A research based specialty pharmaceutical company focused on infectious diseases

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Medivir in a nutshell
– strong momentum in all parts of the company

- World class expertise in polymerase and protease drug targets - Strong pipeline of innovative infectious disease drugs
- All major projects are moving with a high momentum
- Medivir has a strong position in HCV drug development, four programs including all 3 validated target classes, two in-house driven
- 15 marketed products in the Nordics generating annual sales of €60 m with an EBITDA of ~€12 m
- Strong financial position, aiming for profitability in a few years

Our aim is to become a profitable research-based specialty pharmaceutical company with main focus on infectious diseases, which creates value for our shareholders and enhances patients' quality of life

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
- Daclatasavir (BMS)

NS5B nucleotide
Partnered with
Johnson&Johnson tibotec

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Internal NS5B nucleotide
Unpartnered

Internal NS5A project
Unpartnered

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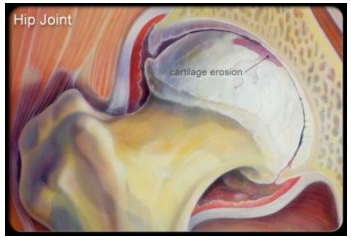
Strongly committed to innovation driven R&D - developing novel antivirals

Building on a longstanding protease inhibitor development experience

Two major internal cathepsin inhibitor programs:

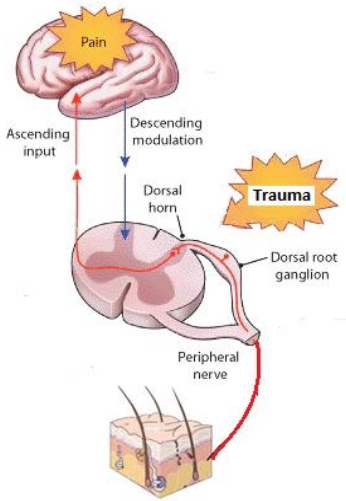
Cathepsin K:

- 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
- Phase I to start in Q2 2012



Cathepsin S:

- Neuropathic pain and autoimmune diseases
- Potent, selective and orally bioavailable inhibitors developed
- Proof-of-principle demonstrated in a rodent model of neuropathic pain
- Late optimization phase aiming for candidate drug selection 2012



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

Polymerase inhibitor – nucleotide NS5B inhibitor

- Properties similar to the most advanced clinical nucleotides
- Both purines and pyrimidines
- High potencies in the replicon assay
- High triphosphate levels and long triphosphate t1/2 in human hepatocytes
- No observed cytotoxicity
- Aiming for Candidate Drug selection in Q4, 2012

NS5A inhibitor

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

Internal unpartnered projects

Polymerase inhibitor – nucleotide NS5B inhibitor

Johnson & Johnson tibotec

•Liver targeted nucleotide polymerase inhibitor program as part of existing partnership

•Clinical Drug candidate selected and IND preparatory activities on-going

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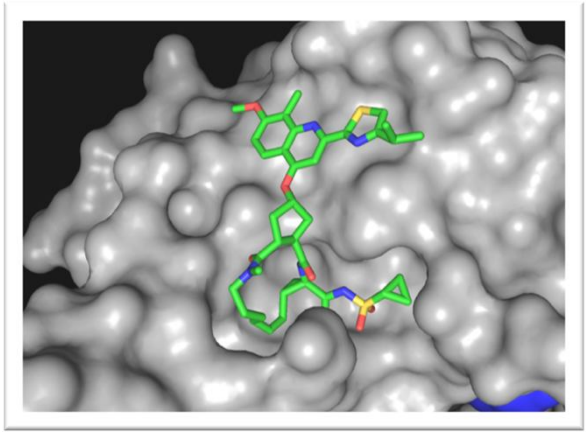
Strong commitment in hepatitis C
– four major programs on-going

Protease inhibitor – TMC435

- Investigational, one pill, once daily, oral HCV protease inhibitor
- Potent antiviral activity in patients infected with HCV genotype 1
- Antiviral activity demonstrated against genotypes 1, 2, 4, 5, and 6 isolates
- Favorable safety profile
- Currently in Phase III clinical development



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	Patient population	SVR24
PILLAR	Treatment naive	**81 - 86%**
DRAGON	Treatment naive (Japan)	**82%**
ASPIRE	Relapsers	**85%**
	Partial responders	**75%**
	Null responders	**51%**

Efficacious in broad HCV patient populations

- G1 population, the most prevalent and difficult-to-treat
  - o Treatment naïve and treatment experienced patients
  - o Cirrhotic and non-cirrhotic patients

