



S|E|B ENSKILDA

Biotech lunch - Stockholm

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Pipeline

Project	Indication(s)	Partners / - date of agreement	Terms	Medivir's markets	Explorati ve phase	Optimiz ation	Preclini cal dev.	Phase I	Phase II	Phase III	US NDA EU MAA
Lipsovir® (ME-609)	Labial herpes	In-house									
TMC435 (HCV PI)	Hepatitis C	Tibotec / 2004	EUR 80.5 m + royalties FTE funding	Nordic region	[Progress bar: Exploratory phase to Phase II]						
HCV POL	Hepatitis C	Tibotec / 2008	EUR 142-272 m + royalties, FTE funding	Nordic region	[Progress bar: Exploratory phase to Preclinical dev.]						
MIV-710 (Cath K)	Osteoporosis, osteoarthritis, bone metastases	In-house			[Progress bar: Exploratory phase to Preclinical dev.]						
MIV-711 (Cath K)	Osteoporosis, osteoarthritis, bone metastases	In-house			[Progress bar: Exploratory phase to Preclinical dev.]						
HIV PI	HIV	Tibotec / 2006	EUR 64 m + royalties, FTE funding	Nordic region	[Progress bar: Exploratory phase to Optimization]						
BACE	Alzheimer's	In-house			[Progress bar: Exploratory phase to Optimization]						
Cathepsin S	Neuropathic pain, rheumatoid arthritis, multiple sclerosis	In-house			[Progress bar: Exploratory phase to Optimization]						
COPD PI	COPD	In-house		World exc. China	[Progress bar: Exploratory phase to Optimization]						
Renin	Hypertension	In-house			[Progress bar: Exploratory phase to Optimization]						

■ Protease inhibitor
 ■ Polymerase inhibitor
 ■ Polymerase inhibitor/hydrocortisone

Lipsovir® – for the treatment of cold sores

Our first product launch

Background

- First topical treatment that is clinically proven to prevent ulcerative cold sores with early treatment initiation
- Treatment with Lipsovir® prevented the development of cold sores in 42% of patients in the phase III-studies
- Lipsovir® is a patented combination of hydrocortisone (an anti-inflammatory agent) and acyclovir (an antiviral) intended for the topical treatment of cold sores
- The indication text endorsed by the FDA, states *“Acyclovir and Hydrocortisone Cream is indicated for the early treatment of recurrent herpes labialis (cold sores) to reduce the likelihood of ulcerative cold sores and to shorten the lesion healing time”*

Status

- FDA approved our NDA for Lipsovir® July 31 with the strongest possible label. Treatment is approved for adults and children 12 years or older
- We received European approval for Lipsovir® in 14 countries in mid October 2009, also with the strongest possible label. We are now in negotiations for the regulatory status in these countries, expected to be finalized by year end.

Strategy and Market for Lipsovir®

US - Market

- Like other cold sore pharmaceuticals, Lipsovir® will be a prescription (Rx) product in the US
- No product currently marketed for the treatment of cold sores has a corresponding label or has been shown to prevent an outbreak with early treatment
- The value of the topical cold sore cream market is approximately USD 150-180 M/year
- Main competitors are, Zovirax cream, Denavir cream and Abreva

EU – Market

- In Europe, Lipsovir® will be marketed as **Xerclear™**
- It will be marketed as OTC in some countries and as Rx in others, with an overall shift to OTC over time
- The value of the main European markets is approximately USD 200 M/year

Strategy

- Medivir will launch Lipsovir® in the Nordic region during Q1 2010
- Sign a joint venture / partnering agreement in the US and prepare for product launch by summer 2010
- Appoint distribution partners in Europe and prepare product launch by H2-2010

