naïve patients

DRAGON (C215) – 92
genotype-1 infected
treatment-naïve patients

ASPIRE (C206) – 462
genotype-1 infected
treatment-experienced
patients

Recently Initiated

Phase 3 studies

QUEST 1 (C208) 375
genotype-1 infected
treatment-naïve patients

QUEST 2 (C216) 375
genotype-1 infected
treatment-naïve patients

PROMISE (C3007) 375
genotype-1 infected
relapsed patients

Phase 3 studies started in Japan
both in naïve and
treatment experienced
genotype-1 infected
patients

For additional information on inclusion and exclusion criteria for these studies, please see www.clinicaltrials.gov

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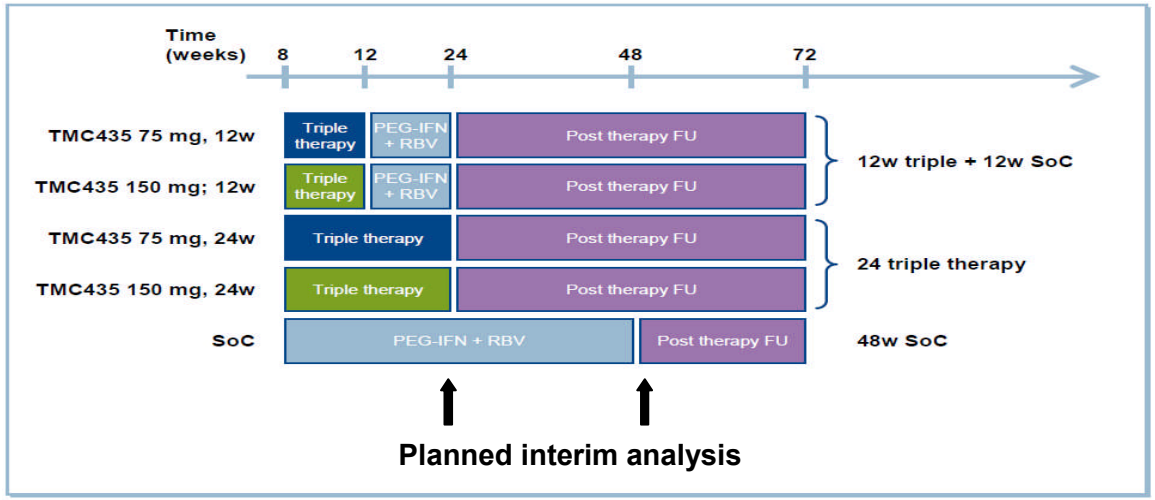
TMC435 Phase 2b: Study Design & Findings
48 week interim analysis

PILLAR (C205)

- TMC435-C205 is a global phase 2b study in 386 genotype-1 treatment-naïve patients
- Once daily (*q.d.*), 75 mg and 150 mg, of TMC435 + SoC:
  - 12-week triple therapy followed by SoC alone up to week 24
  - 24-week triple therapy
- Response-guided treatment duration in TMC435 arms
  - End treatment at Week 24, if
    - HCV RNA <25 IU/mL detectable or undetectable at Week 4, *and*
    - HCV RNA <25 IU/mL undetectable at Weeks 12, 16, and 20
  - All other patients continued Peg/RBV for up to 48 weeks



PILLAR C205 Week 48 Interim Analysis

Safety and Efficacy

1. **Phase 2b 48-week (SVR24) Interim Results of TMC435 in Treatment-naïve Patients Chronically Infected with Genotype-1 Hepatitis C Virus**
2. **In the TMC435 treatment groups 83% of patients were able to stop all therapy at week 24**
3. **Potent and consistent antiviral efficacy was demonstrated with SVR24 rates of up to 84%**
4. **No clinically relevant difference in safety and tolerability between TMC435 and placebo groups**

Sustained Virological Response 4 and 24 Weeks after Planned End of Treatment (EoT);					
% (n/N)	**TMC435 12PR24 75mg q.d. N=78**	**TMC435 24PR24 75mg q.d. N=75**	**TMC435 12PR24 150mg q.d. N=77**	**TMC435 24PR24 150mg q.d. N=79**	**Placebo N=77**
SVR4	**87.2 (68/78)**	**86.5 (64/74)**	**84.9 (62/73)**	**88.5 (69/78)**	**71.2 (42/59)**
SVR24	**83.6 (61/73)**	**76.1 (51/67)**	**83.1 (59/71)**	**84.4 (65/77)**	**N/A**