Robust clinical efficacy data, and large safety data base with approximately 1800 patients treated today

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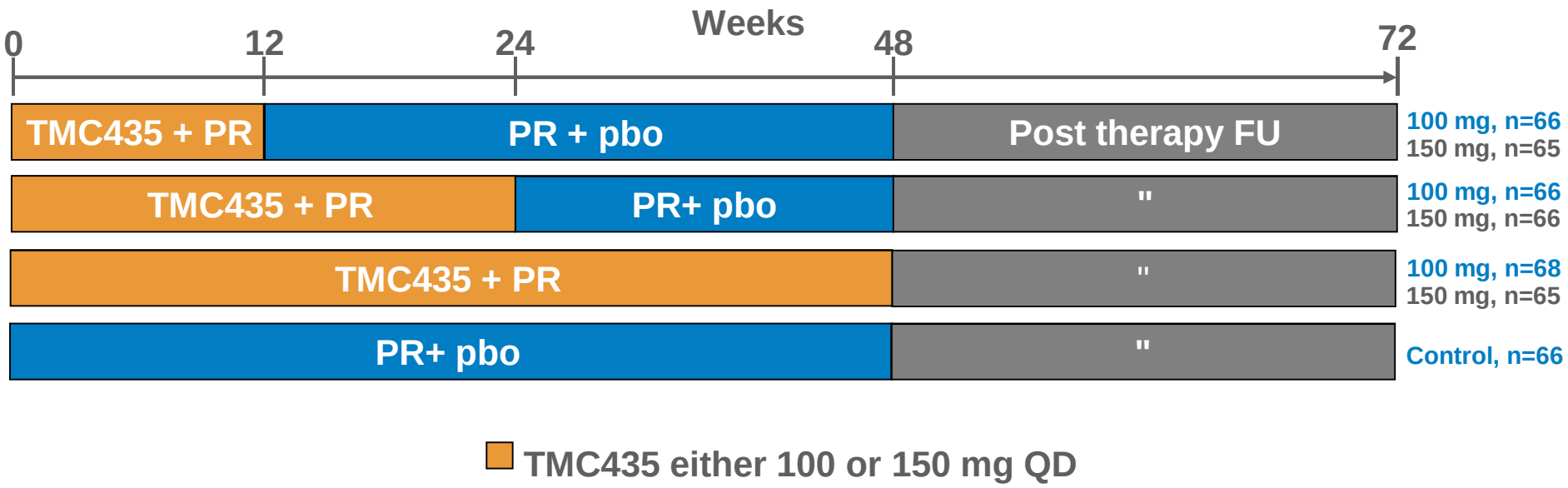
ASPIRE study:

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



- **Primary endpoint:** SVR24
- **Key secondary endpoints:** Virologic response at other time points, viral breakthrough and relapse rates, safety and tolerability

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ASPIRE study:
baseline demographics and disease characteristics

	TMC435 150 mg* PR48, n=199	Pbo PR48, n=66
Patient demographics		
Male, %	68	64
Race, White, %	93	94
Age, years, median (range)	50	50
Body weight, kg, median (range)	80.5	84.8
IL28B genotype CC†, %	17 (n=142)	22 (n=50)
Disease characteristics		
Genotype 1a, %	42	41
HCV RNA ≥800 000 IU/mL at baseline, %	85	83
Metavir Score, F3 / F4, %	15 / 20	20 / 16
ALT 2.5x-10x>Upper Limit of Normal, %	17 / 2	12 / 5

