Handelsbanken November 18 2009

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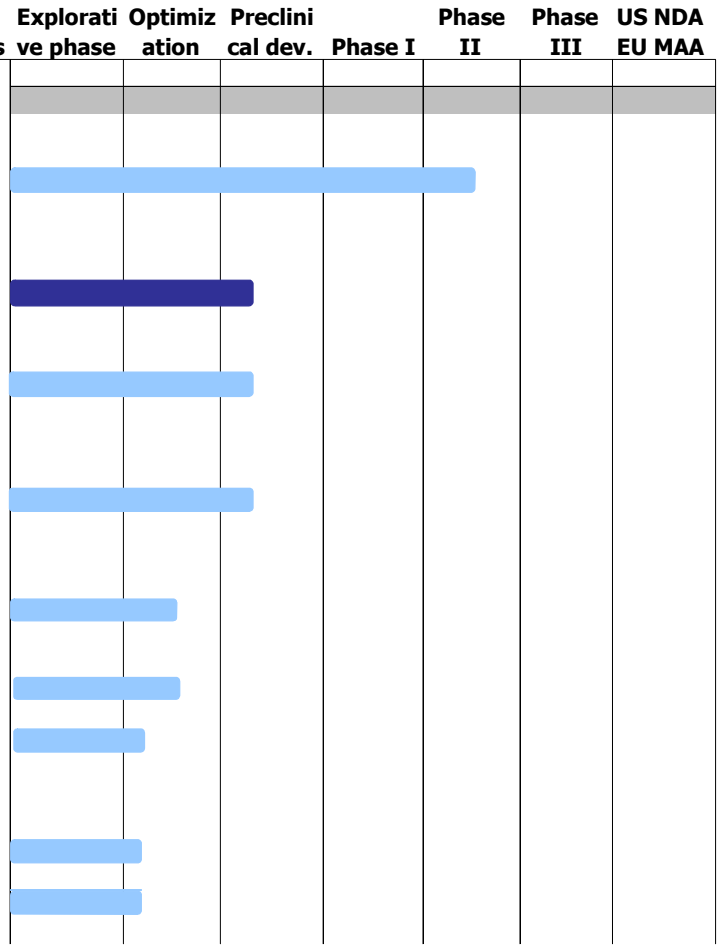
Pipeline

Project	Indication(s)	Partners/-date of agreement	Terms	Medivir's markets
Lipsovir® (ME-609)	Labial herpes	In-house		
TMC435 (HCV PI)	Hepatitis C	Tibotec / 2004	EUR 80.5 m + royalties FTE funding	Nordic region
HCV POL	Hepatitis C	Tibotec / 2008	EUR 142-272 m + royalties, FTE funding	Nordic region
MIV-710 (Cath K)	Osteoporosis, osteoarthritis, bone metastases	In-house		
MIV-711 (Cath K)	Osteoporosis, osteoarthritis, bone metastases	In-house		
HIV PI	HIV	Tibotec / 2006	EUR 64 m + royalties, FTE funding	Nordic region
BACE	Alzheimer's	In-house		
Cathepsin S	Neuropathic pain, rheumatoid arthritis, multiple sclerosis	In-house		
COPD PI	COPD	In-house		World exc. China
Renin	Hypertension	In-house		



