



Medivir

A specialty pharmaceutical company focused on infectious diseases

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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

Medivir's Strategy

- Innovative and “a partner of choice”
→ creating value for our partners and shareholders
- Create and retain higher value in our projects
→ late stage (PoC) out-licensing, co-development rights, expanded territories
- Continue to look for strategic product in-licensing and acquisition opportunities

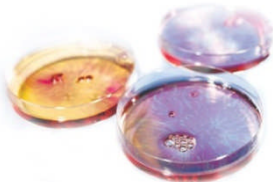
We aim to become a profitable research-based specialty pharmaceutical company with focus on the development and commercialisation of high-value infectious disease treatments

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

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

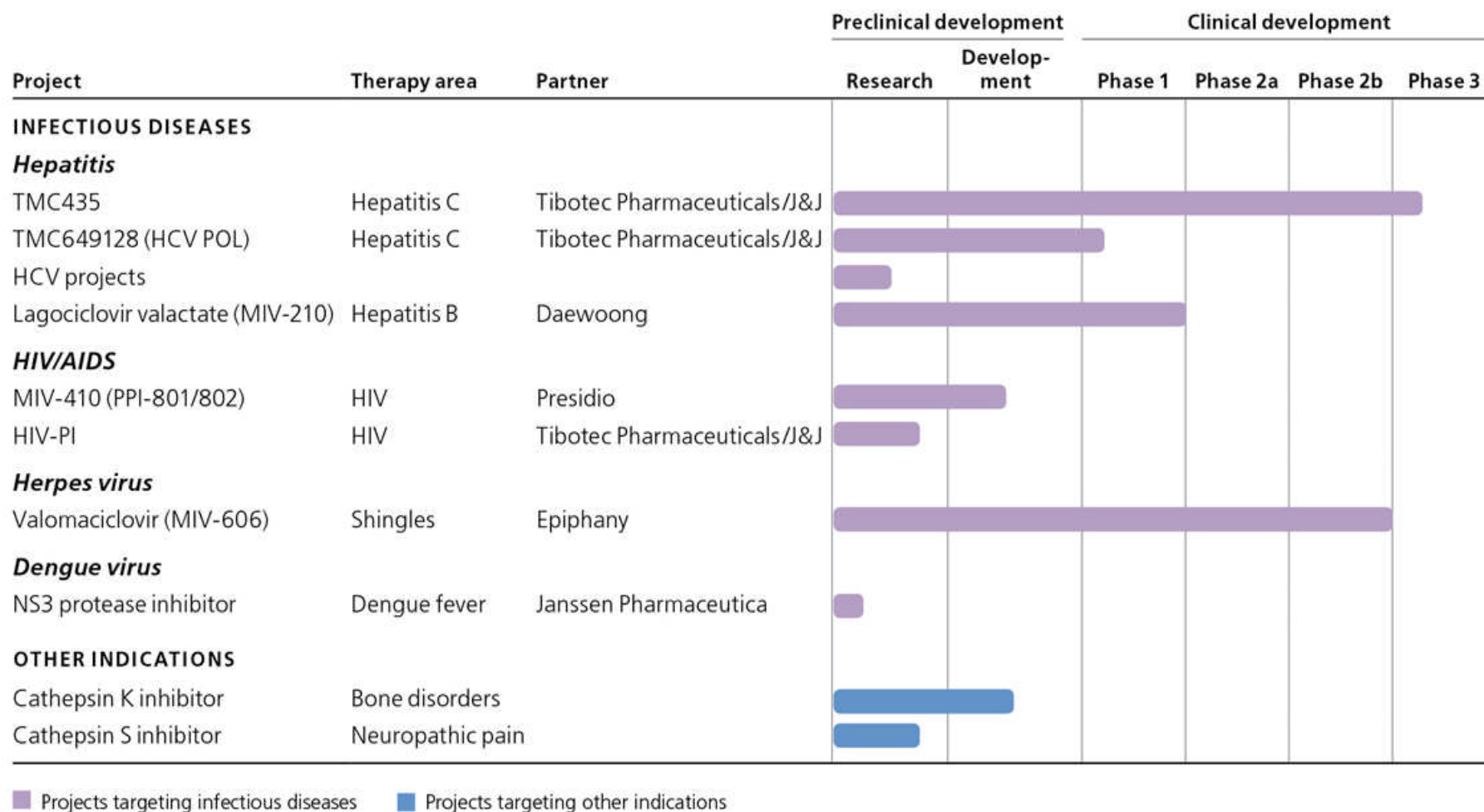
Medivir has retained the Nordic commercial rights

