



# Medivir

*A specialty pharmaceutical company focused on infectious diseases*

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**Presenter:  
Rein Piir CFO / IR**

## Medivir in Brief

Listed:	1996
Ticker:	MVIR
Exchange:	OMX NASDAQ
Market Cap (SEK):	3,900 Million

### First Product Xerclear™ / Xerese™ in Global Launch Phase

- Launch begun in Nordic region; Launched in US March 2011
- Nordic infrastructural and commercial capability secured through acquisition of BioPhausia

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

- World leading science in the field of infectious disease R&D
- TMC435 – a potential blockbuster in hepatitis C
- 10 projects in clinical and pre-clinical development
- 7 partnerships with pharmaceutical and biotech companies

### Experienced international management team

- Company supported by a highly experienced team with a strong skill base to ensure Medivir's success

### Strong long-term commitment of institutional shareholders

- Over 1/3 international shareholders

## Medivir Vision



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

# Medivir's Strategy

**Our goal is to become a profitable specialty pharmaceutical company focused on the development and commercialisation of high-value infectious disease treatments**

- Continue to innovate and be a partner of choice, creating value for our partners and shareholders
- Create and retain more value in our projects: later licensing, co-development rights, expanded territories
- Be looking for product in-licensing and acquisition opportunities globally

# Key Innovation and Commercialisation at Medivir



## TMC435 - Potentially best in class hepatitis C drug

- Strong safety profile – no adverse events over SoC in P2b
- Excellent antiviral activity in P2b PILLAR and ASPIRE studies
- High convenience – one pill, once daily, no food interactions
- Global Phase 3 trials ongoing



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

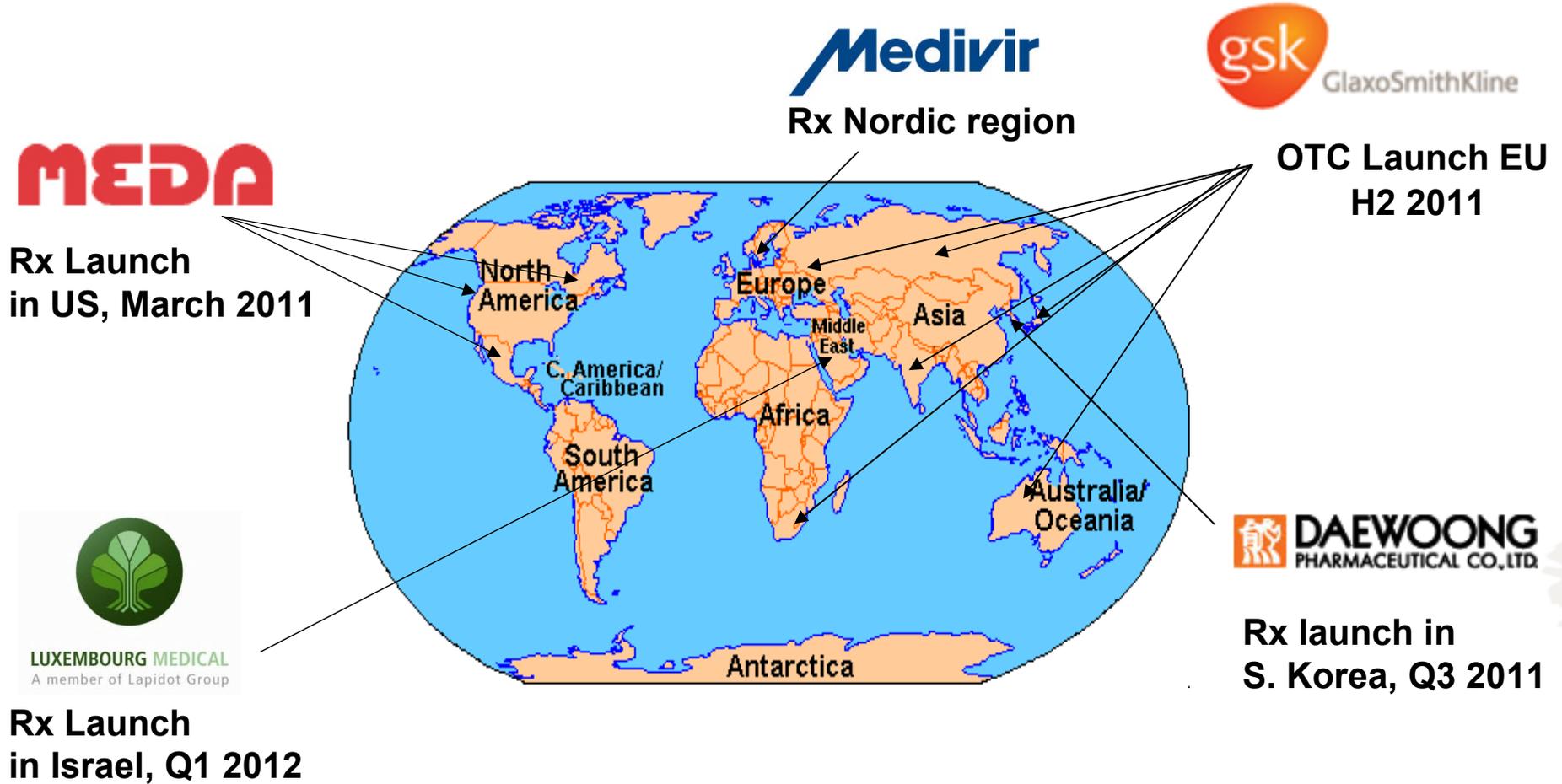
- First step towards becoming a profitable research-based pharmaceutical company
- Differentiated product profile - unique indication text
- Significant blue-chip marketing partners.