Protease inhibitor Polymerase inhibitor Polymerase inhibitor/hydrocortisone

Hepatitis C – Our projects in collaboration with

tibotec Johnson&Johnson

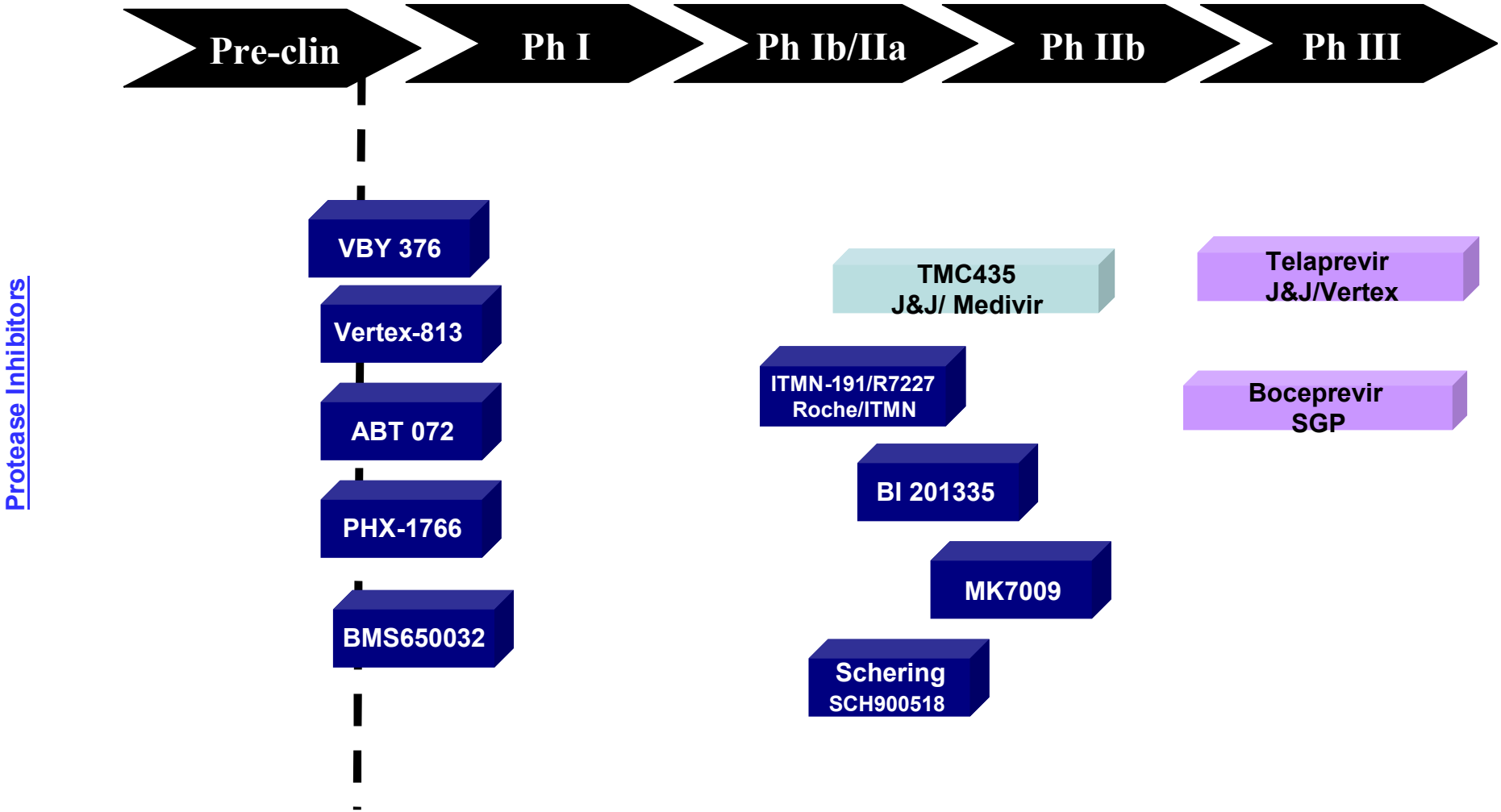
TMC435

HCV-PI advancing through several ongoing clinical trials

Nucleoside HCV Polymerase Inhibitor in preclinical IND phase

Next stage start of phase I trials

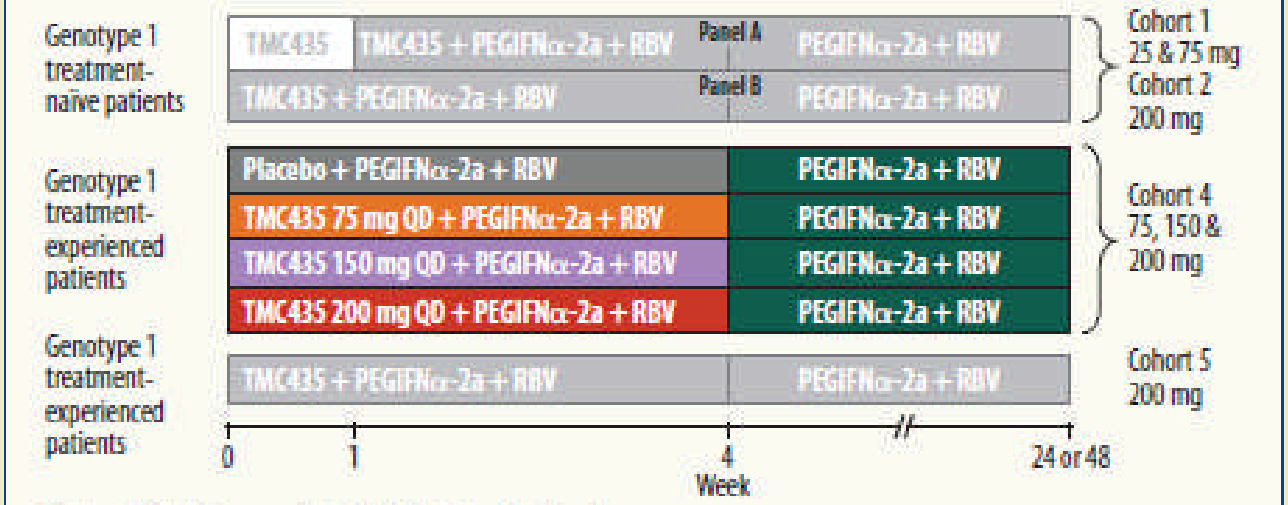
HCV PI Competitive Landscape



TMC435 C201 Phase IIa study:

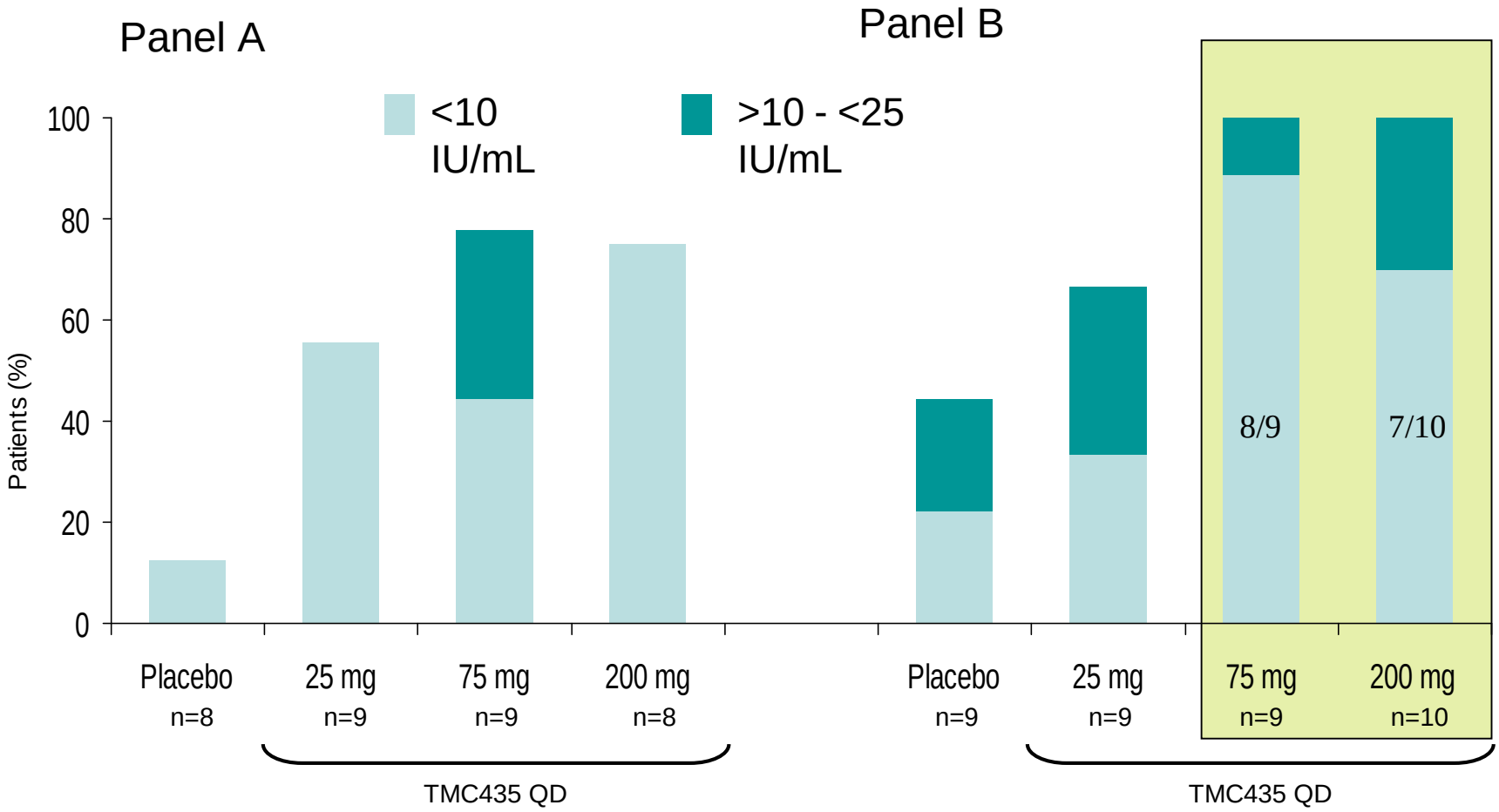
Cohorts 1 and 2 in treatment-naïve and cohorts 4 and 5 in treatment-experienced, genotype-1 HCV-infected patients

Figure 1. OPERA-1 study design.