* < 25 log10 IU/mL undetectable
q.d.: once daily, PR: pegIFNalpha-2A and ribavirin,
SVR4 and SVR24: patients with undetectable HCV RNA 4 and 24 weeks after planned EoT, respectively.
N/A: Patients in the control arm continue SoC until Week 48 and SVR24 data was not available

Presented at EASL

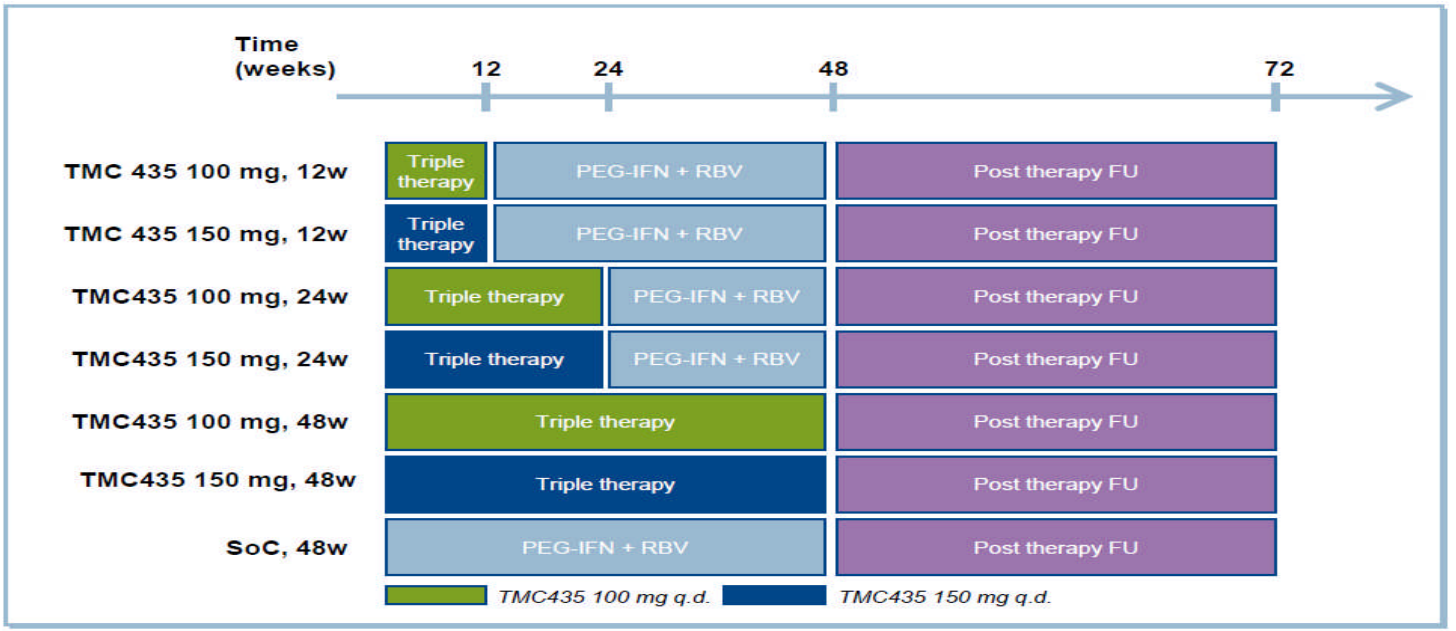
- **Oral Presentation:**
  - "Impact of IL28B genotype and pretreatment serum IP-10 in treatment-na?ve genotype-1 HCV patients treated with TMC435 in combination with peginterferon α-2a and ribavirin in PILLAR study" - Thursday, March 31, 2011 from 17:00 to 19:00

- **Poster Presentations:**
  - Late-breaker "The ASPIRE trial: TMC435 in treatment-experienced patients with genotype-1 HCV infection who have failed previous PEG/RBV treatment" - Thursday, March 31, 2011 - Saturday, April 2, 2011
  - "Pharmacokinetics of TMC435 in subjects with moderate hepatic impairment" - Thursday, March 31, 2011 from 09:00 to 18:00
  - "Treatment outcome and resistance analysis in HCV genotype-1 patients previously exposed to TMC435 monotherapy and re-treated with TMC435 in combination with pegIFNα-2a/ribavirin" - Saturday, April 2, 2011 from 09:00 to 18:00