Hepatitis C – Our projects in collaboration with



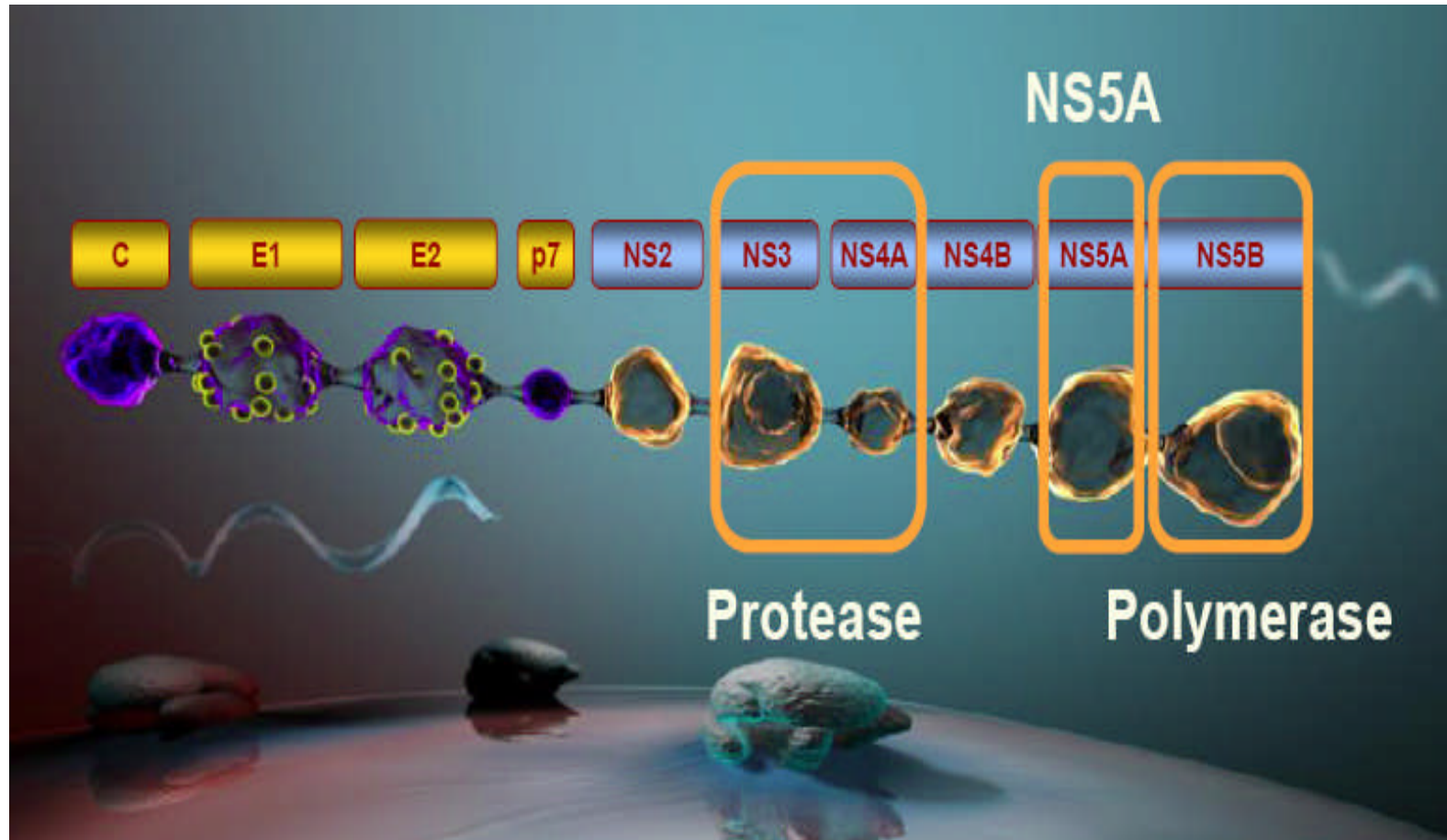
TMC435

HCV-PI advancing through several ongoing clinical trials in phase II

Nucleoside HCV Polymerase Inhibitor in preclinical IND phase

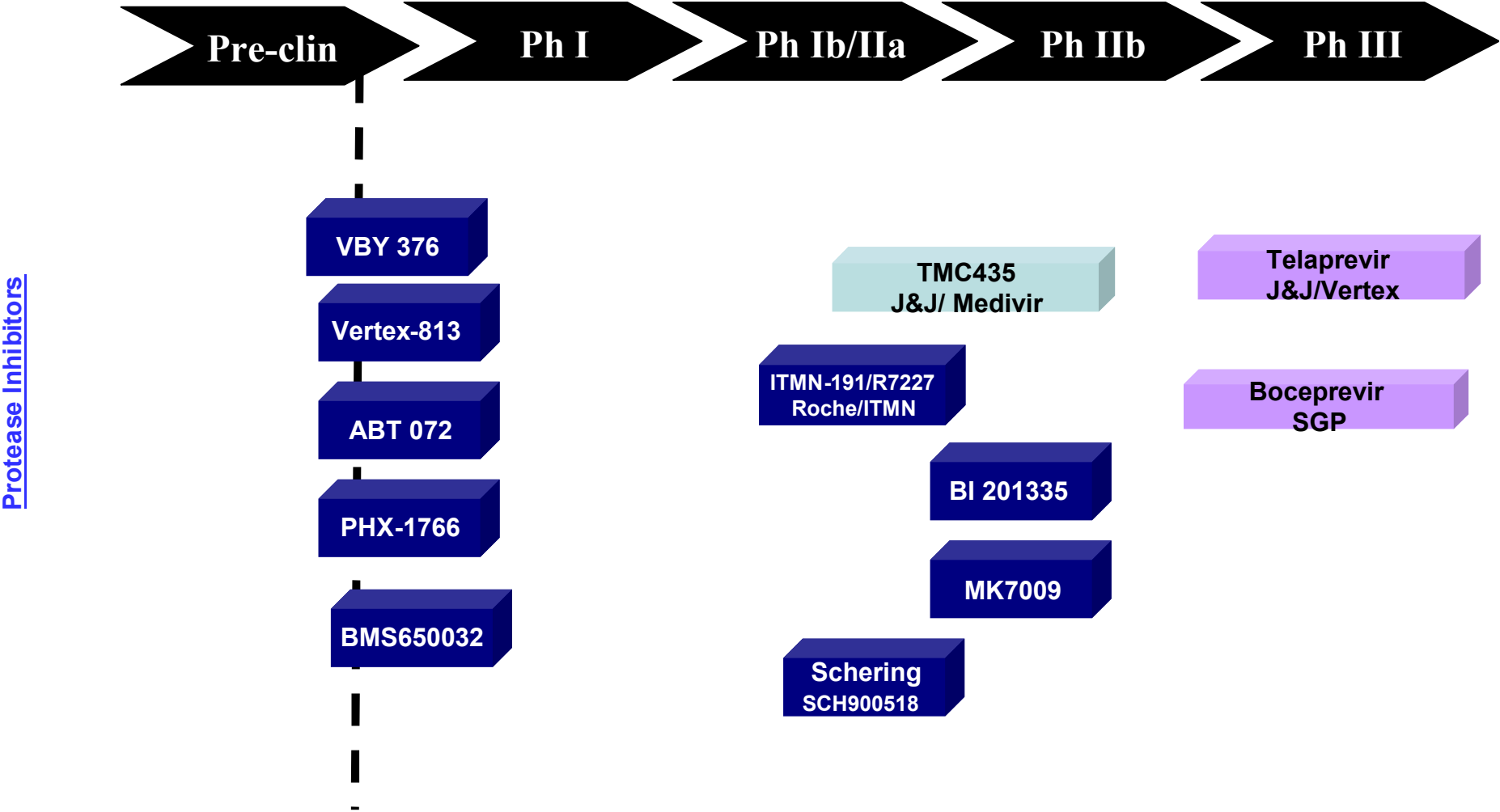
Next stage start of phase I trials

