

Medivir presenting at

**S|E|B** ENSKILDA

## Biotech lunch - Stockholm

2 April 2009

Rein Piir, CFO / IR

Bertil Samuelsson, VP Discovery & Research

Medivir contact [rein.piir@medivir.se](mailto:rein.piir@medivir.se)

[www.medivir.com](http://www.medivir.com)



# Medivir Pipeline April 2009

## Prioritized projects

Project	Indication(s)	Partners/ Date of agreement	Terms	Medivir's markets	Exploratory phase	Optimization	Preclinical dev. *	Phase I	Phase II	Phase III	NDA
<b>Lipsovir®</b> (ME-609)	Labial herpes	In-house			[Green bar spanning from Exploratory phase to Phase III]						
<b>TMC435</b> (HCV-PI)	Hepatitis C	Tibotec / 2004	EUR 80.5 m + royalties and FTE funding	Nordic region	[Orange bar spanning from Exploratory phase to Phase II]						
<b>MIV-701</b> (Cath K)	Osteoporosis, osteoarthritis, bone metastases	In-house			[Orange bar spanning from Exploratory phase to Phase II]						
<b>HCVPOL</b>	Hepatitis C	Tibotec / 2008	EUR 142-272 m + royalties and FTE funding	Nordic region	[Purple bar spanning from Exploratory phase to Preclinical dev. *]						
<b>MIV-710</b> (Cath K)	Osteoporosis, osteoarthritis, bone metastases	In-house			[Orange bar spanning from Exploratory phase to Preclinical dev. *]						
<b>HIVPI</b>	HIV	Tibotec / 2006	EUR 64 m + royalties and FTE funding	Nordic region	[Orange bar spanning from Exploratory phase to Optimization]						
<b>BACE</b>	Alzheimer's	In-house			[Orange bar spanning from Exploratory phase to Optimization]						
<b>Cathepsin S</b>	Rheumatoid arthritis, multiple sclerosis	In-house			[Orange bar spanning from Exploratory phase to Optimization]						
<b>COPD PI</b>	COPD	In-house		World	[Orange bar spanning from Exploratory phase to Optimization]						
<b>Renin</b>	Hypertension	In-house			[Orange bar spanning from Exploratory phase to Optimization]						

Inhouse preclinical program

Inhouse preclinical program

Inhouse preclinical program

# Medivir - Key achievements during the last 12 months

- Strong phase IIa data to be presented for TMC435 (hepatitis C protease inhibitor) at EASL in 23-25 April
- Medivir sharpens the strategic focus and strengthens its financial position. Cost savings to be carried out during 2009, new cost base of SEK 150m when entering 2010
- Cathepsin K Candidate Drug MIV-710 selected on February 4th, 2009
- Cash position by end of year 2008 (SEK 284m) with present yearly structural burn rate of SEK 200m
- Hepatitis C polymerase Candidate Drug selected on December 9th in the JNJ/Tibotec collaboration program triggering a milestone payment of € 2.6m
- Applications for approval of Lipsovir (labial herpes) filed in the US and Europe. Approval target date late autumn 2009
- Our biggest deal ever signed in May with JNJ/Tibotec for hepatitis C nucleoside polymerase inhibitors (>USD 190m)



## Commercial focus in the coming 12 months

<b><i>LIPSOVIR</i></b>	<ul style="list-style-type: none"> <li>◆ Regulatory approval in EU &amp; US</li> <li>◆ Secure optimal partnership structure for both EU, US &amp; RoW</li> </ul>
<b><i>HEPATITIS C</i></b>	<ul style="list-style-type: none"> <li>◆ HCV PI, TMC435: start of phase IIb clinical trials</li> <li>◆ HCV PI, TMC435: Present more data from the phase IIa study</li> <li>◆ HCV-Polymerase inhibitors: Completion of preclinical GLP safety studies and start of phase I clinical trials</li> </ul>
<b><i>CATHEPSIN K</i></b>	<ul style="list-style-type: none"> <li>◆ Partnering process initiated</li> </ul>
<b><i>HIV PI</i></b>	<ul style="list-style-type: none"> <li>◆ Candidate Drug selection by Tibotec/J&amp;J</li> </ul>
<b><i>BACE, Alzheimer's</i></b>	<ul style="list-style-type: none"> <li>◆ CD selection and partnering of the BACE program</li> </ul>
<b><i>PHARMA SALES</i></b>	<ul style="list-style-type: none"> <li>◆ Strategic evaluation of Lipsovir for the Nordic markets</li> <li>◆ Secure new co-promotion deals and potential own product(s)</li> </ul>
<b><i>Financial</i></b>	<ul style="list-style-type: none"> <li>◆ Secure a lower cost base</li> </ul>



- We filed an NDA with US (FDA) and EU regulatory authorities for Lipsovir® in October
- In December, these authorities announced that they had validated the NDA and that their review and evaluation process had begun
- We expect to receive the outcome of this process in autumn 2009
- The objective is to enter partnerships to commercialize Lipsovir® globally.