The planned Cohort 3 was cancelled prior to the initiation of treatment
Patients are followed-up for 24 weeks after end of treatment to assess SVR rate
PEGIFNα-2a, pegylated interferon α-2a
RBV, ribavirin
SVR, sustained virologic response

TMC435: Cohorts 1 and 2 in treatment-naïve HCV-infected patients - Potent Antiviral Activity at week 4 and at week 12



- 9/9 patients (100%) in the 75 mg arm and 10/10 patients (100%) in the 200 mg arm of Panel B had HCV RNA <10 IU/mL (under limit of detection) at Week 12 (e.g. 4-weeks of TMC435/SoC plus 8-weeks of SoC alone)

TMC435 C201 Phase IIa study:

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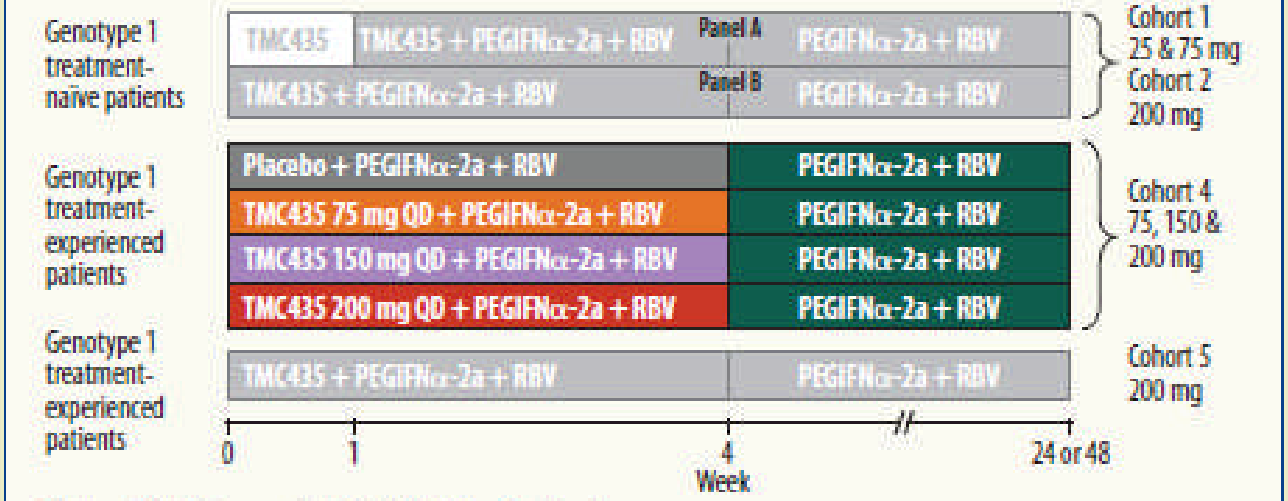

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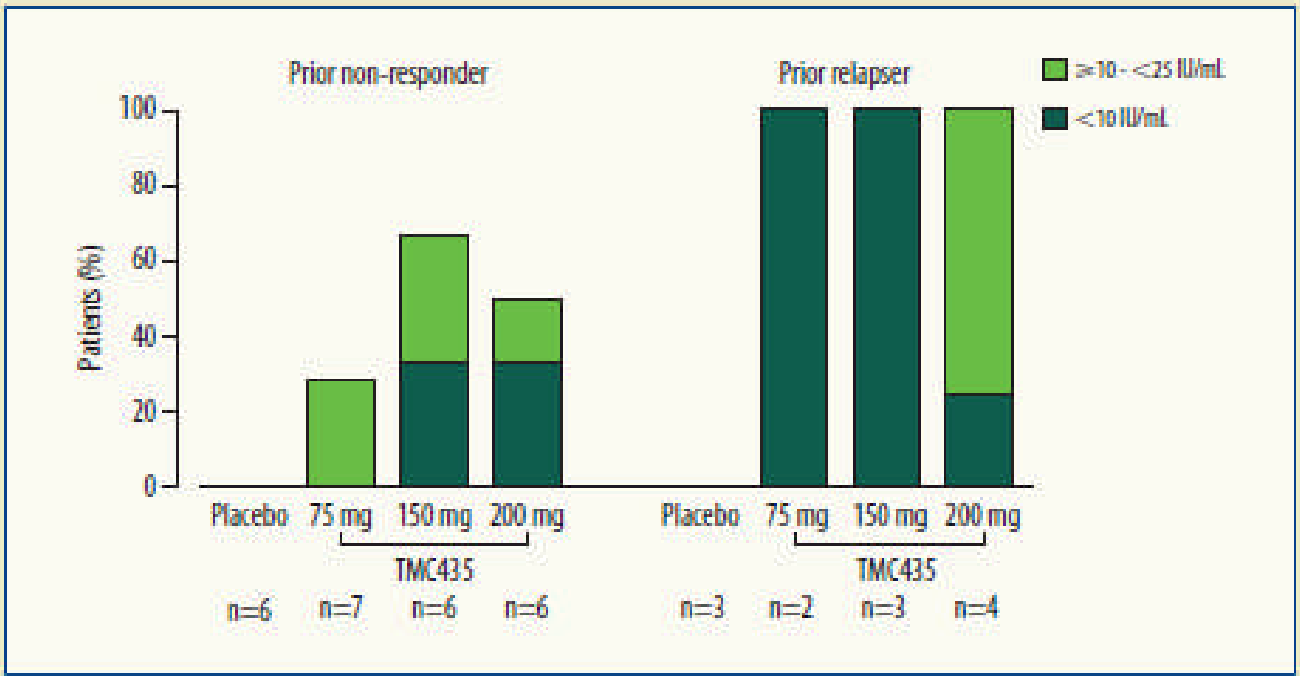
Viral load reduction in treatment-experienced patients cohort 4