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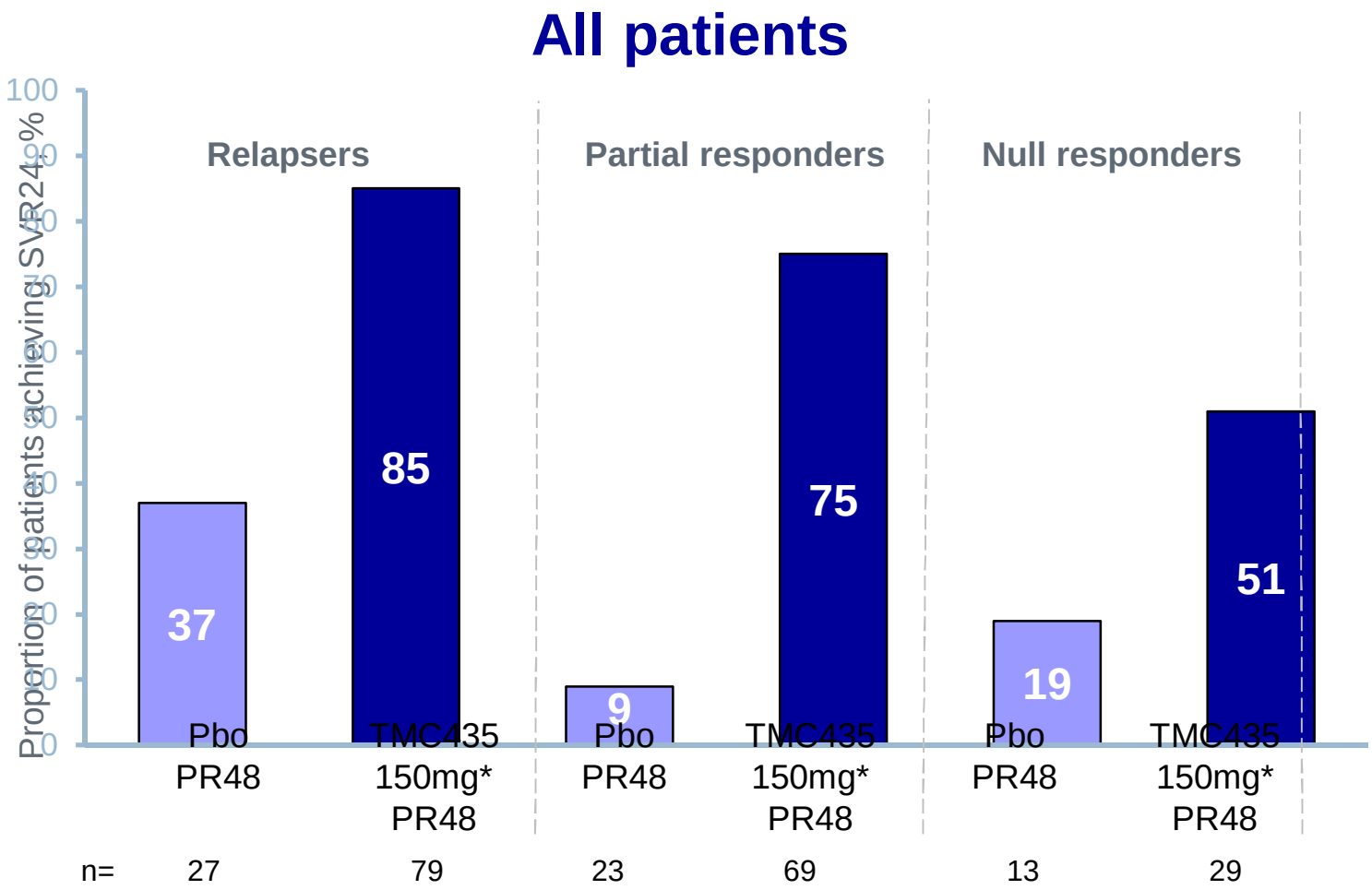
*Dose groups combined; †data available for patients who consented to DNA research only;