- 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

Strong pipeline with multiple paths to value creation



Dengue Fever

Medical need and market opportunity

- Dengue virus is a mosquito-borne infection causing a severe flu-like illness, and sometimes a potentially lethal complication - dengue haemorrhagic fever
- Up to 50 million infections occur annually in over 100 endemic countries
- Annual death rate approximately 30,000
- Appr. 40% of world population are now at risk¹

Development strategy

- Focus on inhibition of the dengue virus NS3 protease essential for viral replication
- Joint venture with Janssen Pharmaceutica utilising Medivir strong know-how in protease inhibitor drug discovery

Commercial strategy

- Both parties are contributing 50:50 resources to the research program
- Increased potential upside from co-development deal

Cathepsin K inhibitors for bone disorders – MIV-710/711

Creating value for shareholders by developing products further under own management

Disease and market	MIV-710 and MIV-711
<ul style="list-style-type: none">• Cathepsin K is involved in bone resorption, thus osteoporosis, osteoarthritis and metastatic bone disease are all potential indication areas• Estimated combined global market opportunity in excess of USD 12 billion	<ul style="list-style-type: none">• MoA support maintained beneficial effect on bone formation in contrast to other anti-resorptives,• Proof-of-principle demonstrated in preclinical models (including osteoarthritis)• Two Candidate Drugs selected: MIV-710 and MIV-711• Potent and long duration of activity• A low, once daily human dose QD anticipated• Strong IP position

Upcoming events in next 12 months

Start of phase I clinical trials with MIV-711 expected in Q1 2012

Cathepsin S inhibitor – Neuropathic pain and Rheumatoid Arthritis

Creating value for shareholders by developing products further under own management

Disease and market

- Approximately 25 million patients worldwide suffer from neuropathic pain
- Estimated global market opportunity for neuropathic pain in excess of USD 2.3 billion, and rheumatoid arthritis (RA) is estimated to USD 7 billion

Upcoming events in the coming 12 month

- Candidate drug selection

Cathepsin S inhibitor program

- Strong link to **Neuropathic pain**
 - Cathepsin S is essential for activation of the soluble fractalkine on neurons → neuro-inflammation
 - Secreted by activated microglial cells in CNS in rodent models
 - Overexpressed in DRG infiltrating macrophages and near site of peripheral injury in rodent models
- Potent, selective and orally bioavailable inhibitors developed by Medivir
- Proof-of-principle demonstrated in a rodent model of neuropathic pain
- Strong link to **Rheumatoid arthritis**
 - Crucial role in antigen presentation, which is key to establish an immune response
 - Proof of principle demonstrated in preclinical CIA disease models



Hepatitis C - present and future therapies

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

Hepatitis C - Blockbuster Market

Market Value and TMC435 potential

- Globally ~170 million (3-4% of world population) infected with hepatitis C virus - 80% develop chronic disease
- Approximately 12 million HCV infected in the US, Europe and Japan
- Estimated market value of over USD 10 billion in 2015
 - Next generation of interferon-free DAA combinations (2017) will transform and grow the HCV treatment landscape
- Higher than expected US prices for recently approved PIs, Incivek™ (49,200 USD) and Victrelis™ (26,400-48,400 USD)
- Treatment-experienced patients, currently ~ 0.6 million, representing ~half of the market value
- TMC435 strongly positioned as a backbone component of future DAA combination treatments