## Strong Pipeline in development

- A strong pipeline of innovative infectious disease drug candidates in development with leading pharma partners
- World class expertise in polymerase and protease drug targets and drug development

# Global Launch of Xerclear®/Xerese® 2011



# 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 capture a significant share of the protease inhibitor market due to highly competitive attributes of TMC435
- To give high priority and focus on pre-launch activities to facilitate broad and fast market access for TMC435 well in advance of launch

## Unmet medical need – Large market with substantial growth potential

- 115,000 Chronic HCV patients in the Nordics
- 3,150 HCV receive treatment at a yearly treatment cost of SEK 175.000m (SoC)
- 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 2012. TMC will be second generation protease inhibitor to enter market.

## 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 increase over time as PI's gain recognition

# Acquisition of BioPhausia – our new commercial capability



## BioPhausia



- **Best-in-class hepatitis C drug** with blockbuster potential
- **Recognition** through prominent partner



- **Proven capability** of taking a drug from idea to market
- **Strong cash position** – business approaching sustainable revenue stream



- One of the most **promising hepatitis C portfolios**
- Strong **track record in discovery** of clinical candidate drugs in infectious disease




- Established **commercial platform**
- Broad **knowledge and experience** in several therapy areas



- **Key competence** within regulatory affairs, sales and distribution
- **Small and flexible organisation** - quick response time and decisions