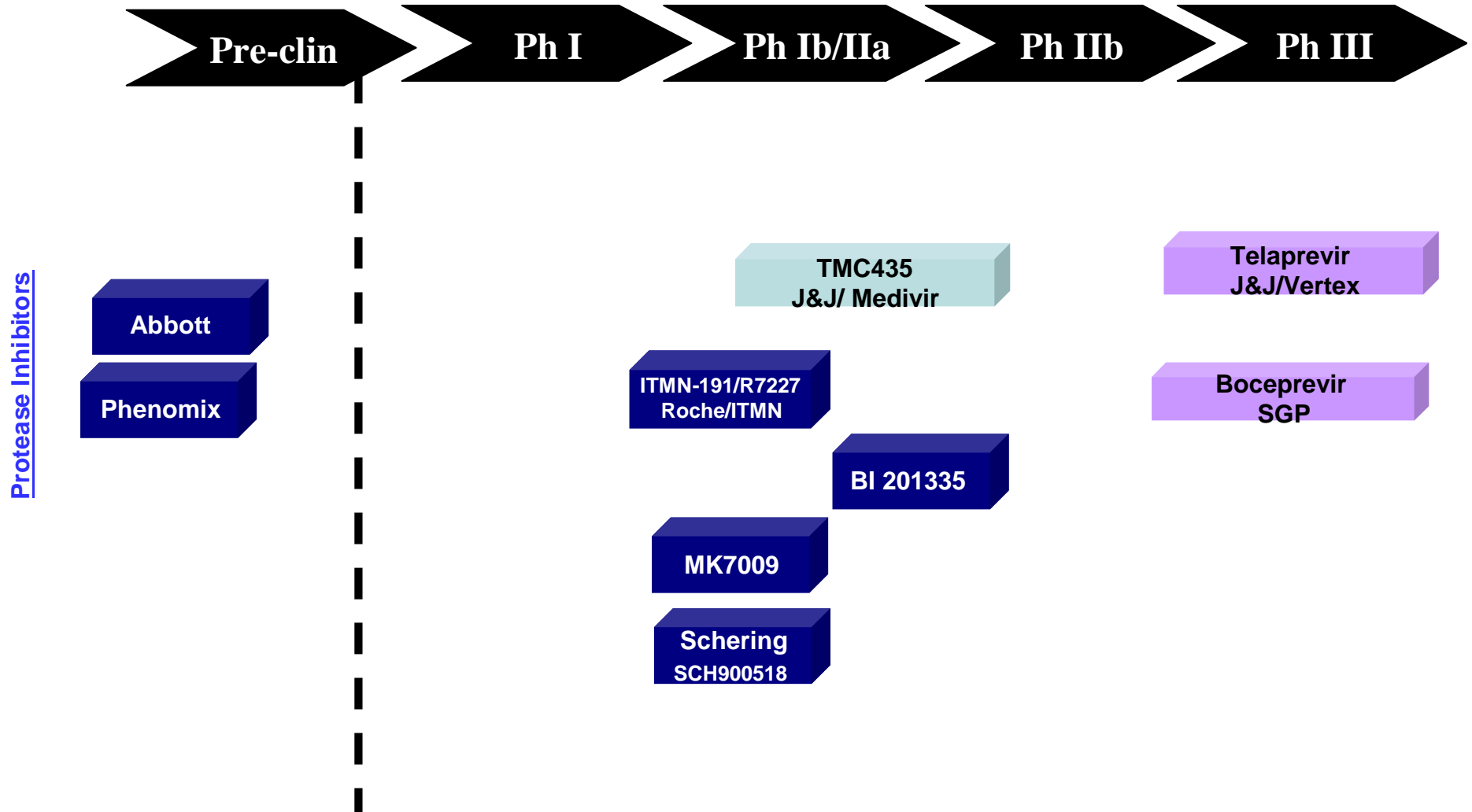
**TMC435 - in collaboration with  
Tibotec / J&J**

**Presently in final stage of phase IIa for  
genotype 1 treatment naïve patients and  
treatment experienced patients**

**Phase IIb will start during spring**



# HCV PI Competitive Landscape



# Hepatitis C protease - TMC435 - Medivir/Tibotec

## Status

- Phase IIb will start during spring 2009

## Results from IIa

- Data from 25 and 75 mg dose groups in naïve patients presented in November 2008.

