*A specialty pharmaceutical company focused on infectious diseases*

# Jefferies Health Care Conference
# London 27 September

**Rein Piir EVP Corporate Affairs & IR**

# Medivir in Brief

| | |
|---|---|
| **Listed:** | **1996** |
| **Ticker:** | **MVIR** |
| **Exchange:** | **OMX NASDAQ** |
| **Market Cap (SEK / €):** | **3.200 / 350 Million** |

## Focused infectious disease pipeline – multiple paths to value creation

- World leading science in the field of infectious disease
- TMC435 – a potential hepatitis C blockbuster in Phase III development
- 10 projects in clinical and pre-clinical development, 7 in partnerships with pharma, all Nordic marketing rights kept by Medivir

## Product sales and market presence

- Nordic infrastructure and sales of own products secured through acquisition of BioPhausia, today bringing € 50m in sales and €10 m in EBITDA.
- The launch of Xerclear® (in-house developed cold sore treatment) via partners initiated in the US (Rx) in March 2011 and in EU (OTC) by GSK expected in Q1-2012

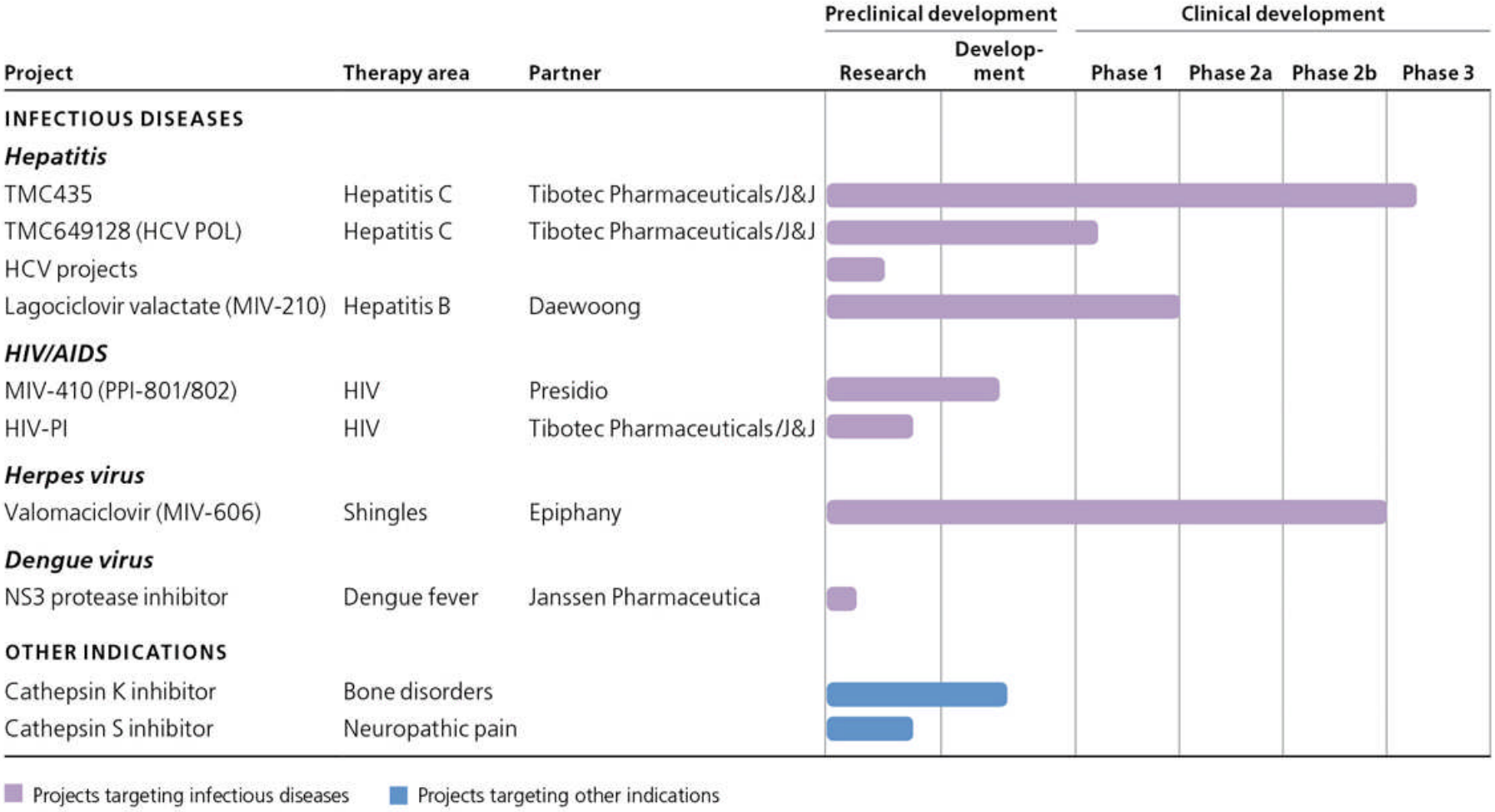
## Strong balance sheet

- €75 in cash and secured cash runway towards launch of TMC435 in late 2013

## Strong commitment of long-term institutional shareholders

- Approximately 30% international shareholders

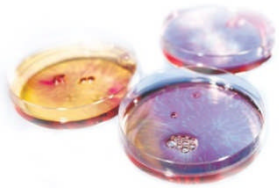
# Strong pipeline with multiple paths to value creation



# Key innovation and commercialisation at Medivir

## TMC435 – Considered best in class hepatitis C drug

- Excellent antiviral activity and strong safety profile demonstrated in Phase IIb studies
- High convenience – one pill, once daily, no food interactions
- Global Phase III trials and interferon-free combination trials ongoing



## Strong pipeline in development

- Strong pipeline of innovative infectious disease drugs
- World class expertise in polymerase and protease drug targets