Medivir will receive royalties on worldwide sales



Our hepatitis C franchise

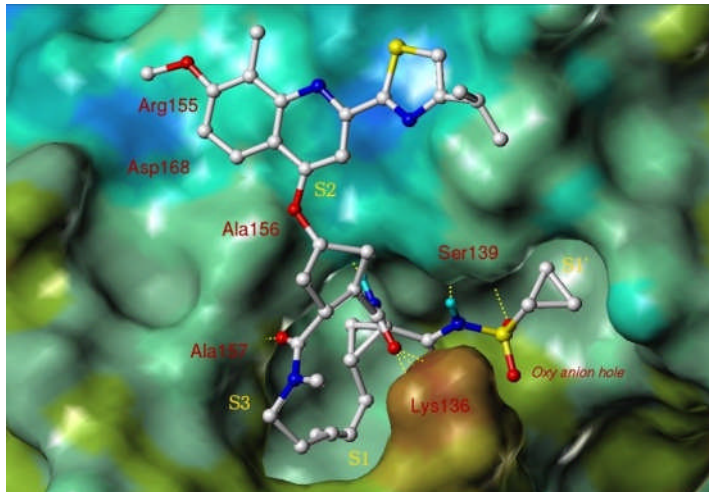
Partnered and in-house product portfolio

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 Pharmaceuticals (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

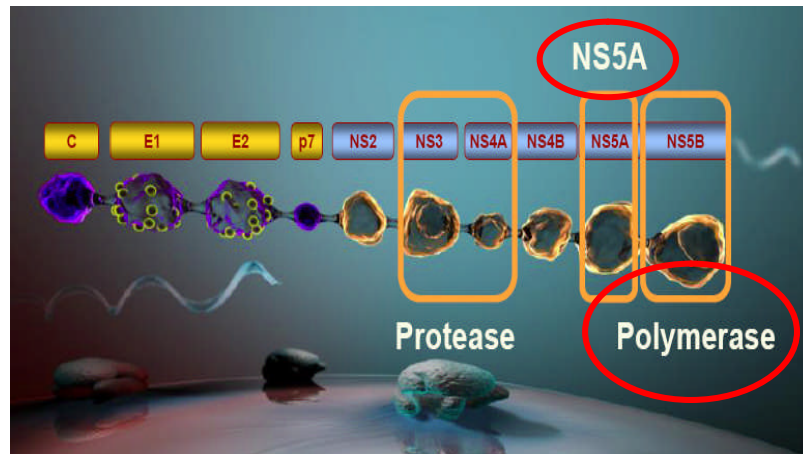
Medivir commitment to HCV - 2nd DAA programs

TMC649128 (HCV PolI)