STAT-Cs: Paradigm Shift in HCV Treatment expected



Kwong A, et al. Drug Discovery Today: Therapeutic Strategies 2006;3:211-220
Schmitz U, Tan SL. Recent Pat Antiinfect Drug Discov 2008;3:77-92

HCV PI Competitive Landscape



Phase IIa - Conclusions

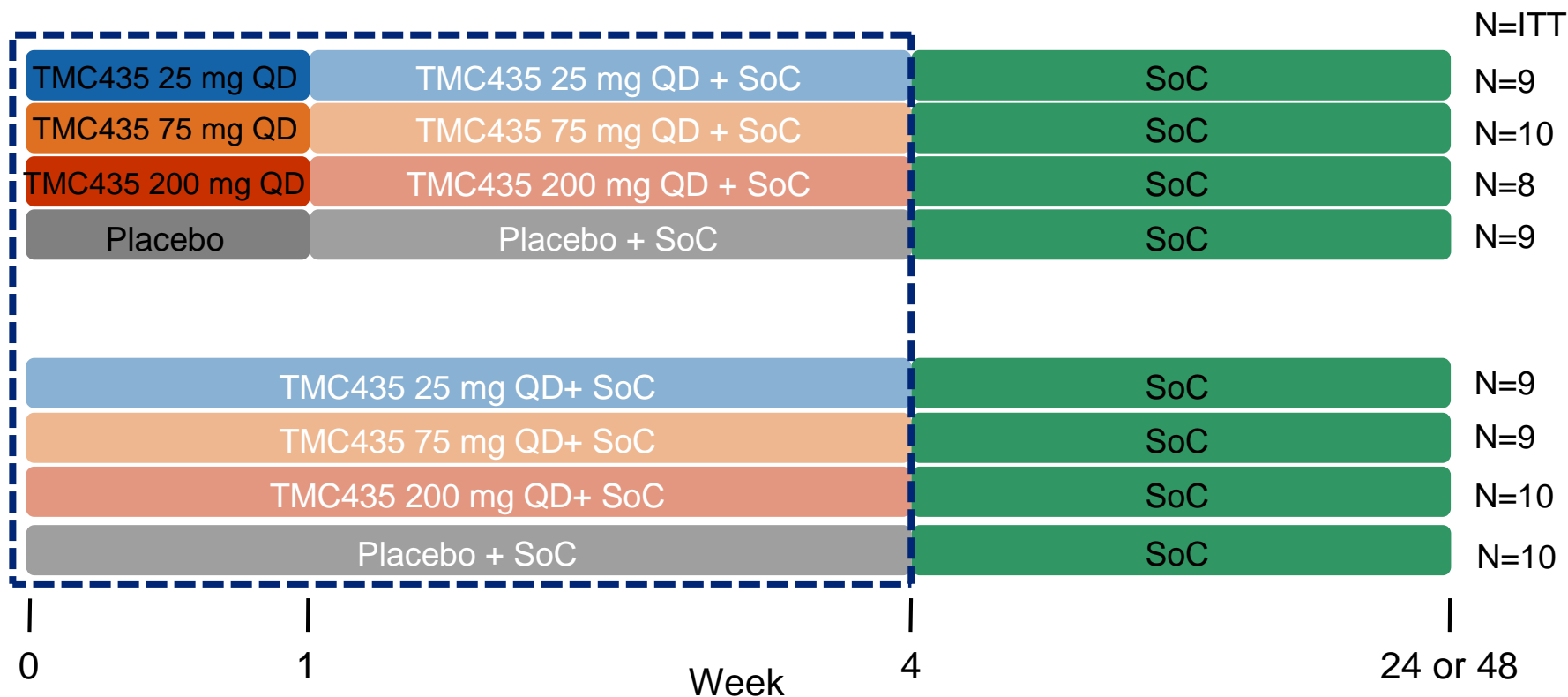
- in treatment naïve and treatment experienced