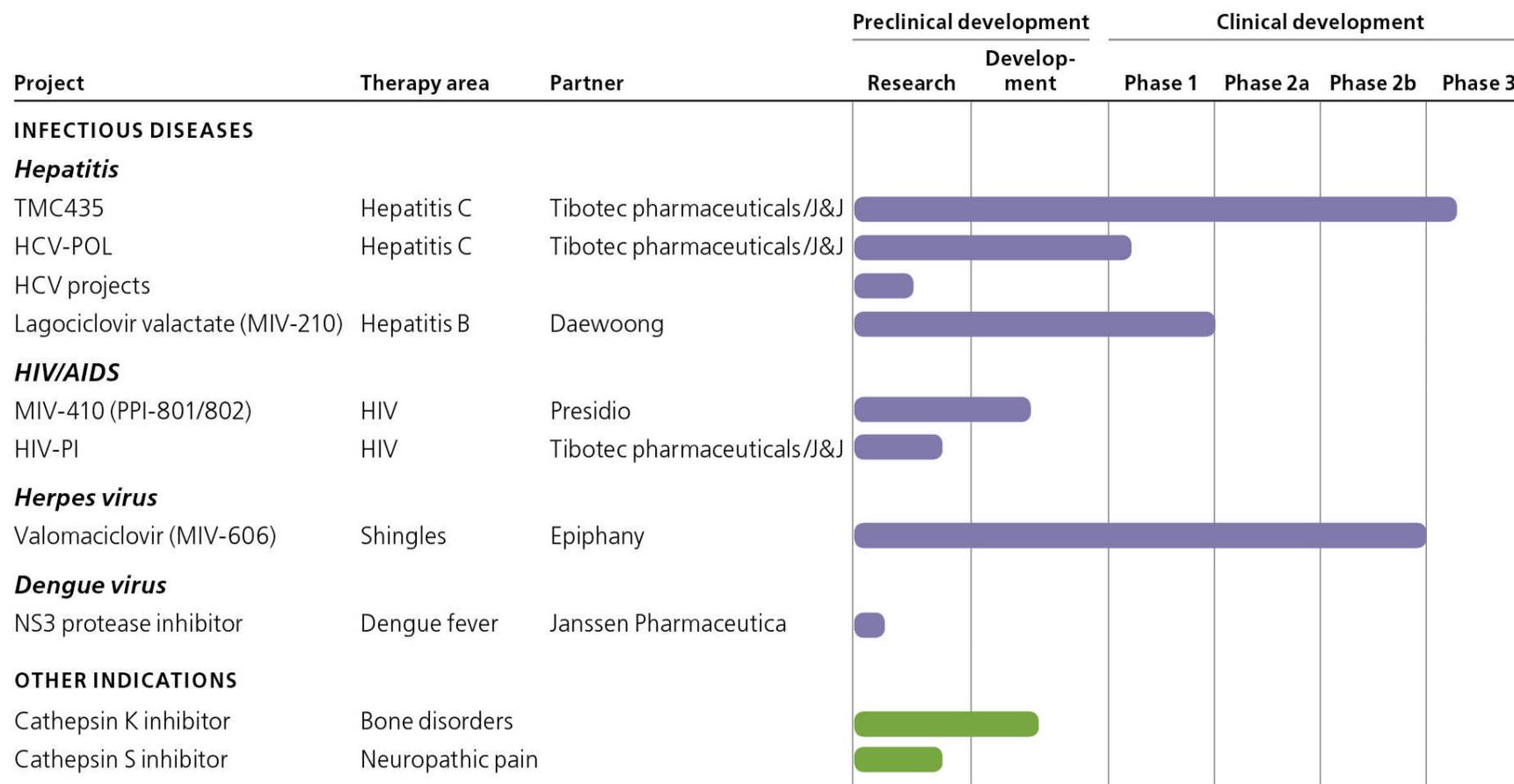
- **Product portfolio** including strong brand names
- **Network** with world-leading drug manufacturers



Expanded commercial platform  
 Customer facing brands maintained  
 Strengthened position to facilitate and optimise expected launch of TMC435 in the Nordic region



# Strong Pipeline with Multiple Paths to Value Creation



■ Projects targeting infectious diseases    ■ Projects targeting other indications