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



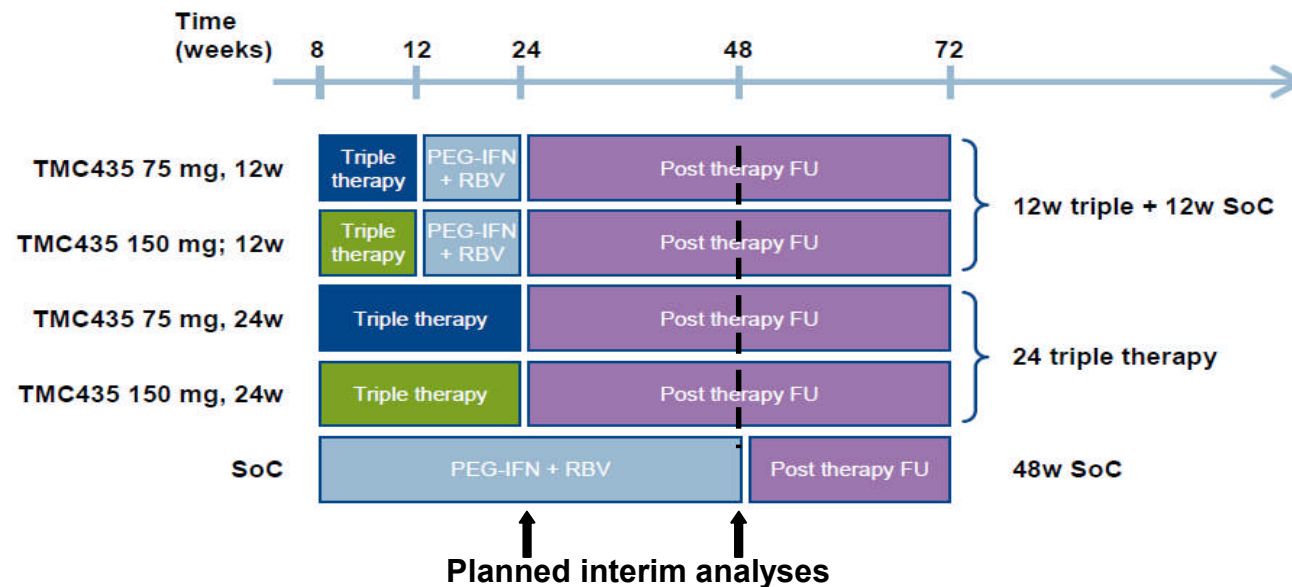
Our hepatitis C franchise