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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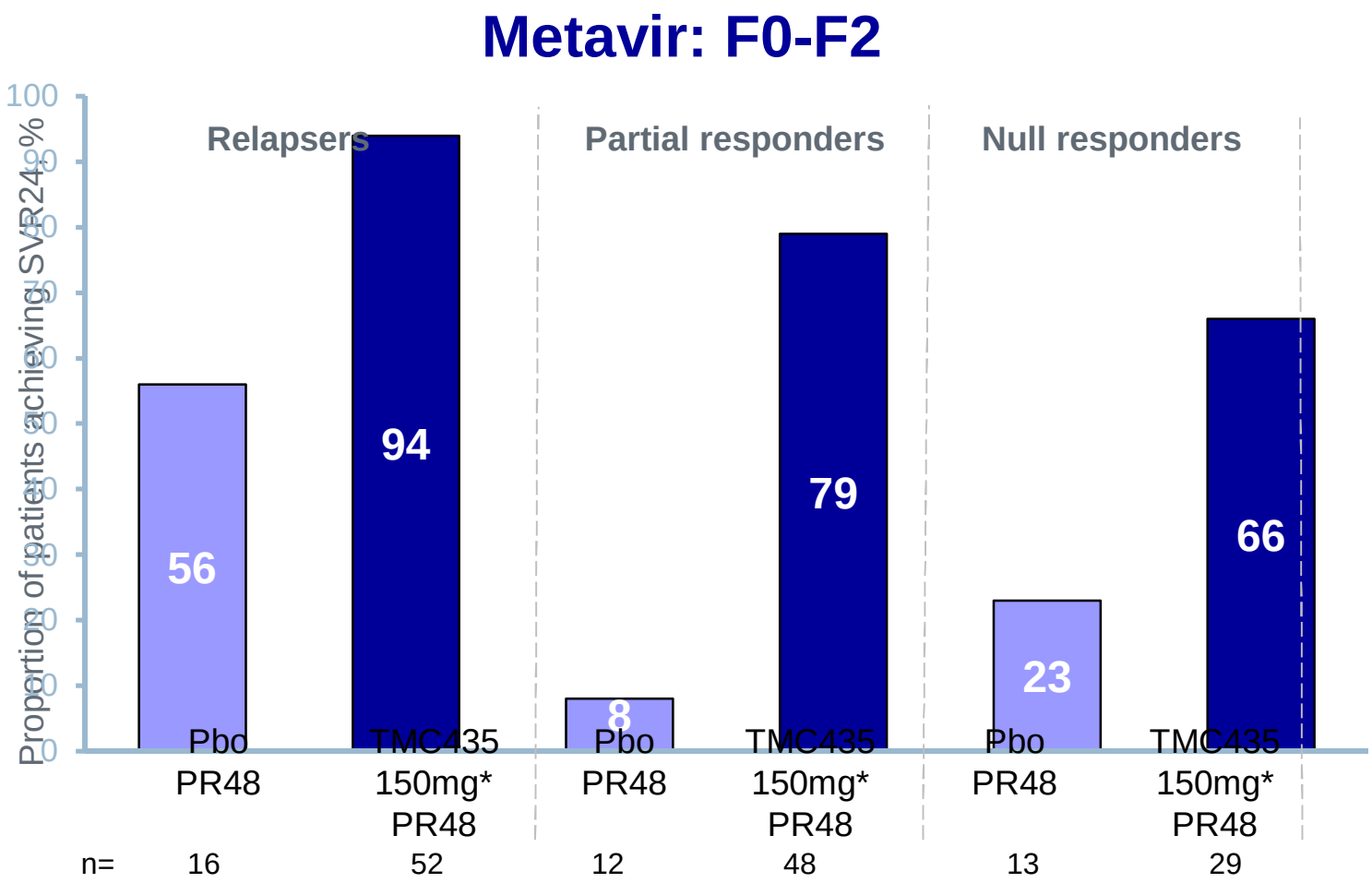
*Dose groups (treatment duration) combined;

ASPIRE study:

Proportion of patients achieving SVR24 by prior response

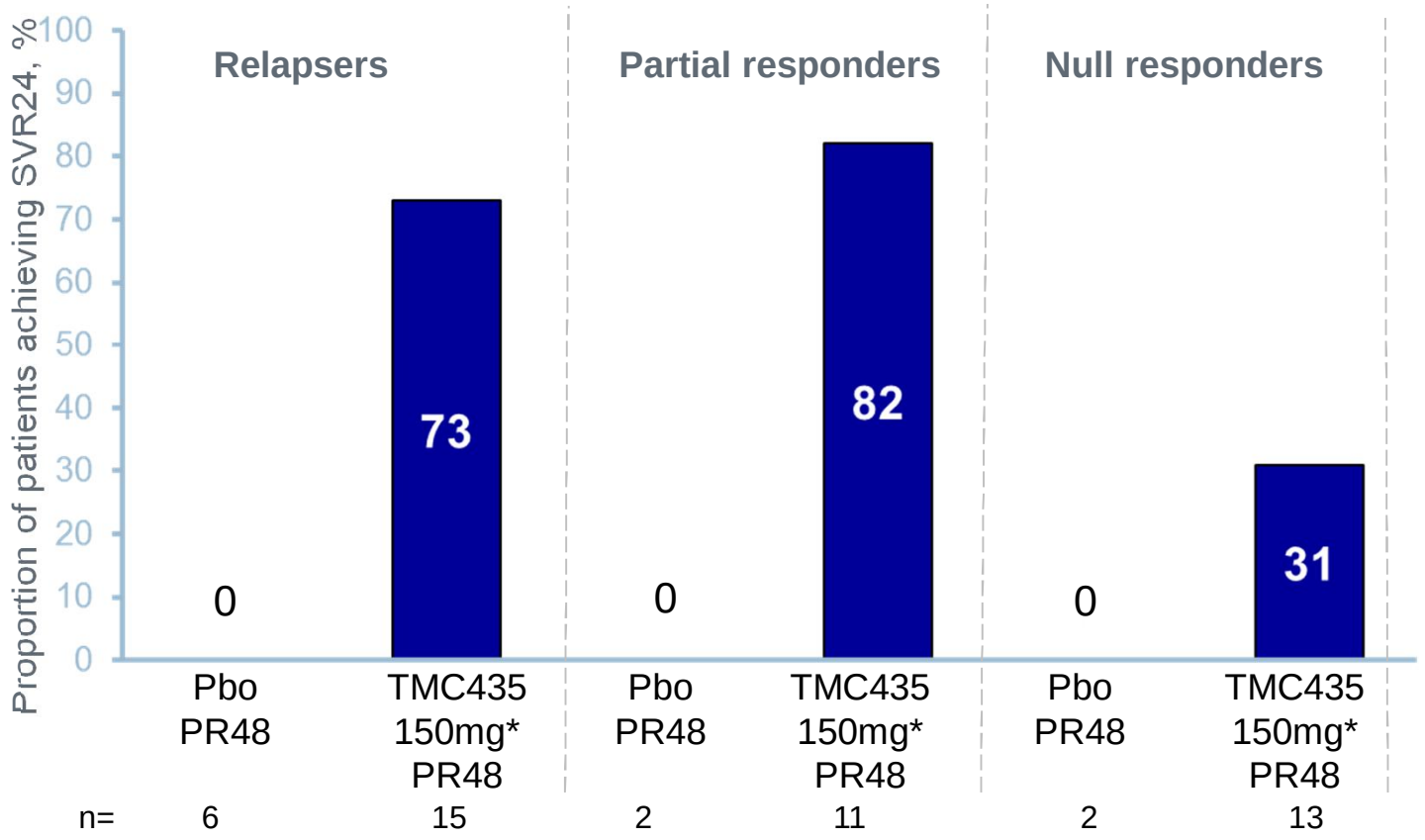


*Dose groups (treatment duration) combined;

ASPIRE study:

Proportion of patients achieving SVR24 by prior response

Cirrhotics (F4)



*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

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

ASPIRE study:
summary

- With TMC435 150 mg in combination with PegIFN/RBV:
  - 85% of prior relapsers achieved SVR24
  - 75% of prior partial responders achieved SVR24
  - 51% of prior null responders achieved SVR24
  - 73, 82, 31% in patients with cirrhosis (relapsers, partials, nulls)
- Once-daily TMC435 was well tolerated in this population

TMC-435: Best-in-class properties in triple combination standard of care treatment

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TMC435 - triple combination

broad phase III clinical development program in genotype-1

QUEST 1 treatment-naïve patients; n=375

QUEST 2 treatment-naïve patients; n=375

PROMISE (C3007) prior relapsed patients; n=375

Japan naïve & experienced patients; n=417 (four studies)

Fully enrolled Q3-11, all patients have finished their TMC435 treatment

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

TMC435 - triple combination

continued clinical development program

Selected ongoing studies:

C3001 comparing TMC435 vs telaprevir, in prior null or partial responders; *n=744*

C3011 open label, single arm phase III trial in treatment naïve or treatment experienced, HCV genotype-4 infected patients; *n=100*

C212 open-label study in patients co-infected with HIV; *n=94*

Strong commitment from our partner Janssen Pharmaceuticals

TMC435 – interferon free combinations

TMC435 and GS-7977 (nucleotide NS5B inhibitor)

–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), clinical phase II and III collaboration

–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, strongly positioned to become the principal component of future IFN-free therapies

Strong platform for a leading position in hepatitis C

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Internal NS5A project
Unpartnered

Hepatitis C – Treatment evolution

INF-free combinations delivers promise in early phase II trials

Bertil Samuelsson, CSA

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Evolution of HCV therapy

DAA combinations, INF-free and INF /RBV-free, are now evaluated in phase II clinical trials

Lessons learned from 1, 2 or 3 DAAs (+/- ribavirin)

- Proof-Of-Concept achieved
- Cirrhotic patient data are largely missing. These patients are the most difficult to treat and make up a substantial portion on the available patient pool
- SVR36 might be needed to capture real life relapse rates in an IFN-free setting