# Upcoming News Flow

## Expected key news flow highlights during 2011

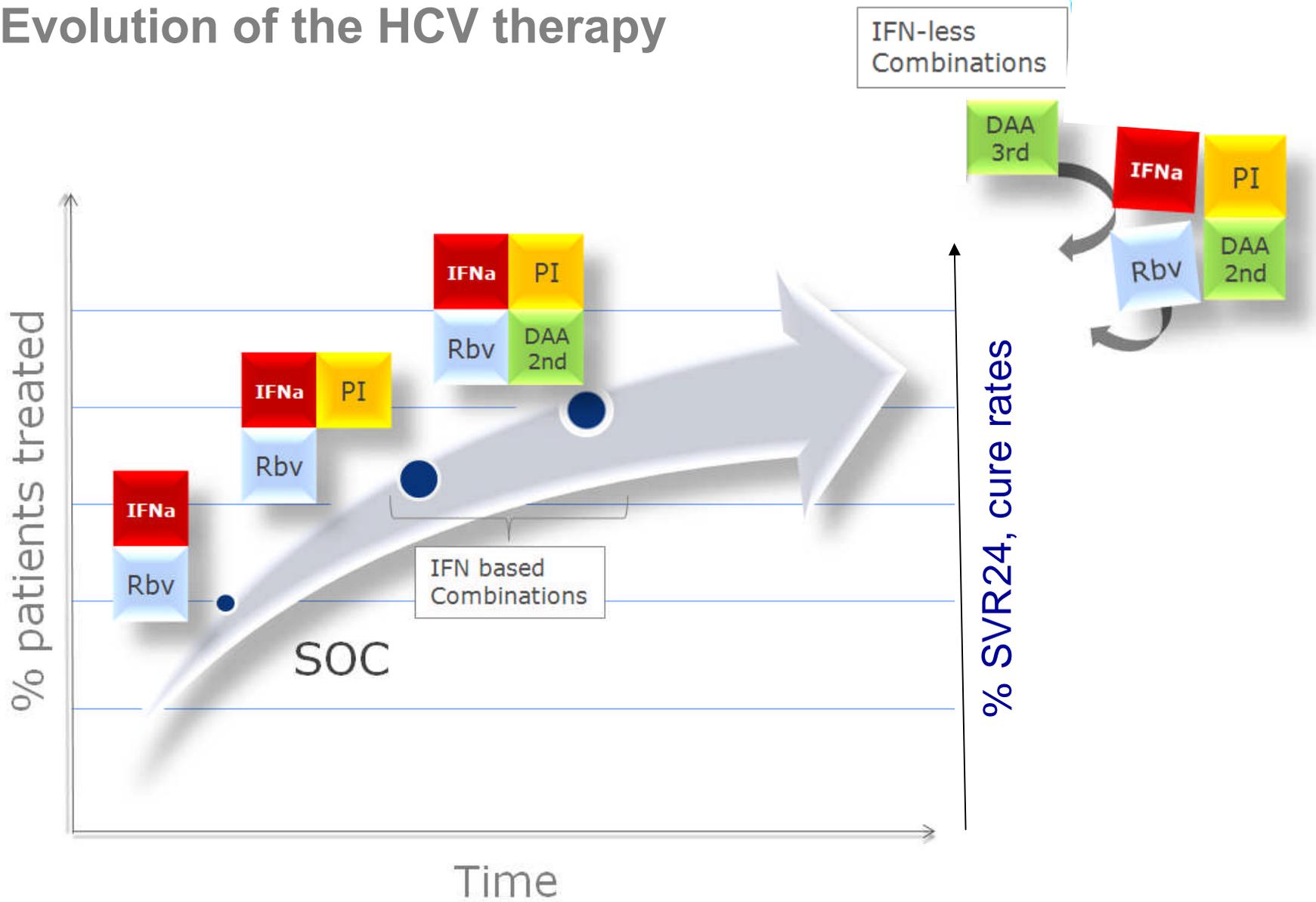
- ✓ Q211 TMC435, 48-week interim data from the phase 2b C206 (ASPIRE) trial in treatment-experienced patients
- Q211 Closing of the BioPhausia offer
- Q3-11 C205 (PILLAR) full SVR24 data
- Q3-11 Start of phase 1b trials with TMC649
- Q4-11 Start of phase 3 trials with TMC435 in treatment-experienced null responders and partial responders patients
- Q4 Phase 1a/1b results with TMC649
- Q4-11 Start of phase 1 trials with MIV-711
- Q4 AASLD – additional data on TMC435
- Q4-11 OTC launch of Xerclear® in Europe by GSK