Figure 3. Response to treatment with once-daily TMC435 75, 150 and 200 mg or placebo in treatment-experienced patients at Day 28.

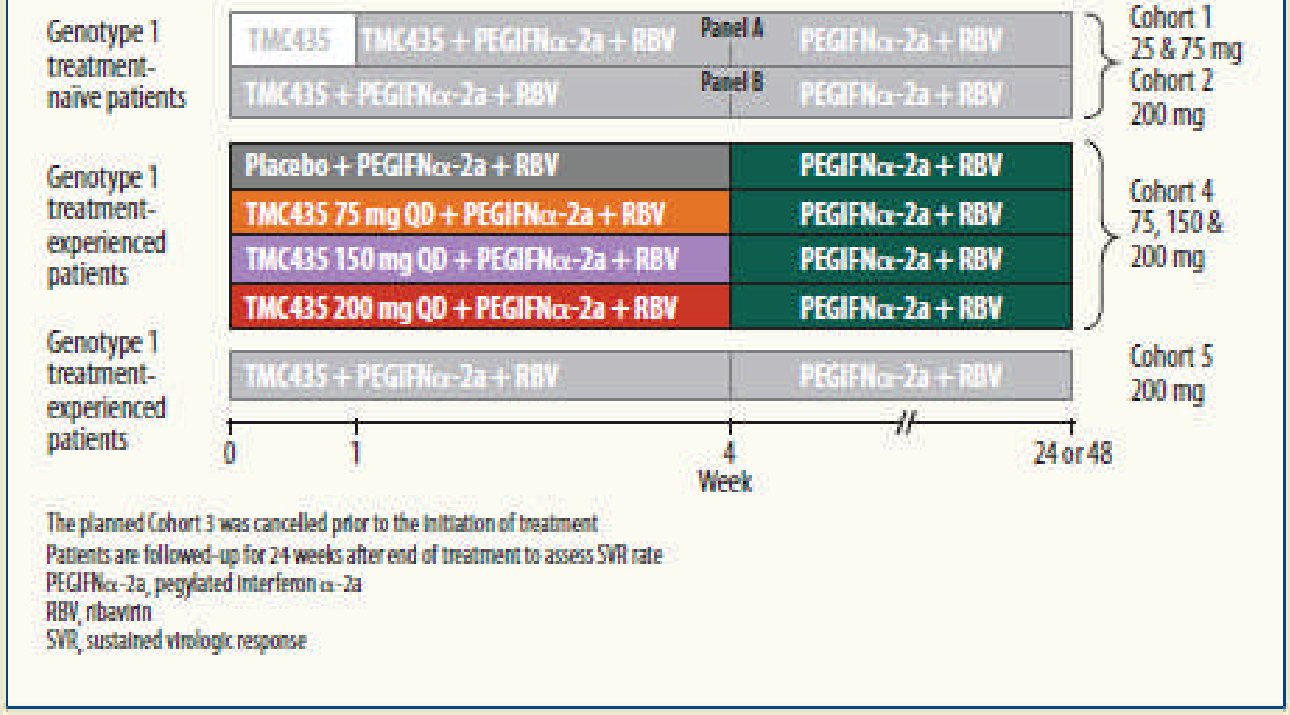


(22%), 5/9 (56%) and 3/10 (30%) patients in 75, 150 and the 200 mg groups reached undetectable levels (< 10 IU/mL) after 4 weeks of treatment, compared to 0/9 patients on placebo.