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

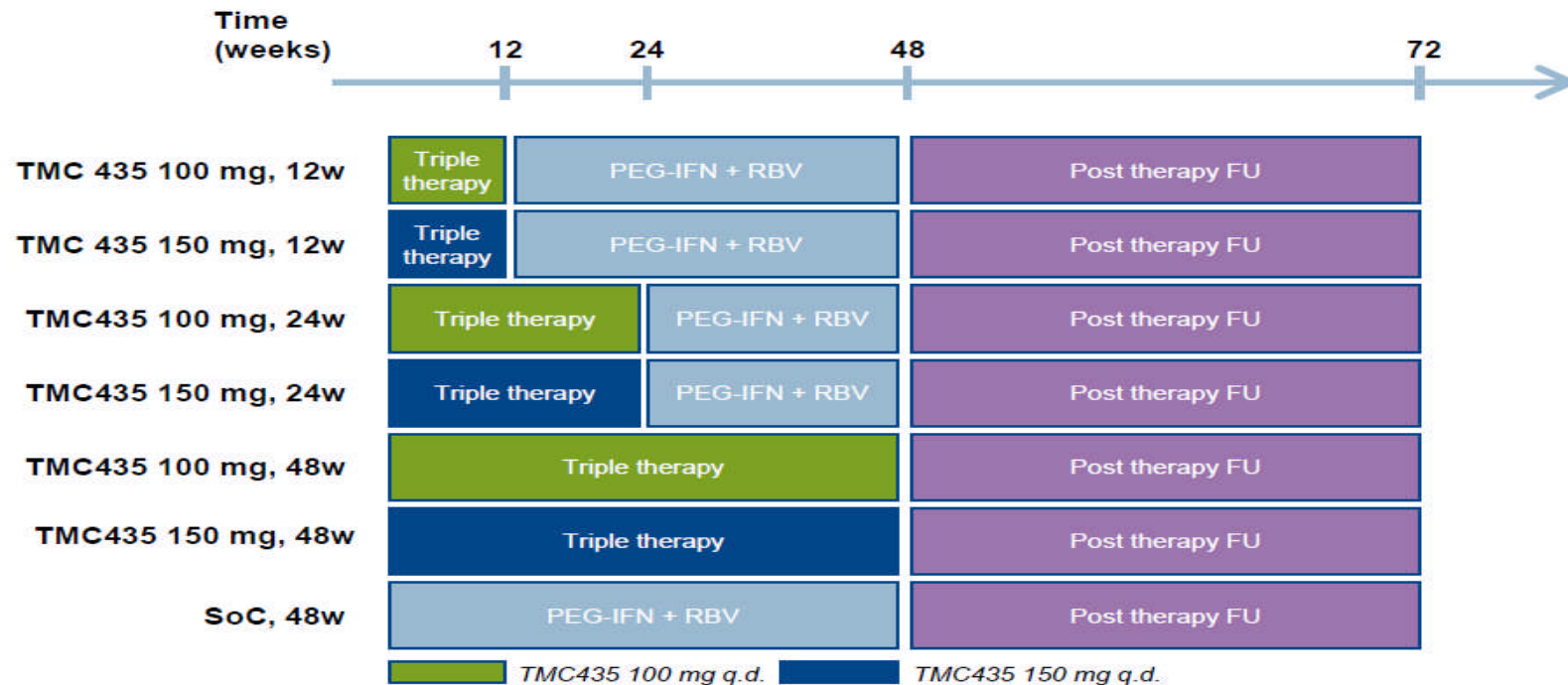
q.d.: once daily, PR: pegIFNalpha-2A and ribavirin,