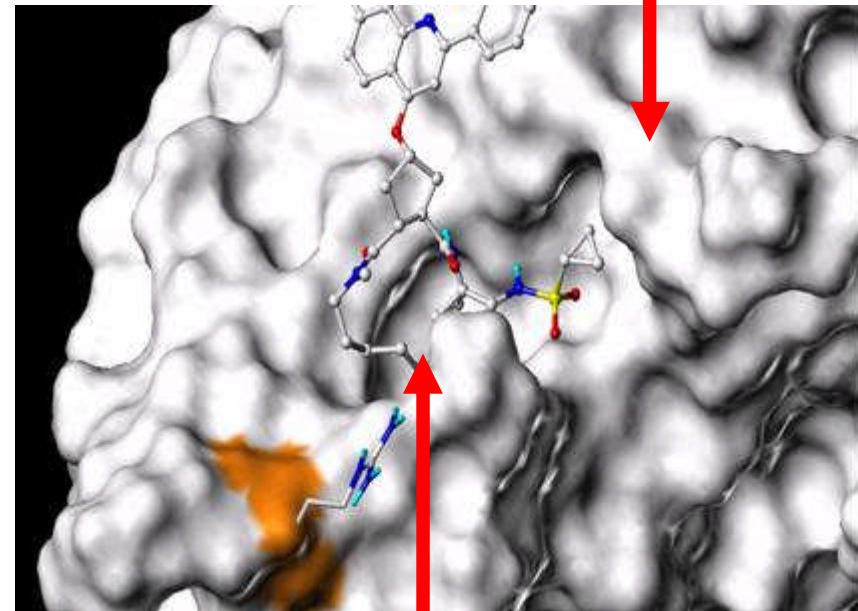
## New data to be presented in April

- Data from 200 mg dose group in naïve patients and data in non-responders and relapsers from the 75, 150 and 200mg dose groups to be presented at EASL 23-25 April 2009

## Licensing agreement

- Upfront & milestones of EUR 80.5m (EUR 47m remains) + royalties on sales
- All development costs covered by Tibotec
- Nordic rights retained by Medivir

NS3/4A:  
Key protease for  
virus replication



Enzyme inhibiting compound



# Opera-1 (cohort 1): Antiviral efficacy in 25 and 75 mg, presented at AASLD in November 2008

Table 3: Mean HCV RNA changes from baseline and number of patients with HCV RNA levels below lower limit of quantification (LLQ) and detection (LLD) per treatment arm.

Dose/Treatment	Time point (Day)	Mean HCV-RNA change (Log <sub>10</sub> IU/mL)	< LLQ n/N <25 IU/mL	< LLD n/N <10 IU/mL
Panel A Placebo	7	-0.08	0/6	0/6
Panel A TMC435 25 mg	7	-2.63	1/9	0/9
Panel A TMC435 75 mg	7	-3.43	0/9	0/9
Panel B Placebo	7	-1.77	0/6	0/6
	14	-2.56	0/6	0/6
	28	-3.83	3/6	2/6
Panel B TMC435 25 mg	7	-3.47	1/9	0/9
	14	-4.19	3/9	1/9
	28	-4.74	6/9	3/9
Panel B TMC435 75 mg	7	-4.55	1/9	0/9
	14	-5.15	7/9	3/9
	28	-5.52	9/9	8/9

RVR of 89%

HCV RNA levels were assessed with Roche COBAS Taq Man HCV/HPS assay v2 with an LLQ of 25 IU/mL and an LLD of ~10 IU/mL. To calculate mean HCV RNA values, results below LLQ are imputed with 24 IU/mL and values below LLD with 9 IU/mL.