TMC435 C201 Phase IIa study:

Cohorts 1 and 2 in treatment-naïve and cohorts 4 and 5 in treatment-experienced, genotype-1 HCV-infected patients

Figure 1. OPERA-1 study design.



Antiviral activity and safety of TMC435 combined with pegylated interferon and ribavirin in hepatitis C patients with genotype 1 who had previous exposure to TMC435

H. Reesink,[1] J. de Bruijne,[1] C. Weegink,[1] O. Lenz,[2] K. Simmen,[2] M. Peeters,[2] G. De Smedt,[2] V. Sekar[3] and R.Verloes[2]

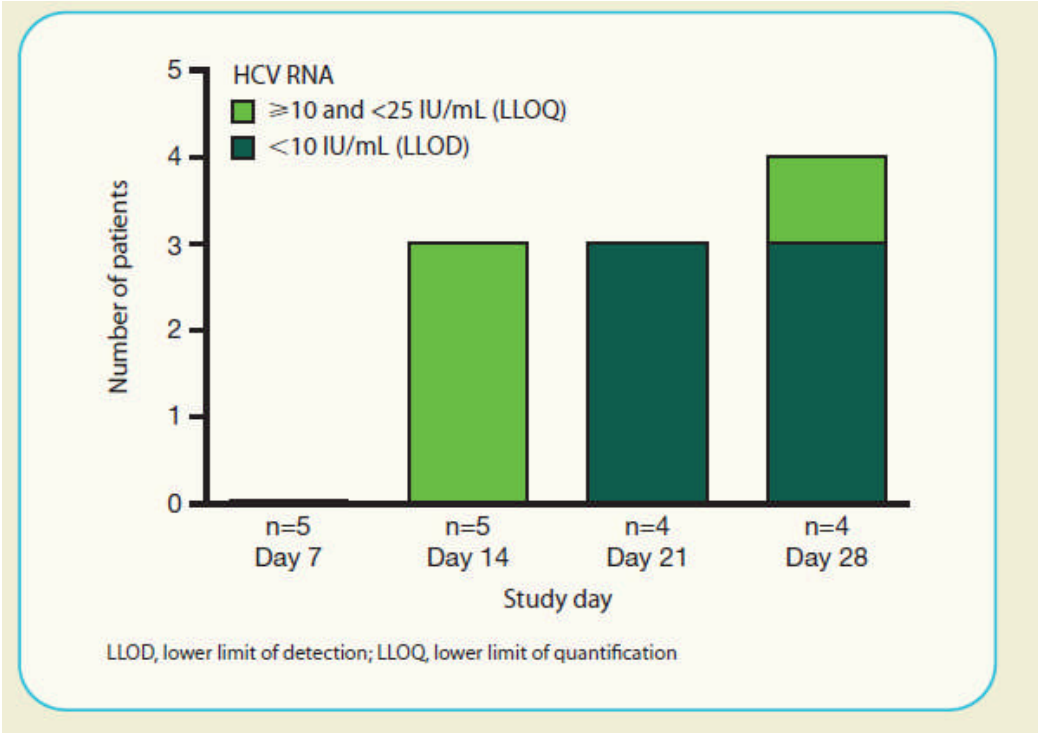
[1]Academic Medical Center, Amsterdam, The Netherlands; [2]Tibotec BVBA, Mechelen, Belgium; [3]Tibotec Inc., Yardley, PA, USA

OPERA-1 is a Phase IIa double-blind, randomized, placebo -controlled trial investigating different doses of TMC435 in both treatment-naïve and treatment-experienced patients across multiple cohorts. Cohort 5 comprised prior non-responders and relapsers to interferon (IFN)-based therapy who had previously received 5 days of monotherapy with TMC435 200 mg once daily (QD) in a Phase Ib trial (Study C101).

Four out of five patients completed triple therapy with TMC435 200 mg QD whilst one patient discontinued due to increased blood bilirubin. At Day 28, all four patients who completed treatment achieved HCV RNA <25 IU/mL with an overall mean change from baseline of 5.86 log10 IU/mL. Three of those four patients had HCV RNA below the lower limit of detection (<10 IU/mL) at Day 28

No viral breakthroughs (defined as >1 log10 IU/mL increase from nadir in HCV RNA) were observed within 4 weeks.

The most common adverse event (AE) during triple therapy was influenza-like illness (n=4). There were no serious AEs.