**BioPhausia**

## Commercial presence and platform

- Product portfolio including strong brand names
- Established commercial platform to be used at TMC435 launch in Nordic region
- Key competence within regulatory affairs and logistics


## Xerclear® / Xerese™ - in global launch phase 2011

- Differentiated product profile - unique preventive effect and blue-chip marketing partners

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# Hepatitis C in the Nordic region
# - Major market with substantial growth potential

## The Nordic HCV market

- An estimated 115.000 chronic HCV patients in the Nordic region
- About 3.000 are currently treated yearly at a patient cost of SEK 175,000 ( €20,000)
- The treatment rates will increase as new, safer and improved treatments are introduced

## Medivir has retained the Nordic commercial rights

- High priority and focus on pre-launch activities to facilitate broad and rapid market access for TMC435 well in advance of launch
- Aiming to capture a significant share of the protease inhibitor market due to the highly competitive attributes of TMC435
- Medivir will in addition receive royalties from TMC435 sales in rest of the world

## 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 patient will rapidly increase as PI's gain recognition

# Our hepatitis C franchise

Partnered and in-house product portfolio

# Commercializing TMC435 – Our Core Product

- Strong safety profile: no adverse events over SoC in the Phase IIb PILLAR and ASPIRE studies
- Excellent anti-viral efficacy shown in Phase IIb PILLAR and ASPIRE studies
- High convenience: one pill, once daily, no food interactions
- Fully enrolled Phase III clinical trials: approval anticipated late 2013

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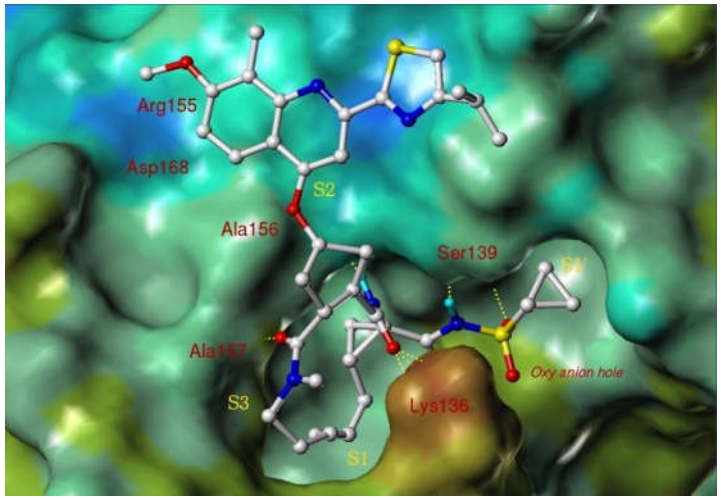
# Medivir commitment to HCV - TMC-435