TMC 435 Phase 2b study design

ASPIRE (C206)

- TMC435-C206 is a global phase 2b study in 462 genotype-1 treatment-experienced patients
- Once daily (*q.d.*), 100 mg and 150 mg, of TMC435 + SoC:
  - 12-week triple therapy followed by 36 weeks of SoC
  - 24-week triple therapy followed by 24 weeks of SoC
  - 48-week triple therapy



Antiviral Efficacy in TMC435 ASPIRE C206

24-Week Interim Data

	TMC12/PR48 100 mg (N=66)	TMC24/PR48 100 mg (N=65)	TMC48/PR48 100 mg (N=66)	TMC12/PR48 150 mg (N=66)	TMC24/PR48 150 mg (N=68)	TMC48/PR48 150 mg (N=65)	Pbo48/PR48 (N=66)
HCV RNA <25 IU/mL undetectable, % (n/N)							
Overall population Week 4 (RVR)	**67.7** (44/65) ***	**59.4** (38/64) ***	**53.8** (35/65) ***	**63.1** (41/65) ***	**70.8** (46/65) ***	**66.2** (43/65) ***	**1.5** (1/65)
Prior null responder	**33.3** (5/15)	**50.0** (8/16)	**25.0** (4/16)	**35.3** (6/17)	**41.2** (7/17)	**41.2** (7/17)	**0.0** (0/16)
Prior partial responder	**65.2** (15/23)	**40.9** (9/22)	**60.9** (14/23)	**65.2** (15/23)	**69.6** (16/23)	**68.2** (15/22)	**0.0** (0/23)
Prior relapser	**88.9** (24/27)	**80.8** (21/26)	**65.4** (17/26)	**80.0** (20/25)	**92.0** (23/25)	**80.8** (21/26)	**3.8** (1/26)
Overall population Week 24	**87.1** (54/62) ***	**84.5** (49/58) ***	**85.2** (52/61) ***	**85.7** (54/63) ***	**90.8** (59/65) ***	**90.3** (56/62) ***	**51.9** (28/54)
Prior null responder	**71.4** (10/14)	**83.3** (10/12)	**68.8** (11/16)	**70.6** (12/17)	**81.3** (13/16)	**93.3** (14/15)	**44.4** (4/9)
Prior partial responder	**86.4** (19/22)	**80.0** (16/20)	**85.7** (18/21)	**86.4** (19/22)	**90.9** (20/22)	**86.4** (19/22)	**19.0** (4/21)
Prior relapser	**96.2** (25/26)	**88.5** (23/26)	**95.8** (23/24)	**95.8** (23/24)	**96.3** (26/27)	**92.0** (23/25)	**83.3** (20/24)

***Statistically significant difference versus placebo, p<0.001

ITT; 25%

- **The TMC435 treatment arms demonstrate high response rates**
- **The antiviral efficacy was enhanced in all patient groups through week 12 and 24**
- **Notably, the null responder group demonstrated significant response rates**

Excellent antiviral activity

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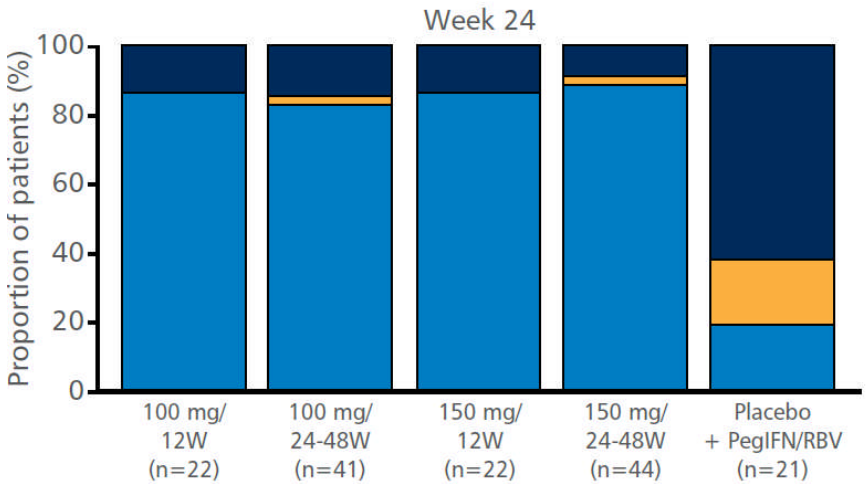
Antiviral Efficacy in TMC435 ASPIRE C206