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

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 12PR48 N=66	TMC435 24PR48 N=68	TMC435 48PR48 N=65	All TMC435 PR48 N=199	Placebo PR48 N=66
Prior Relapser	EoT SVR4	92 (24/26) 84 (21/25)	93 (25/27) 93 (25/27)	92 (24/26) 85 (22/26)	92 (73/79) 87 (68/78)	70 (19/27) 50 (12/24)
Prior Partial Responder	EoT SVR4	78 (18/23) 64 (14/22)	83 (20/24) 86 (18/21)	86 (19/22) 82 (18/22)	83 (57/69) 77 (50/65)	17 (4/23) 11 (2/18)
Prior Null Responder	EoT SVR4	65 (11/17) 56 (9/16)	71 (12/17) 60 (9/15)	77 (13/17) 56 (9/16)	71 (36/51) 57 (27/47)	25 (4/16) 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 BI24PR48	Telaprevir INCIVIK T12PR48	Boceprevir VICTRELIS B44PR48	TMC435 PR48	Placebo 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

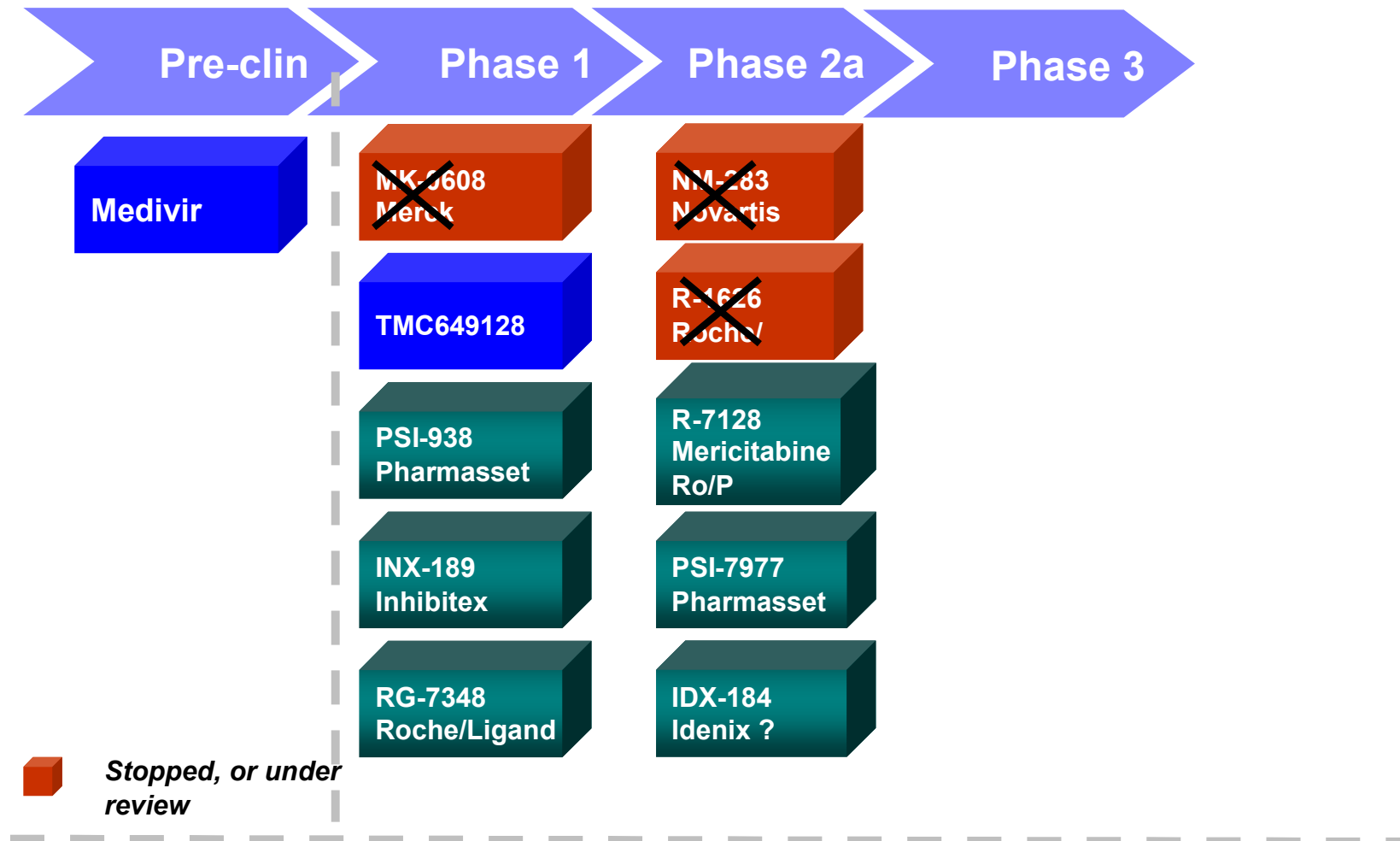
Expected key news flow highlights during the coming 9 month