## The commercial opportunity

- € 80.5 million deal value
  - € 30 million still outstanding
  - Royalties on sales worldwide
- Medivir retain Nordic market rights
  - Prevalence of chronic HCV infected ~115,000
  - Current treatment rates ~ 3 000




## Summary &Status

- Potent HCV NS3/4A protease inhibitor
- Broad global clinical development program ongoing:
  - Phase III combination trials with PEG/RBV ongoing
  - IFN-free combinations with DAA agents initiated and/or in planning phase
- Long patent life
  - IP extending to 2026 and 2028

***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 - Late Stage Clinical Development Program

## Phase IIb
**Follow Up**

**PILLAR (C205)** (n=386)
Genotype-1 infected treatment-naïve patients
*(SVR24 results at AASLD 2011)*

**DRAGON (C215)** (n=92)
Genotype-1 infected treatment-naïve patients
*(SVR24 results at Digestive week Japan Oct-11)*

**ASPIRE (C206)** (n=462)
Genotype-1 infected treatment-experienced patients
*(SVR24 results, late Q4-11)*

## Phase III
**Ongoing (fully enrolled)**

**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

**Japan phase III program**

Genotype-1 infected *naïve and treatment experienced* patients

## IFN free combination studies with other DAAs

**TMC435 and TMC647055,** a non-nucleoside NS5B inhibitor developed by Tibotec Pharma-ceuticals (initiated)

**TMC435 and PSI-7977,** a nucleotide NS5B inhibitor.
A Phase II, interferon-free, 12 or 24 weeks, +/- ribavirin PoC study in genotype-1 prior null responders (to be initiated)

**TMC435 and TMC649128,** a nucleoside NS5B polymerase inhibitor developed in collaboration with Tibotec (in planning)

**TMC-435: Regulatory filing in 2013, approval anticipated late 2013**

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For additional information please see www.clinicaltrials.gov

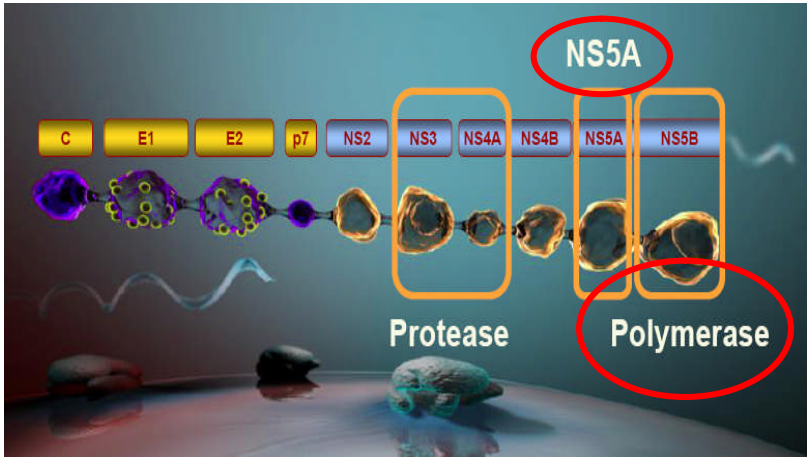
# Medivir commitment to HCV - 2nd DAA programs