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, most pronounced in the highest dose groups. The mechanism of action is under active investigation.**

OPERA-1 (Cohorts 1 and 2): study design - Treatment-naïve, genotype-1 HCV-infected patients

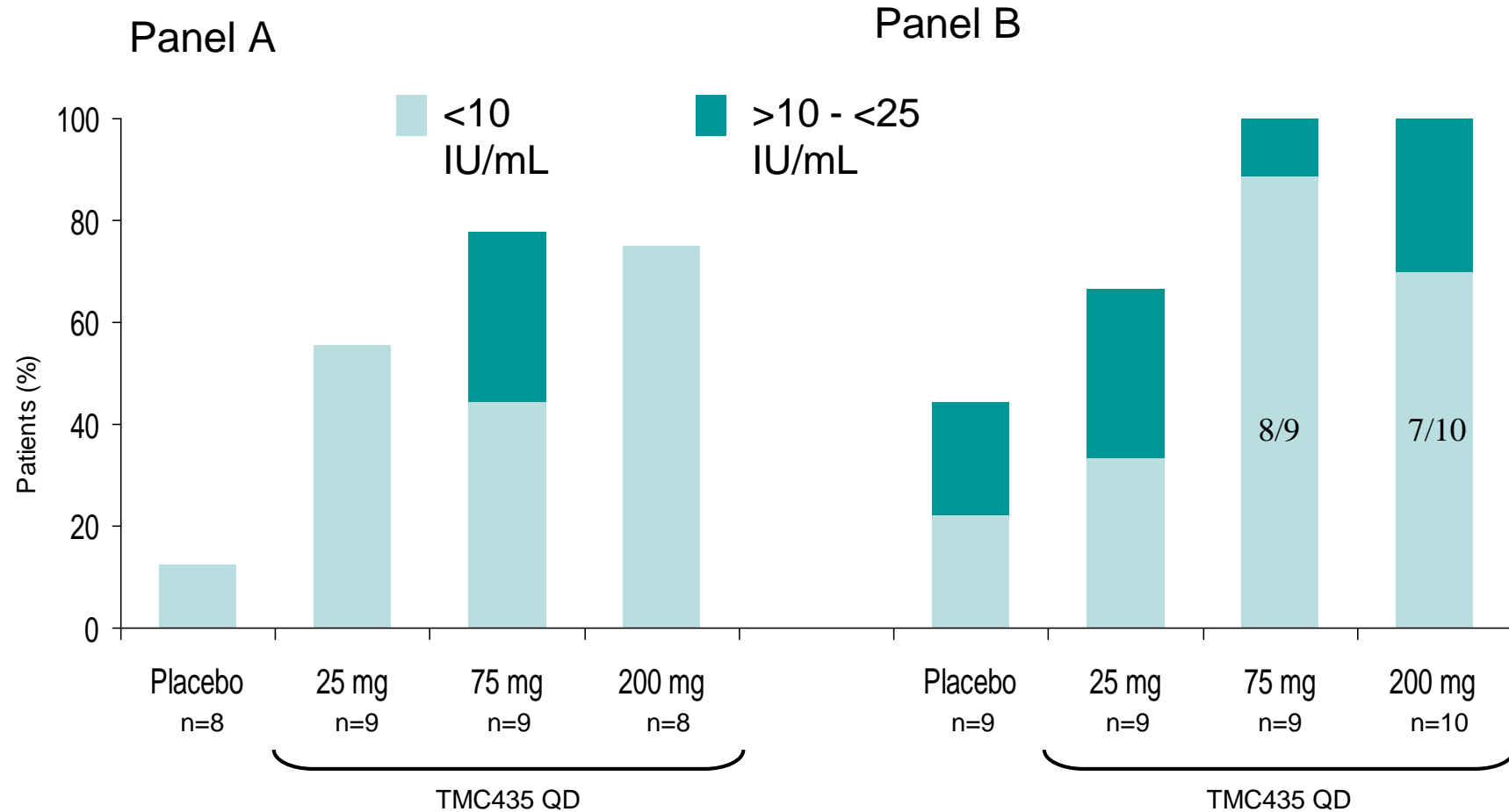
- Cohort 1: TMC435 25 and 75 mg QD
- Cohort 2: TMC435 200 mg QD