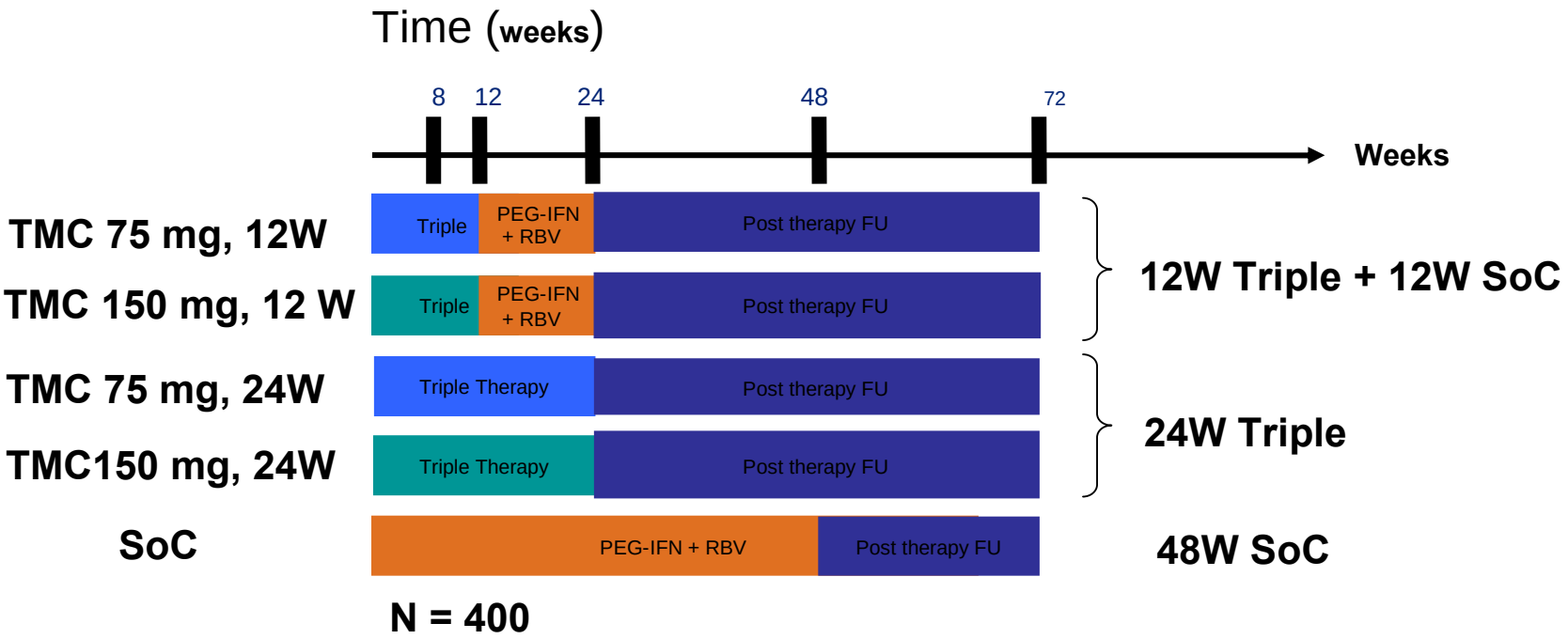
ALT and AST levels decreased over the 4-week treatment period. Other than an increase in bilirubin, no clinically relevant changes were observed in any other laboratory parameters, ECG parameters, or vital signs.

Conclusions - from phase IIa studies (Opera-1) in treatment naïve and treatment experienced

In both treatment-naïve and treatment experienced patients infected with HCV genotype-1, TMC435 in combination with SoC over 4 weeks of treatment:

- **demonstrated potent antiviral activity**
- **was generally safe and well tolerated**
- **was not associated with AE-related treatment discontinuations.**
- **Mild and reversible increases in bilirubin was observed, mostly observed in the highest dose groups (200 mg). The mechanism of action has been investigated**
  - **No evidence of hepatotoxicity**

Phase IIb study (C205) in treatment-naïve HCV patients – patient enrolment completed