## TMC649128 (HCV Pol)

Johnson&Johnson tibotec

### A major commercial opportunity

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




### Summary & Status

- Nucleoside/tide NS5B inhibitor
- An ideal DAA agent for future TMC435 IFN-free combination regimen
- High barrier to resistance and broad genotype coverage
- Long patent life
  - IP extending to 2027 and 2029
- Phase Ib trial in gt1 HCV patients initiated

### Preclinical In-House Programs

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

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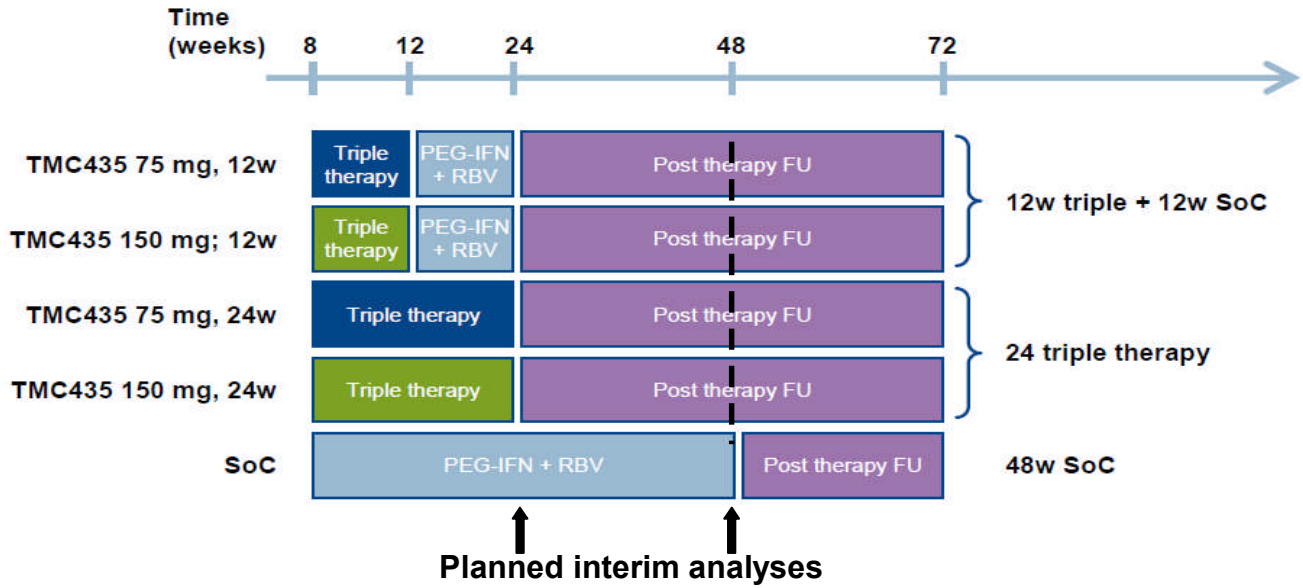
# Our hepatitis C franchise

## TMC435 - results clinical development

# TMC435 Phase 2b (PILLAR C205) - study design

- 386 genotype-1 treatment-naïve patients
- Once daily (*q.d.*), 75 mg and 150 mg TMC435 + SoC:
  - 12-week triple therapy followed by SoC alone up to week 24 or
  - 24-week triple therapy
- Response-guided TMC435 treatment duration:
  - 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