SoC = pegylated interferon α -2a + ribavirin (PEG-IFN α -2a + RBV)
 ITT, intent-to-treat population

TMC435: Phase IIa data - Potent Antiviral Activity at Day 28

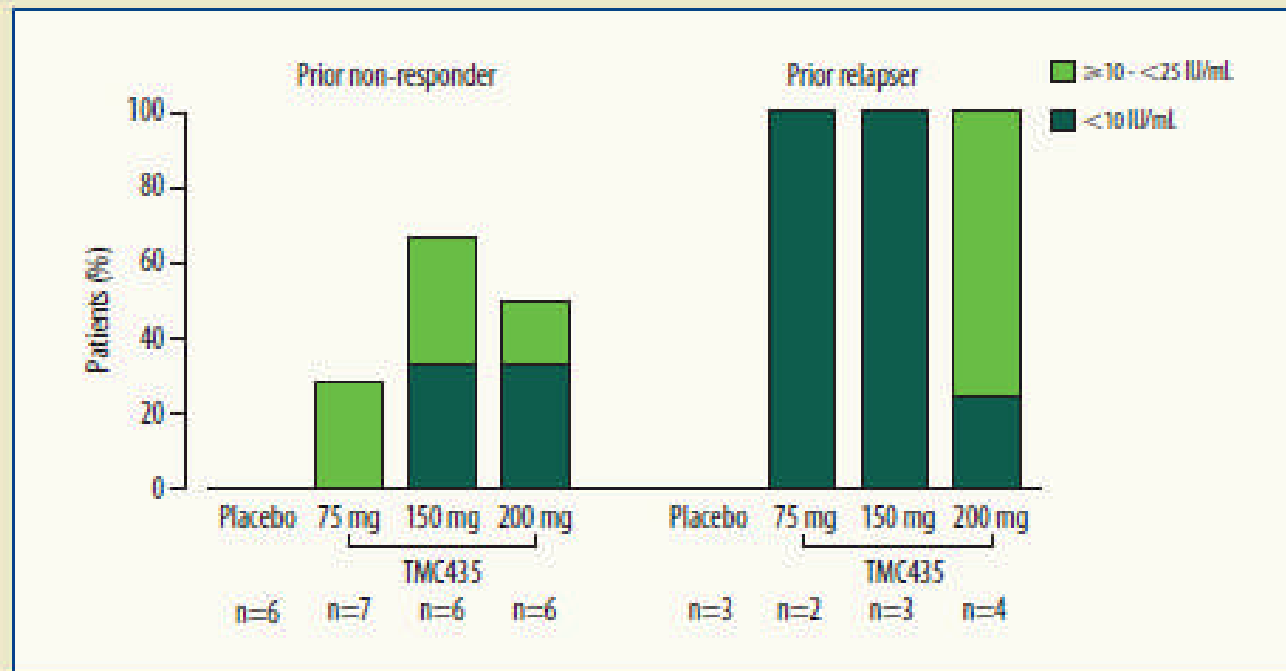
Treatment Naïve Patients



- 6/9 (67%) patients in the 25 mg arm, 9/9 (100%) patients in the 75 mg arm and 10/10 (100%) patients in the 200 mg arm of Panel B had HCV RNA <10 IU/mL at Week 12 (4-weeks TMC435 + SoC, 8-weeks SoC only)

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.



2/9 (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.