# **Our hepatitis C franchise**

Partnered and in-house product portfolio

# Evolution of the HCV therapy



# HCV Clinical Pipeline

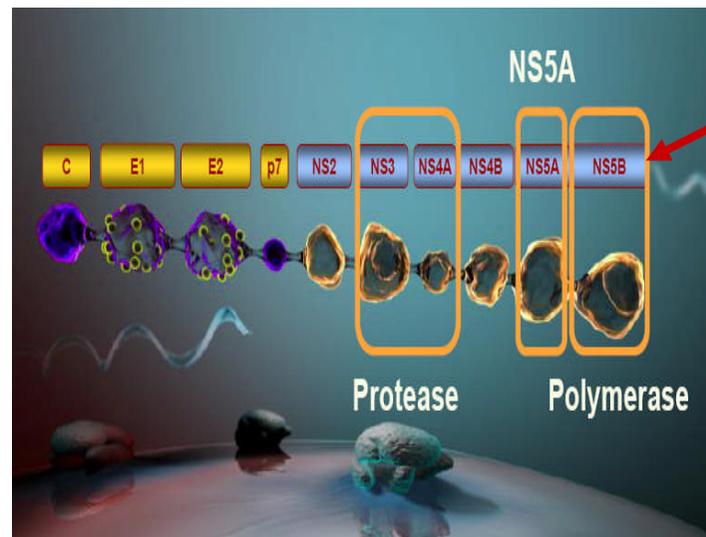


## TMC649 (HCV Pol) – a major commercial opportunity

- EUR 147 million deal value
  - ~ EUR 100 million outstanding
  - Royalties on global sales
- Medivir retain Nordic market rights
  - Prevalence of chronic HCV infected ~115,000
  - Current treatment rates ~ 3 000