# TMC435 Phase 2b (PILLAR C205)
## - 48-week interim analysis of safety and efficacy (SVR24)

**Patient population:** Treatment-naïve genotype 1 patients

**Efficacy:** 83% of patients were able to stop all therapy at week 24 in the TMC435 treatment groups

Potent and consistent antiviral efficacy with SVR24 rates of up to 84%

**Safety:** 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

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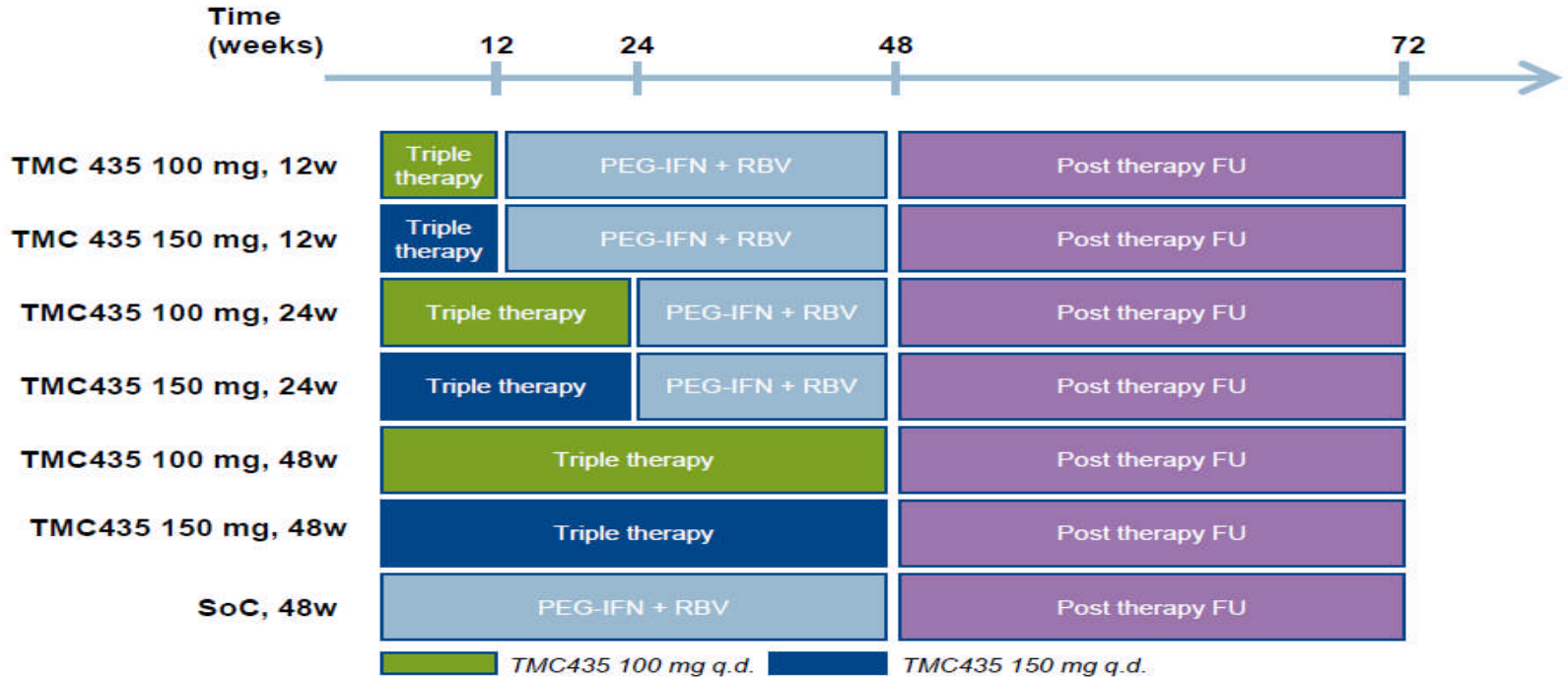
# TMC435 Phase 2b (ASPIRE C206, treatment experienced)
## - study design

- 462 genotype-1 treatment-experienced patients (relapser, partial- and null responder patients)
- Once daily (*q.d.*), 100 or 150 mg 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



# TMC435 Phase 2b (ASPIRE C206)
## - 48 week interim analysis of safety and efficacy

**Patient population:** Treatment experienced patient group
62 percent (287/462) of patients had advanced liver disease (Metavir F2-F4)

**Excellent Efficacy:** TMC435 shows high SVR4 rates in prior treatment failures, also in the very difficult to treat partial and null responder patient groups, compared to PEG/RBV alone:

- 87% vs. 50% in prior relapsers,
- 77% vs. 11% in prior partial responders and
- 57% vs. 23% in prior null responders