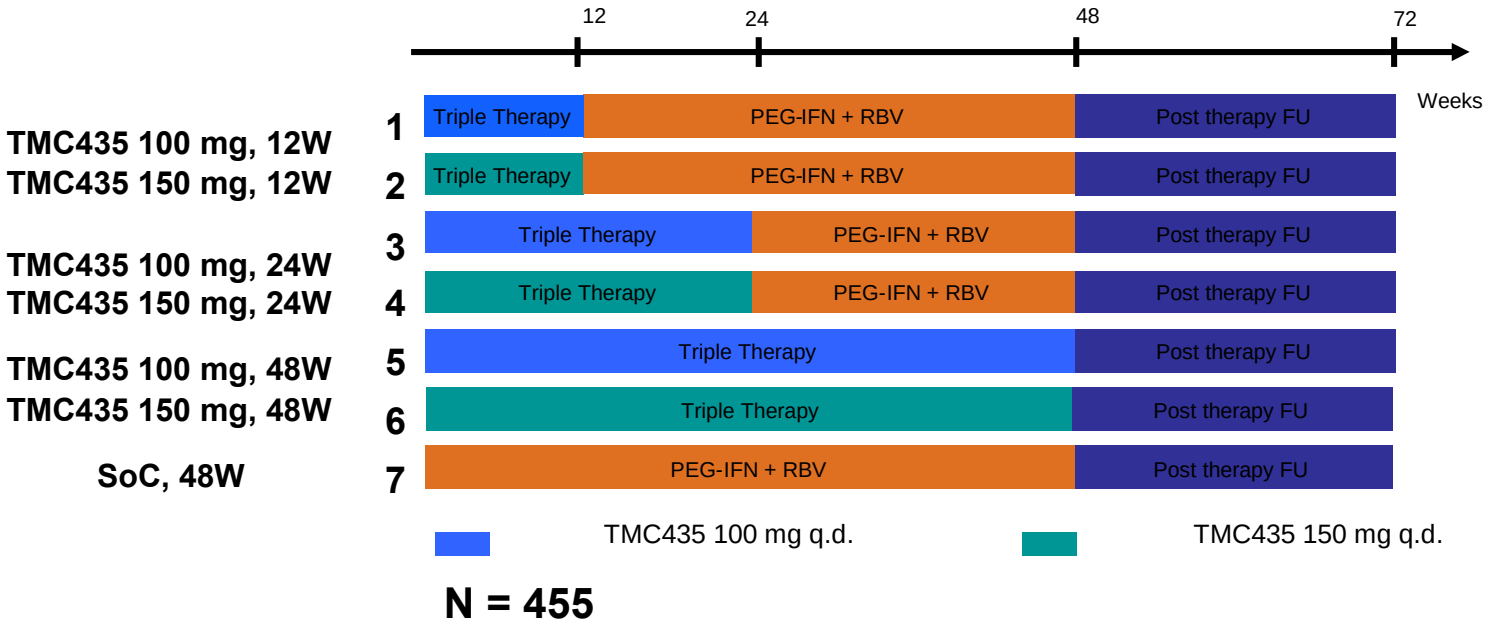


N = 400

Primary endpoint: Proportion of patients with undetectable virus levels 24 weeks after planned end-of-treatment (SVR24)

SoC: Ribavirin 1000-1200 mg BID + pegIFNalpha-2A 180 μg weekly

Phase IIb study (C206) in treatment-experienced HCV patients with TMC435 started late September



N = 455

Primary endpoint: Proportion of patients with undetectable virus levels 24 weeks after planned end-of-treatment (SVR24)

SoC: Ribavirin 1000-1200 mg BID + pegIFNalpha-2A 180 μg weekly

Medivir

TMC435 – additional ongoing key clinical trials

- **TMC435-C215: A phase IIb study in Japan in treatment naïve genotype-1 HCV patients**
  - Patients will receive TMC435 (50 or 100 mg) for a duration of 12 or 24 weeks.
  - In treatment arms 1 and 2, subjects will receive 12 weeks of triple therapy with TMC435 once daily plus SoC followed by 12 weeks of treatment with SoC.
  - In treatment arms 3 and 4, patients will receive 24 weeks of triple therapy with TMC435 once daily plus SoC.
  - In treatment arm 5 (control group), patients will be treated with SoC treatment for 48 weeks

- **TMC435-C202 in treatment naïve genotype 2 to 6 HCV patients**
  - Patients will receive TMC435 during 7 days, once daily dosing at 200mg, as monotherapy. Subsequently, they can continue with Standard of Care (SoC) treatment consisting of pegylated interferon and ribavirin upon agreement with the study doctor

Nucleoside HCV Polymerase Inhibitors

Medivir

Hepatitis C Polymerase

Medivir/J&J program

Status

- Partnership with Tibotec / Johnson & Johnson since May 2008, triggering a € 5 m milestone & 1 year research funding
- Candidate Drug selected in December 2008, milestone of € 2.6m
- Presently in preclinical development phase towards phase I

Next step

- Start of phase Ia

Patents

- Extensive and non-limiting IP filed

Licensing agreement

- Remaining milestones of € 137m + royalties on sales for one product reaching market.
- Additional € 130m for second compound and indication reaching market + royalties on sales.
- FTE Funding for one year, ended May 2009
- All development costs covered by JNJ
- Nordic rights retained by Medivir