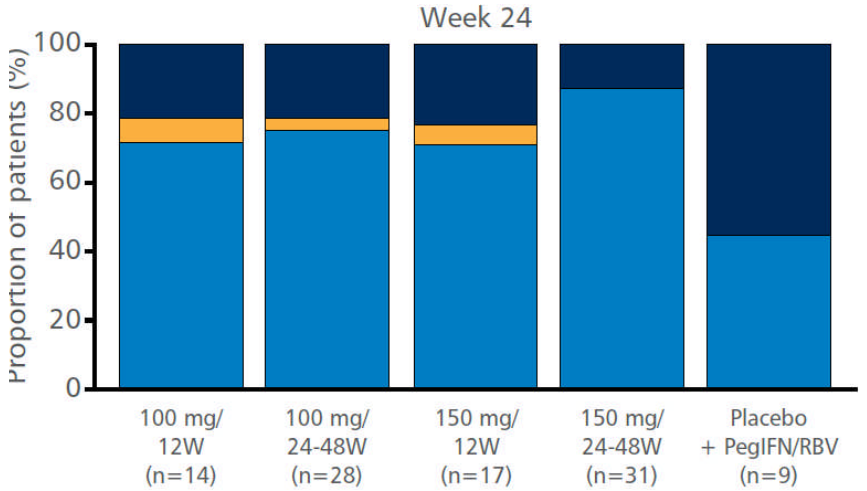
24-Week Interim Data

Response rates at week 24 for:

Partial responders



Null responders



HCV RNA <25 IU/mL undetectable HCV RNA <25 IU/mL detectable HCV RNA >25 IU/mL

- **The TMC435 treatment arms demonstrate high response rates**
- **The antiviral efficacy was enhanced in all patient groups through week 12 and 24**
- **Notably, the null responder group demonstrated significant response rates**

Excellent antiviral activity

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Safety and Tolerability Data at Week 24 in TMC435 ASPIRE C206

Adverse Events

- Median treatment exposure was higher for TMC435 patients compared with placebo (30 weeks for TMC435 compared to 26 weeks in placebo control group), due to higher attrition in the placebo control group which was mainly related to lack or loss of virologic response. This bias should be kept in mind when assessing safety comparisons.
- Overall incidence of AEs was similar across treatment groups.
- The majority of AEs were grade 1 or 2 in severity. Influenza-like illness and pruitus were more commonly reported in TMC435 patients.
- Serious AEs were reported in 5.8% of the patients treated with TMC435 and in 1.5% subjects in the placebo control group. No differences were observed between the TMC435 dose groups.
- AEs leading to treatment discontinuation were reported in 6.1% of the TMC435 treated patients and in 1.5% of the placebo patients.

TMC435 was safe and well tolerated

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ASPIRE Trial Conclusions

- TMC435 treatment arms demonstrate high response rates
- The antiviral efficacy was enhanced in all patient groups through week 12 and 24 and treatment will continue up to week 48
- Notably, the null responder group demonstrated significant response rates
- TMC435 was safe and well tolerated
- 48-week data will be available in Q2 2011

Upcoming News Flow

Expected key newsflow highlights during 2011

- Q2 -11 TMC435, 48-week interim data from the phase 2b C206 (ASPIRE) trial in treatment-experienced patients
- Q3-11 C205 (PILLAR) full SVR24 data
- Q3-11 Start of phase 1 trials with MIV-711
- H2-11 Start of phase 3 trials with TMC435 in treatment-experienced non-responder patients
- H2-11 Phase 1a/1b results with TMC649
- Q4-11 AASLD – additional data on TMC435
- Q4-11 OTC launch of Xerclear® in Europe by GSK
- Q4-11 C206 (ASPIRE) SVR24 data

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