**Promising Safety:** TMC435 was safe and well tolerated at all doses and treatment durations

| Virologic Response Rates in TMC435 Dose Groups (150 mg q.d.) vs Placebo | | | | | | |
|---|---|---|---|---|---|---|
| % (n/N) | | TMC435 **12**PR48 N=66 | TMC435 **24**PR48 N=68 | TMC435 **48**PR48 N=65 | **All TMC435** PR48 N=199 | **Placebo** PR48 N=66 |
| **Prior Relapser** | **EoT** | 92 (24/26) | 93 (25/27) | 92 (24/26) | **92** (73/79) | **70** (19/27) |
| | **SVR4** | 84 (21/25) | 93 (25/27) | 85 (22/26) | **87** (68/78) | **50** (12/24) |
| **Prior Partial Responder** | **EoT** | 78 (18/23) | 83 (20/24) | 86 (19/22) | **83** (57/69) | **17** (4/23) |
| | **SVR4** | 64 (14/22) | 86 (18/21) | 82 (18/22) | **77** (50/65) | **11** (2/18) |
| **Prior Null Responder** | **EoT** | 65 (11/17) | 71 (12/17) | 77 (13/17) | **71** (36/51) | **25** (4/16) |
| | **SVR4** | 56 (9/16) | 60 (9/15) | 56 (9/16) | **57** (27/47) | **23** (3/13) |

# TMC435 Phase 2b (ASPIRE C206)

## - 48-week interim data compared with competitor drugs

- **Excellent efficacy**
  - high SVR4 rates in prior treatment failures, also in the very difficult to treat partial and null responders
  - high efficacy demonstrated despite large proportion of patients with cirrhosis and advanced liver disease; **62 percent** (Metavir F2-F4)
- **Promising safety profile**
  - safe and well tolerated at all doses and treatment durations

**Virologic Response Rates in TMC435 and clinical competitor HCV PIs**

| % (n/N) | | BI201335<br>BI24PR48 | Telaprevir INCIVIK<br>T12PR48 | Boceprevir VICTRELIS<br>B44PR48 | TMC435<br>PR48 | Placebo<br>PR48 |
|---|---|---|---|---|---|---|
| Prior Relapser | **SVR4** | - | - | - | **87** | **50** |
| | **SVR24** | - | **86** | **75** | | |
| Prior Partial Responder | **SVR4** | - | - | - | **77** | **11** |
| | **SVR24** | **50** | **59** | **52** | | |
| Prior Null Responder | **SVR4** | - | - | - | **57** | **23** |
| | **SVR24** | **35** | **32** | - | | |

# TMC435 Phase 2b (ASPIRE C206)

## - treatment experienced patients

### Conclusions 48-week interim analysis:

- ✓ TMC435 treatment arms demonstrate excellent SVR4 response rates in all patient subgroups
- ✓ Notably, the partial and null responder groups demonstrated significant response rates
- ✓ TMC435 was safe and well tolerated

# Upcoming News Flow

## Expected key news flow highlights during the coming 6 month

- ✓ Q2 TMC435, 48-week interim data from the Phase IIb C206 (ASPIRE) trial in treatment-experienced patients
- ✓ Q2 Closing of the BioPhausia offer
- ✓ Q2 Start of Phase Ib trials with TMC649128
- ✓ Q3 TMC435 receives Fast Track Designation from FDA
- ✓ Q3 TMC435 enters in two DAA combination trials
- ✓ Q3 TMC435 Phase III enrollment completed
- ✓ Q3 Appointment of new CEO, Maris Hartmanis
- Q4 Digestive week Japan - C215 (DRAGON) full SVR24 data
- Q4 AASLD - C205 (PILLAR) full SVR24 data
- Q4 AASLD – additional data on TMC435
- Q4 C206 (ASPIRE) full SVR24 data
- Q4 Phase Ib results with TMC649128
- Q1 OTC launch of Xerclear® in Europe by GSK
- Q1-12 Start of Phase I trials with MIV-711
- Q1-12 Start of Phase III trials with TMC435 in prior null and partial responder patients