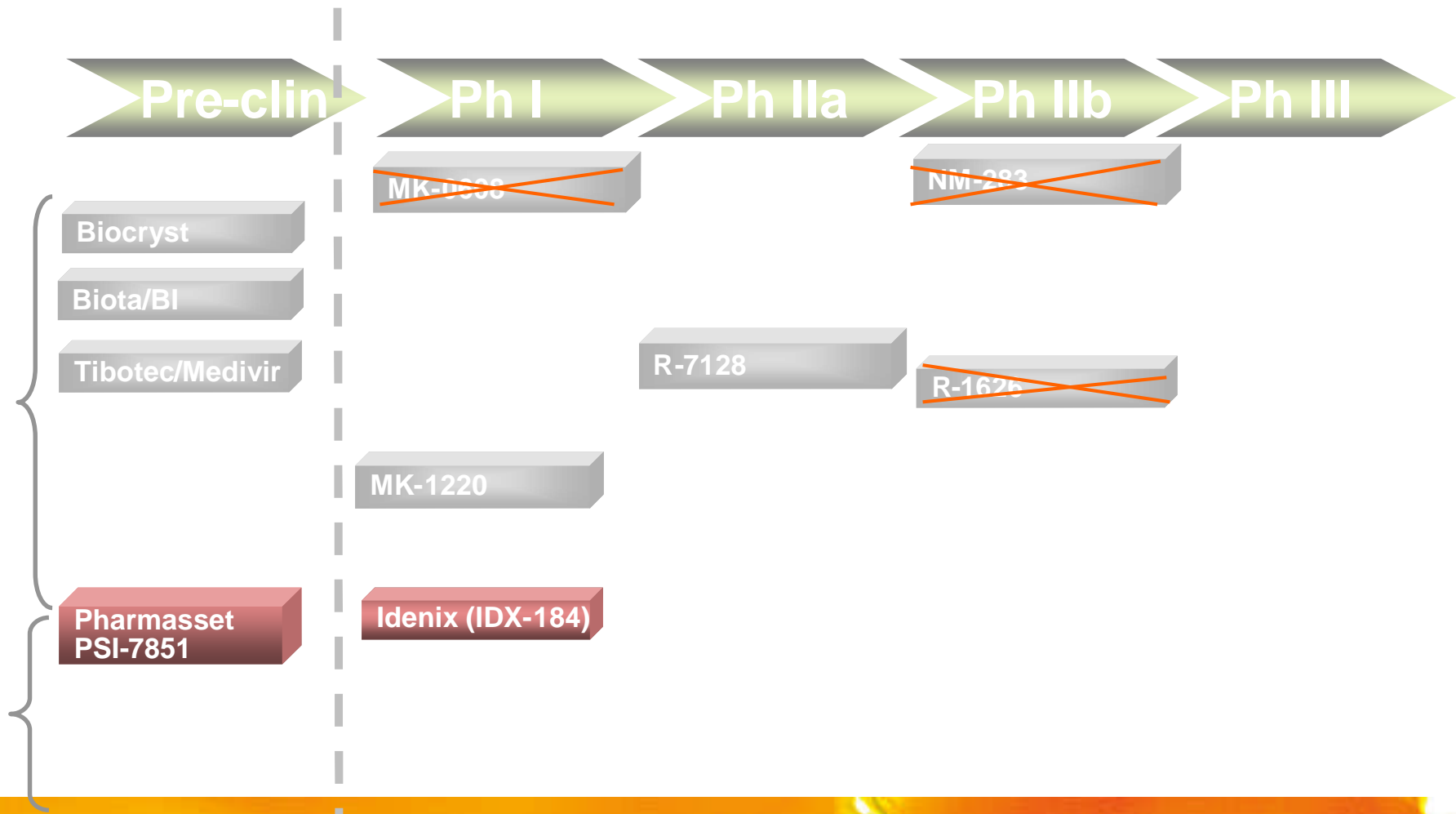


HCV POL - In collaboration with  
Tibotec / JNJ

**Nucleoside HCV Polymerase Inhibitors**



# HCV Nucleoside Competitive Landscape



# Hepatitis C Polymerase - Medivir/J&J program

## Status

- Partnership with Tibotec / Johnson & Johnson since May 15 2008
- Candidate Drug selected on December 9th, 2008, triggering a milestone of € 2.6m
- Selected CD in preclinical development phase towards phase I

## 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, ends May 2009
- All development costs covered by JNJ
- Nordic rights retained by Medivir