Ribavirin will not be part of future HCV combinations

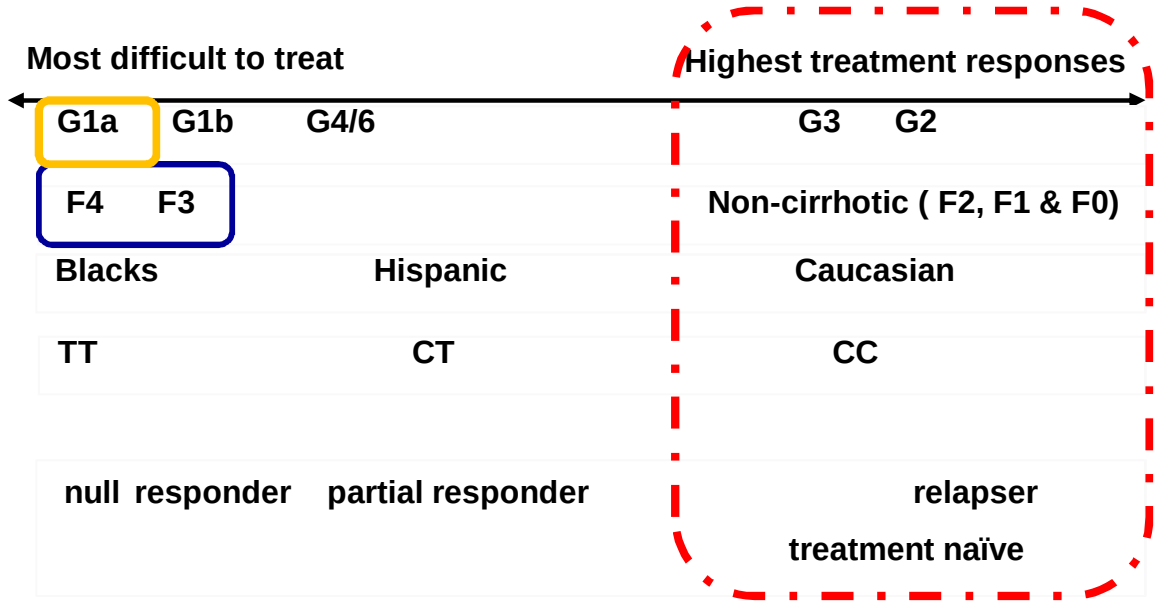
- Ribavirin has severe side effects and safety issues
- *Can cause severe adverse events in patients, e.g. hemolytic anemia, teratogenicity, cough, dyspnea, rash, pruritus, insomnia and anorexia. It is a powerful mutagenic agent and is contraindicated in pregnant women and patients with hemoglobinopathies*

Goals for next generation standard of care treatment s

- 2 DAAs in a combination - 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 and 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	% F4	% F3-4
ASPIRE	18	37

TM435 has in the three large phase IIb trials been addressing the most difficult to treat patients

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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

Combination: Two DAAs + ribavirin

- **BI-201335 + BI-207127 + RBV**
  - SVR12 60%, 16 weeks, G1 treatment naïve patients (SOUND-C2)
- **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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IFN-free combinations - proof-of-concept achieved

One DAA + ribavirin

– GS-7977 + RBV **Cirrhotic patients** **NO**

- o SVR4 11%, 12 weeks in G1 null responders (n=9) ELECTRON trial
- o SVR4 88%, 12 weeks, G1 treatment naïves (n=25), ELECTRON trial

– GS-7977 + RBV **Cirrhotic patients** **Yes**

- o SVR4 59%, 12 weeks, G1 treatment naïves (10/17), QUANTUM trial

One nucleotide DAA + RBV - likely suboptimal combination

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TMC 435 - summary

A best-in-class triple combination - TMC435 + P/R

Broad label and expected on the market by end of 2013 in e.g. EU, US and JPN

- Long patent life, IP extending to 2026 and 2028
- Safe and well tolerated – very important for treatment compliance once on the market
  - Close to 1800 patients have completed TMC435 treatments showing it to be safe and well tolerated
  - Over 1000 additional patients are currently being recruited
- 24-Week duration of treatment in both naïve and in experienced prior relapser patients (response guided)
- Highly efficacious in; a) G1a and G1b, b) treatment naïve and treatment experienced, c) cirrhotic and non-cirrhotic patients, d) regardless of IP-10 level or *IL28B* genotype, i.e. CC, CT or TT, as demonstrated in three large phase IIb trials (PILLAR, ASPIRE and DRAGON)
- Low dose, one tablet once daily, 12 weeks of TMC435,150mg – easy to remember and set up for a Fixed Dose Combination tablet
- Broad genotypic coverage

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Internal NS5A project
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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)