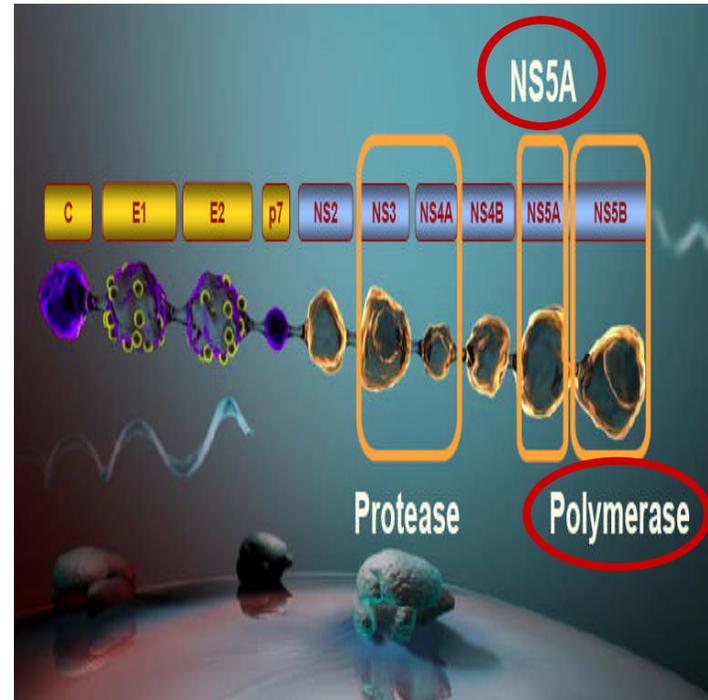
## TMC649 (HCV Pol) – summary status

- 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

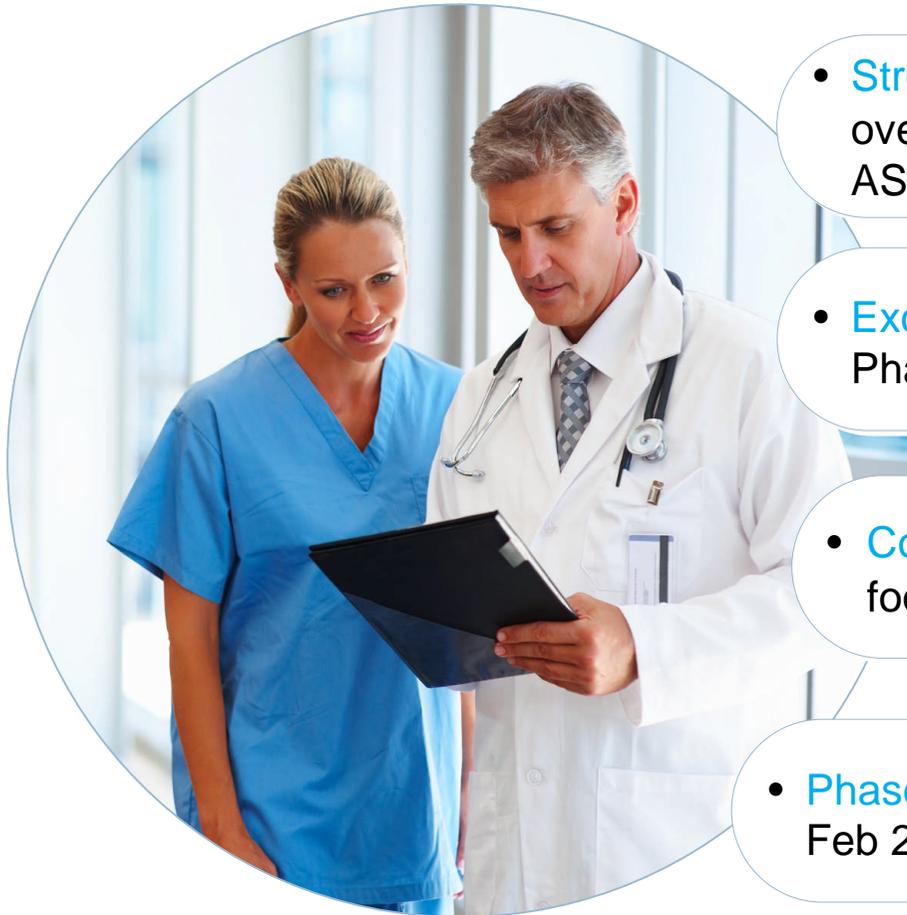


# HCV Preclinical In-House Programs

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



# Commercializing TMC435 – Our Core Product



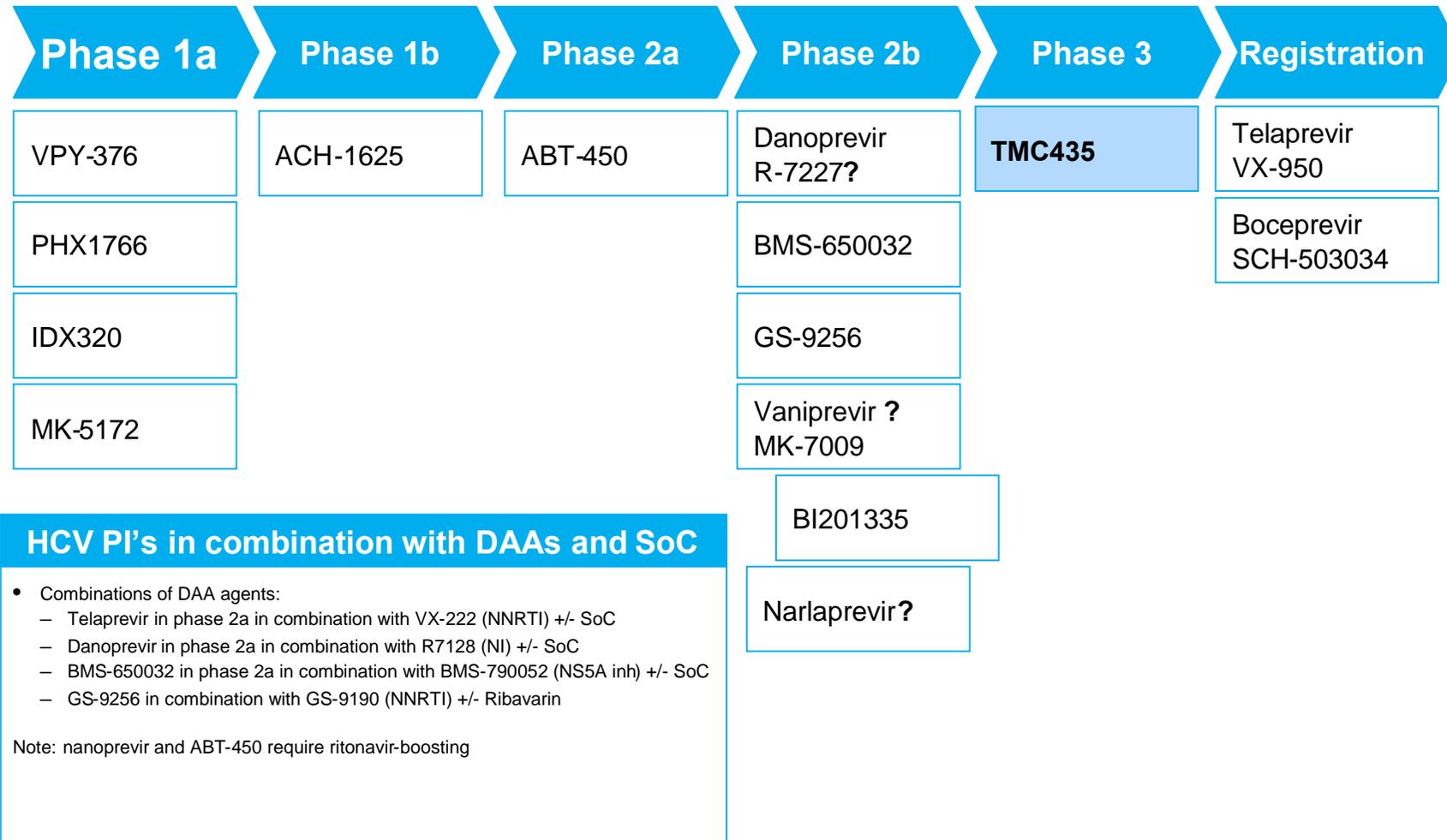
- **Strong safety profile:** no adverse events over SoC in the Phase 2b PILLAR and ASPIRE studies

- **Excellent anti-viral efficacy** shown in Phase 2b PILLAR and ASPIRE studies

- **Convenient:** one pill and once daily, no food interactions

- **Phase 3 clinical trials:** underway since Feb 2011, recruitment progressing well