Cathepsin K inhibitors

**Osteoporosis, Osteoarthritis &  
Bone Metastases**



# Medivir Cathepsin K Inhibitor Program - Status

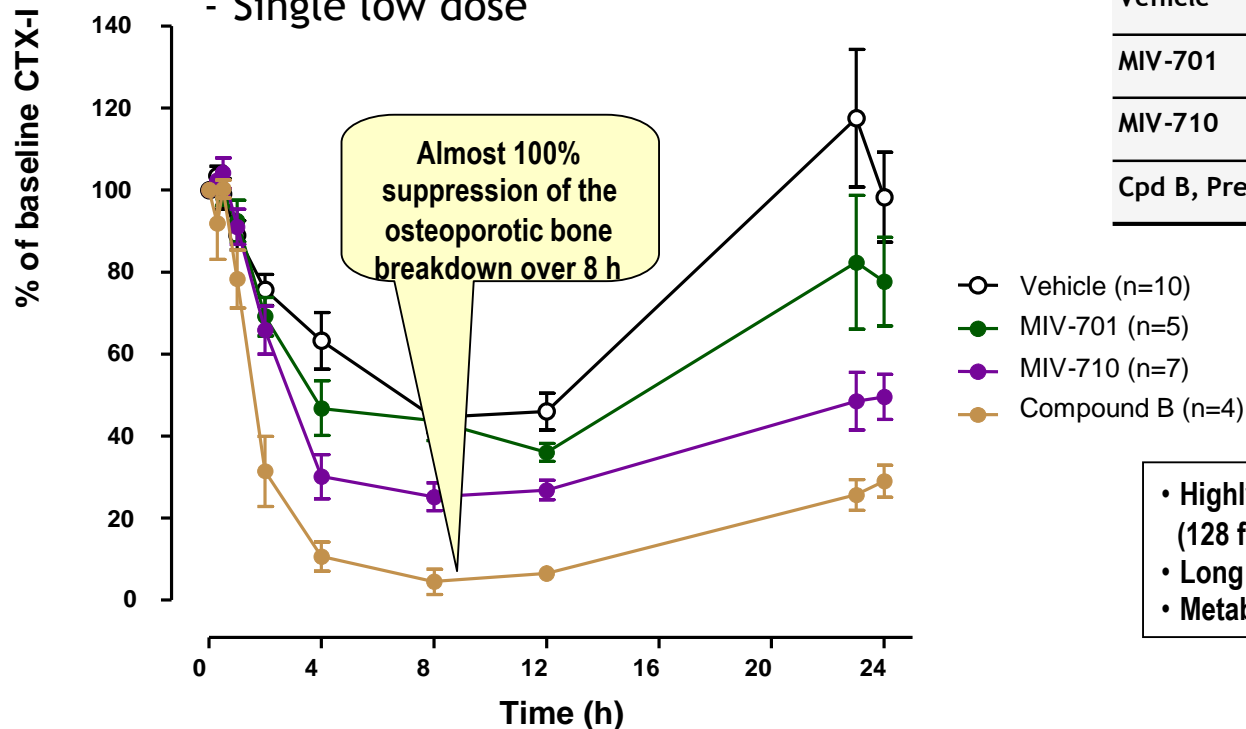
- Cathepsin K inhibitors display potent and reversible anti-resorptive activity on bone whilst not suppressing of the beneficial bone formation, as expected with other anti-resorptives
- MIV-710 is a new Candidate Drug selected in February 2009. It is a follow-on to MIV-701 having superior pharmacokinetic properties
- Strong IP position
- A broad initiative has been initiated to identify a partner for the full program

## MIV-710 and Pre-CD Cpd B

### Highly efficacious based on biomarkers for osteoporosis

Reduction in plasma CTx-I, a biomarker of bone breakdown, in cynomolgus monkeys after:

- Oral administration
- Single low dose



Treatment	Max inhibition (%)	Inhibition at 24h (%)
Vehicle	56	2
MIV-701	64	22
MIV-710	75	51
Cpd B, Pre-CD	95	75

- Highly advantageous plasma exposure (128 fold higher compared with MIV-701)
- Long half live
- Metabolically stable