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- ✓ 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
 - Q4 Digestive week Japan - C215 (DRAGON) full SVR24 data
 - Q4 AASLD - C205 (PILLAR) full SVR24 data
 - Q4 AASLD – additional data on TMC435
 - Q4 Start of Phase III trials with TMC435 in prior null and partial responder patients
 - Q4 C206 (ASPIRE) full SVR24 data
 - Q4 Phase Ib results with TMC649128
 - Q4 OTC launch of Xerclear® in Europe by GSK
 - Q1-12 Start of Phase I trials with MIV-711

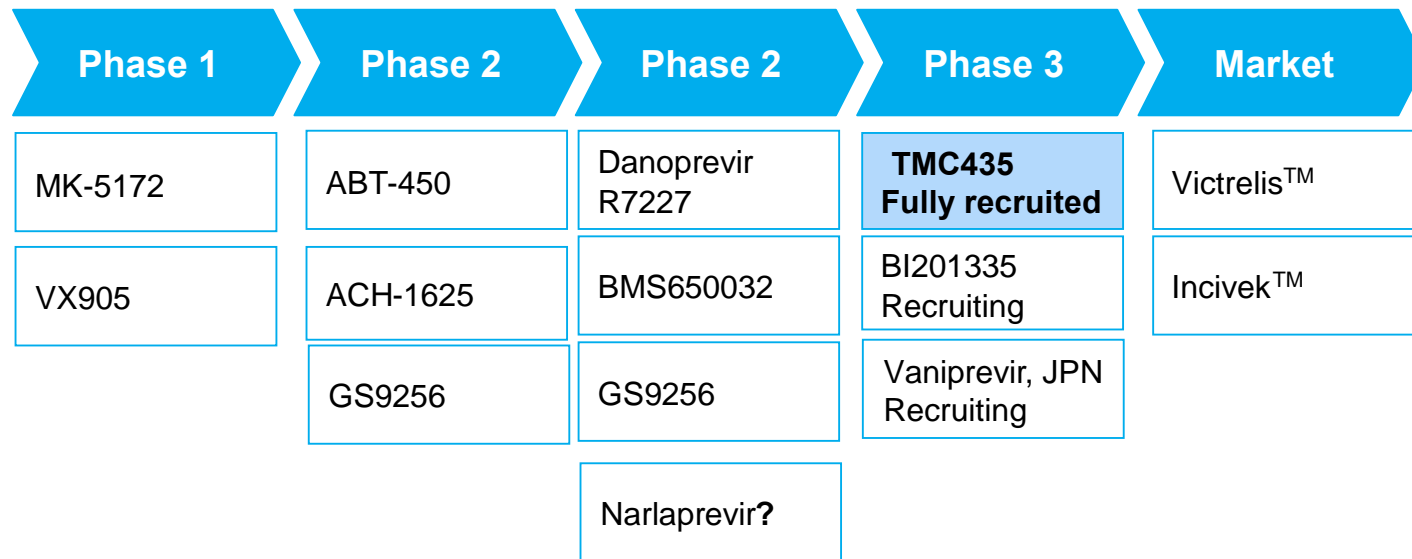


Competitive Environment & Evolution of HCV Therapy

HCV Nucleosides & Nucleotides – Competitive landscape



Hepatitis C PI – the Competitive landscape



HCV PI's in combination with DAAs and SoC

- Example of combinations of DAA agents:
 - TMC435 + PSI7977 (NI)
 - TMC435 + TMC647055 (NNI)
 - Telaprevir + VX-222 (NNI)
 - Danoprevir + R7128 (NI)
 - BMS650032 + BMS790052 (NS5A inh)
 - GS9256 + GS-9190 (NNI)
 - GS9265 + GS9451
 - ABT450 + ABT333 (NNI)/ABT072 (NNI)

Note: danoprevir and ABT-450 require ritonavir-boosting



TMC435 – Next Generation Treatments

**Robust efforts underway to develop
interferon free TMC435 therapy and
TMC435 Quad therapy**

Tough Side Effects of Interferon & Ribavirin

PEGYLATED INTERFERON

- **Flu-like symptoms**
 - Headache
 - Fatigue or asthenia
 - Myalgia, arthralgia
 - Fever, chills
- **Nausea**
- **Diarrhea**
- **Psychiatric symptoms**
 - Depression
 - Insomnia
- **Alopecia**
- **Injection-site reaction**
- **Leukopenia**
- **Thyroiditis**
- **Autoimmunity**
- **Thrombocytopenia**

RIBAVIRIN

- **Hemolytic anemia**
 - Hemoglobin < 10 g/dL in 10% of patients
 - Relative anemia with 2 g/dL hemoglobin decrease in > 70% of patients
- **Teratogenicity**
- **Cough and dyspnea**
- **Rash and pruritus**
- **Insomnia**
- **Anorexia**

Contraindications

PEG-Interferons

- Patients with autoimmune hepatitis
- Patients with decompensated cirrhosis
 - Includes patients on transplant list

Ribavirin

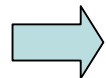
- Pregnant women
- Patients with hemoglobinopathies

Many clinicians and patients will wait to initiate peg IFN + RBV treatment

- With TMC435, 83% of patients can reduce time on treatment by half
- With telaprevir < 60 % of patients will have reduced treatment duration and will experience add-on adverse events (from telaprevir)

IFN Free Therapy – the future dominant market

- Largest market segments long term will be:
 - Naïve diagnosed patients
 - Patients ineligible for IFN-based regimens
- Fixed dose combinations of potent, well tolerated once daily DAAs will dominate the market
 - TMC435: one pill, once daily, potent (150mg) and well tolerated
- TMC435 + 1 DAA +/- RBV could capture medically ineligible segment and some of IFN based regimens
- TMC435 + 2 DAA could replace IFN based regimens



A new competitive regimen would be a “tipping point” for an increased market by:

- increased treatment rates*
- increased diagnosis*
- new pool of treaters*

Evolution of the HCV therapy