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

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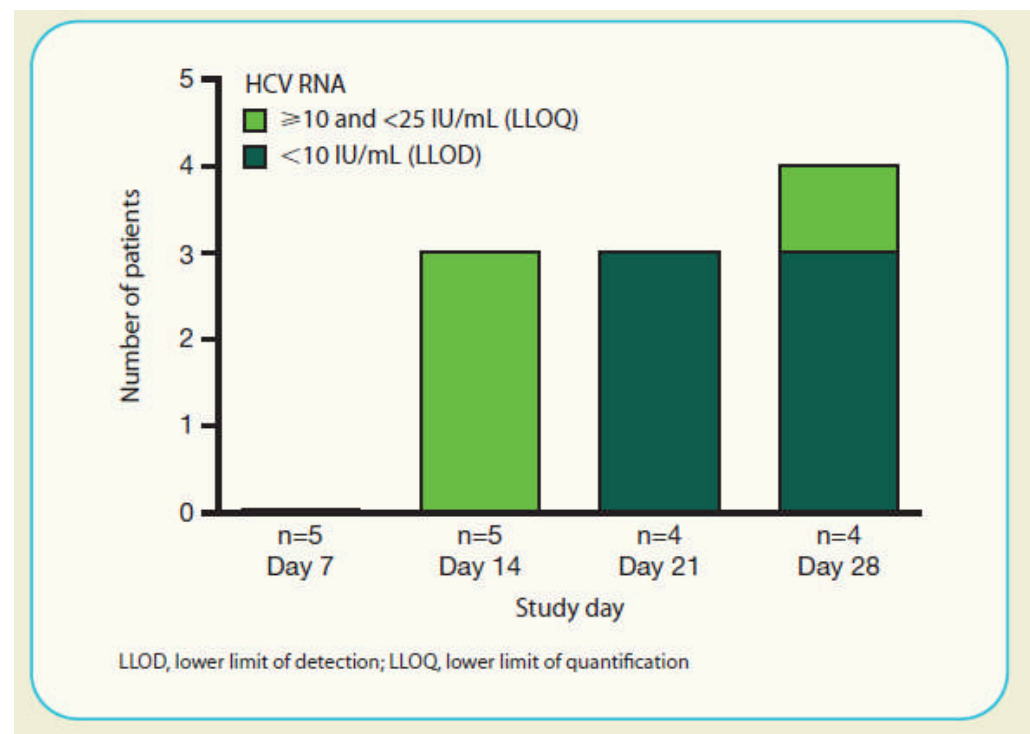
OPERA-1 is a Phase IIa double-blind, randomized, placebo-controlled trial investigating different doses of TMC435 in both treatment-naïve and treatment-experienced patients across multiple cohorts. Cohort 5 comprised prior non-responders and relapsers to interferon (IFN)-based therapy who had previously 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.



TMC435 – many different studies ongoing

The main ongoing clinical trials:

C205 (treatment-naïve) conducted in EU/US

Started in May 2009, all patients are enrolled as of mid October

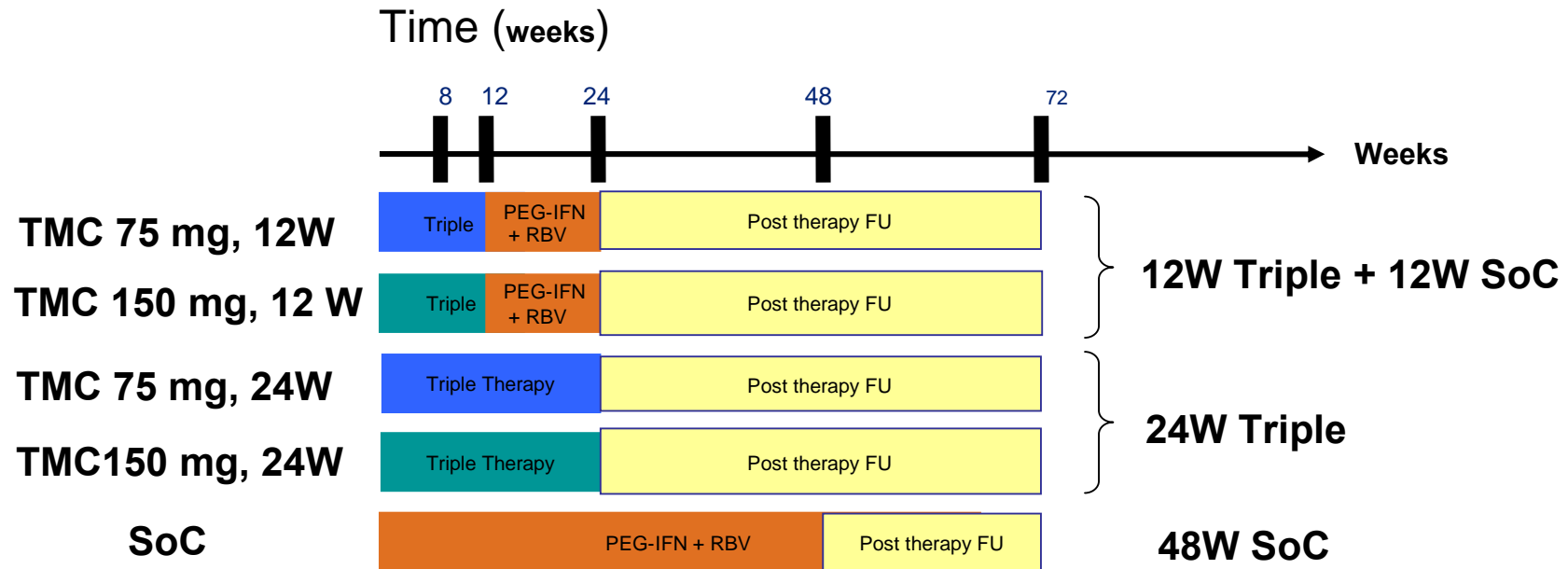
C206 (treatment-experienced) conducted in EU/US