Clinical efficacious dose of ~50 mg once daily expected - low cost of goods





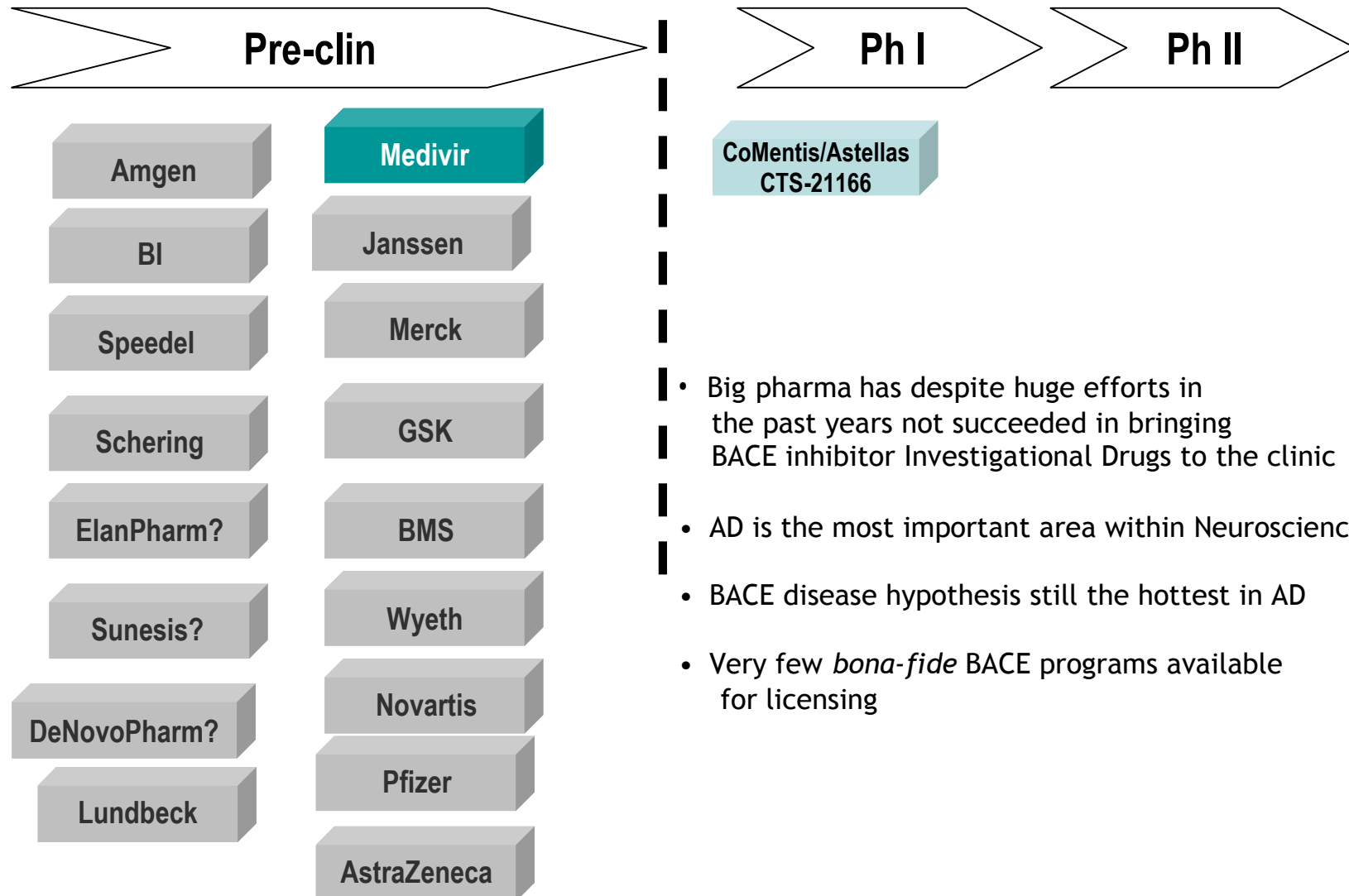
BACE Inhibitors

**Alzheimer's disease**





# BACE-1 Inhibitors in development



- Big pharma has despite huge efforts in the past years not succeeded in bringing BACE inhibitor Investigational Drugs to the clinic
- AD is the most important area within Neuroscience
- BACE disease hypothesis still the hottest in AD
- Very few *bona-fide* BACE programs available for licensing

## Medivir BACE Program

- Novel and patentable lead series
  - ✓ 3 validated novel Lead Series
  - ✓ 2 additional series are at an earlier stage
  - ✓ 1 series at advanced Lead Optimization stage
- Strong IP (patent) position
  - ✓ Extensive and non-limiting IP filed
- Potent BACE inhibitors both on enzyme and in cell-based assay
  - ✓ Lead inhibitors display robust potency,  $IC_{50} \ll 1$  nM, in both BACE enzyme and in cell-based assay, measuring AB40 release
- Activity *in vivo* on reduction of AB40 release in the CNS upon administration of BACE inhibitor
- CD selection expected in approximately 12 month
- Partnering discussions have been initiated