# Hepatitis C PI – the competitive landscape



# 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](http://www.clinicaltrials.gov)

# TMC435 Phase 2b: Strong Safety and Efficacy Data

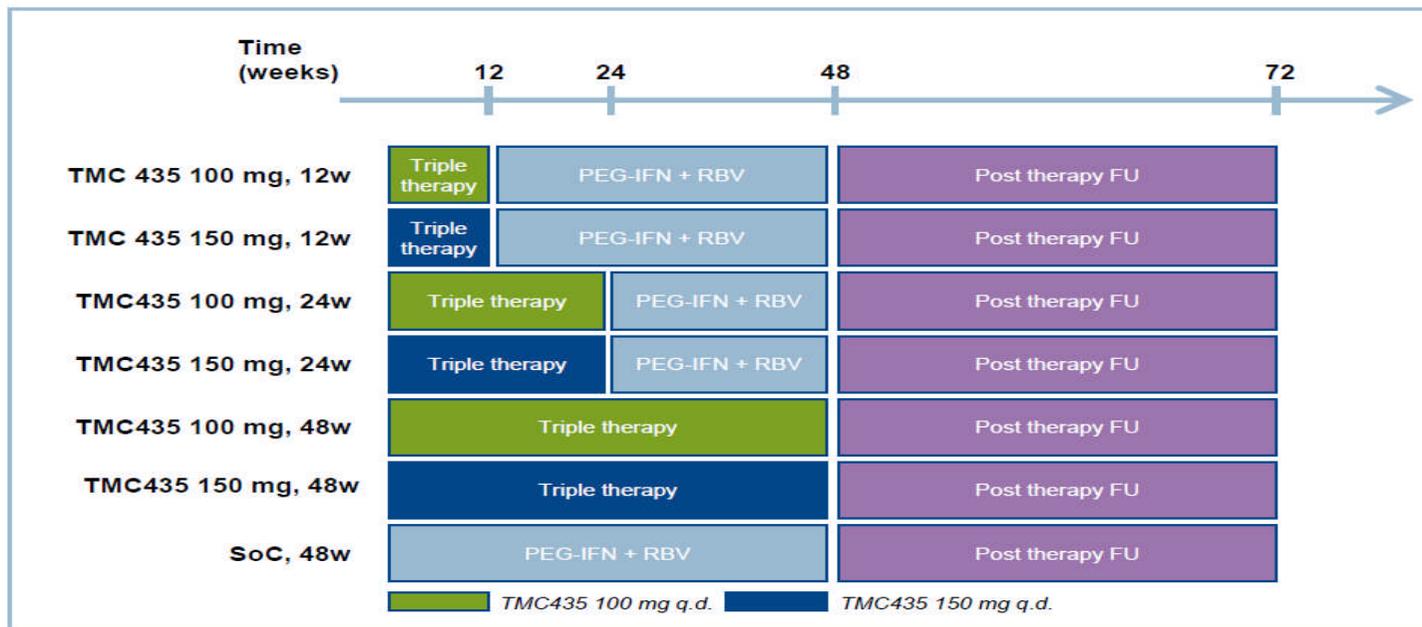
## SVR24 Data from 24-Week Interim analysis Phase 2b PILLAR Trial in Treatment-naïve Hepatitis C Patients

- In the TMC435 treatment groups 83% of patients were able to stop all therapy at week 24
- Potent and consistent antiviral efficacy was demonstrated with SVR24 rates of up to 84%
- TMC435 was safe and well tolerated

# TMC435 Phase 2b study design

## ASPIRE (C206)

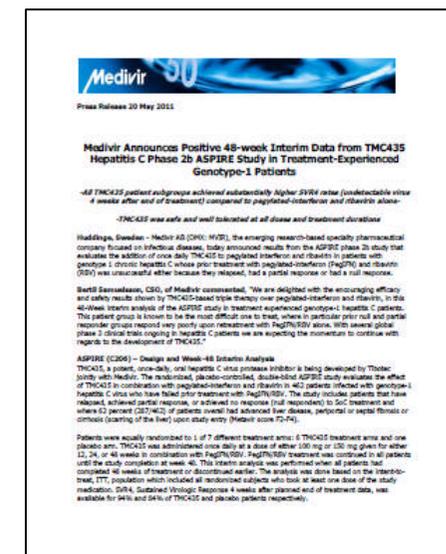
- TMC435-C206 is a global phase 2b study in 462 genotype-1 treatment-experienced patients
- Once daily (*q.d.*), 100 mg and 150 mg, of TMC435 + SoC:
  - 12-week triple therapy followed by 36 weeks of SoC
  - 24-week triple therapy followed by 24 weeks of SoC
  - 48-week triple therapy



# TMC435 - Further Positive Phase 2b 48-Week ASPIRE Interim Data

- All TMC435 patient subgroups achieved substantially higher SVR4 rates (undetectable virus 4 weeks after end of treatment) compared to pegylated-interferon and ribavirin alone
- SVR4 rates: 88% vs. 50% in prior relapsers, 77% vs. 11% in prior partial responders and 57% vs. 23% in prior null responders
- Patient experienced patient group – most difficult to treat
- 62 percent (287/462) of patients overall had advanced liver disease
- TMC435 was safe and well tolerated at all doses and treatment durations

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



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**Rein Piir**

**CFO / IR**

**[rein.piid@medivir.com](mailto:rein.piid@medivir.com)**

**Johan Inbarr**

**Head of Business Development (Medivir Pharma)**

**[johan.inbarr@medivir.com](mailto:johan.inbarr@medivir.com)**

**+46 708 853 893**