Started end September, enrollment well under way

Additional 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

Phase IIb study (C205) in treatment-naïve HCV patients is ongoing, patient enrolment is completed

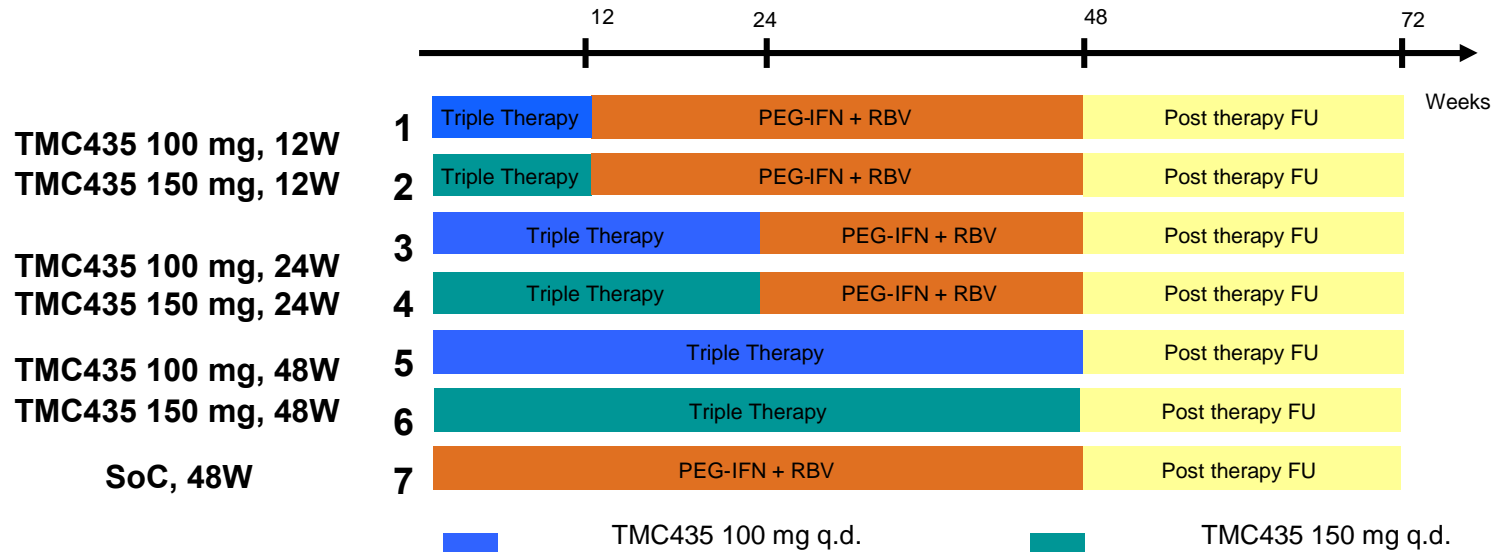


N = 400

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

Nucleoside HCV Polymerase Inhibitors

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

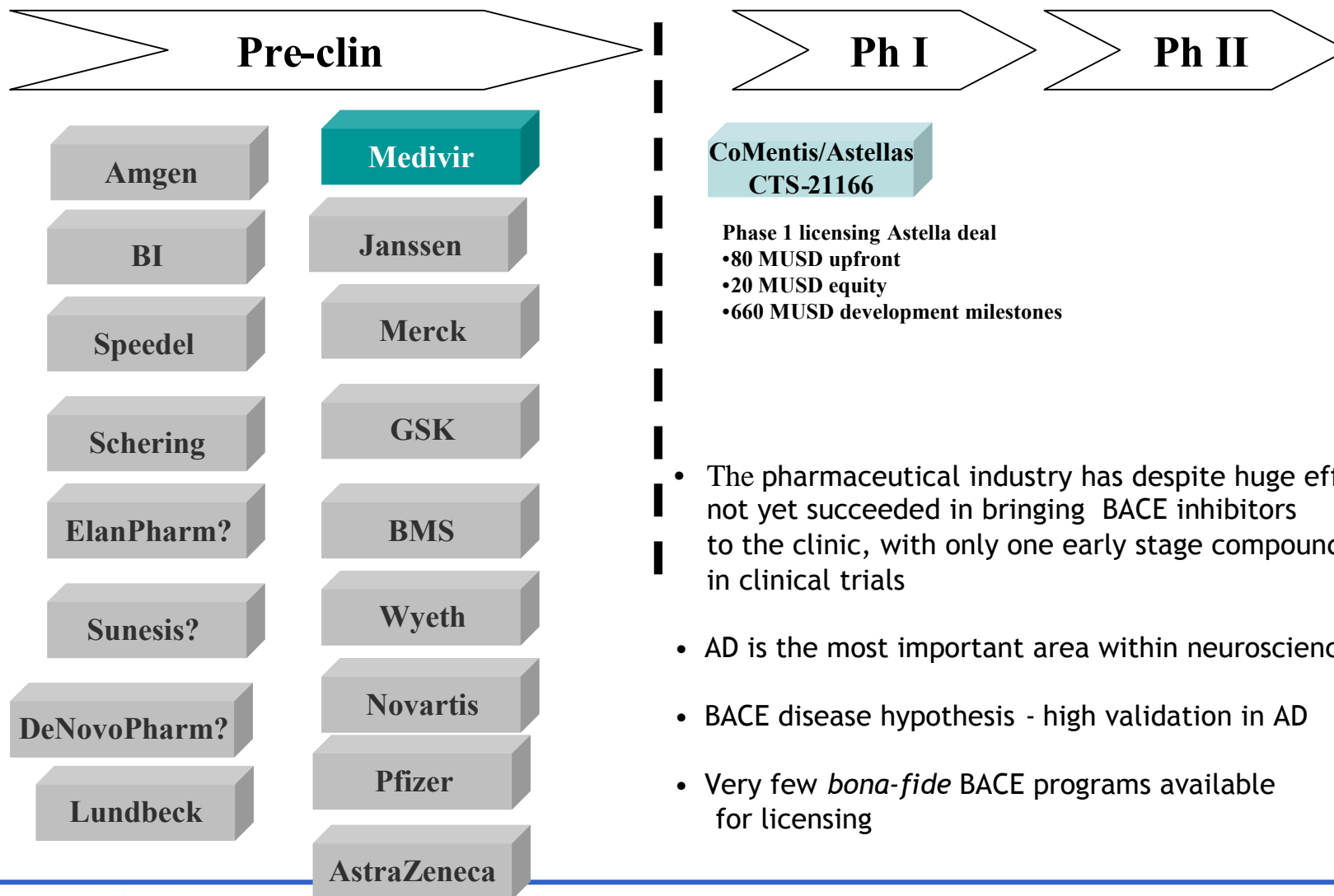
- Remaining milestones of € 137m + royalties on sales for one product reaching market.
- Additional € 130m for second compound and indication reaching market + royalties on sales.
- FTE Funding for one year, ended May 2009
- All development costs covered by JNJ
- Nordic rights retained by Medivir



BACE Inhibitors

Alzheimer's disease

BACE-1 Inhibitors in development



- The pharmaceutical industry has despite huge efforts not yet succeeded in bringing BACE inhibitors to the clinic, with only one early stage compound in clinical trials
- AD is the most important area within neuroscience
- BACE disease hypothesis - high validation in AD
- Very few *bona-fide* BACE programs available for licensing

Corporate objectives going forward

- **Continue to support partnered projects**
- **Lipsovir**
 - Launch Lipsovir in the Nordic region during Q1-2010
 - Sign a joint venture / partnering or distribution agreement in the US and prepare for product launch by summer 2010
 - Appoint distribution partners in Europe and prepare product launch by H2-2010
- **Continue and build R&D investment and partnering strategy [including the preclinical cathepsins K & S and BACE programs]**
- **Identify and/or acquire products to build a revenue generating part of Medivir**
- **Finish the ongoing pipeline overview by Q1-2010 and**
 - Close all R&D projects that are not partnered,
 - Revenue generating or
 - In the agreed pre-clinical research portfolio
- **Broaden our shareholder base outside the Nordic region**