MCB3681: First IV therapy for *Clostridium difficile* infections (CDI) in clinical development

morphochem

Company: Morphochem AG

- Private company based in Munich, Germany

Focus: Clinical Development of MCB3681

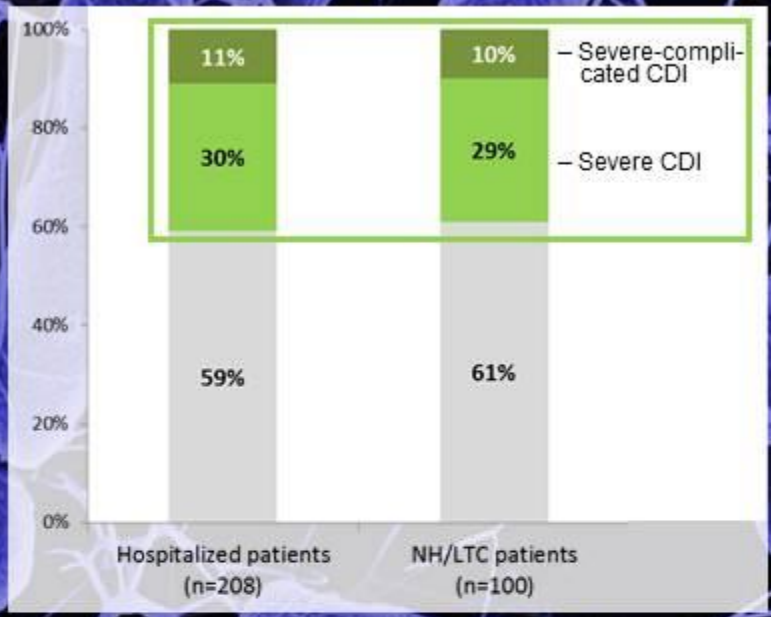
- Active substance of intravenous (IV) prodrug MCB3837
- Antibacterial of novel quinolonyl-oxazolidinone class
- Strong activity against *C. diff* clinical isolates (n=335)
- Safety, tolerability shown in 3 Phase 1 studies (n=90)
- High MCB3681 concentrations and pharmacodynamic effect on Gram-positives in feces of healthy volunteers without harming Gram-negatives incl. bacteroides

Lead Indication: Intravenous Treatment of CDI

- *C. difficile* is an urgent public health threat (US CDC)
- CDI incidence in hospitalized patients estimated at >1 million in the US and EU by 2021
- Up to 40% of hospitalized CDI patients diagnosed with severe/ severe-complicated CDI (see graph)
- Many severely ill patients cannot be treated with oral CDI therapy
- No approved IV treatment available, IV metronidazole and IV tigecycline used off-label (see table)

Next step: Phase 2 study

- IND submitted to the US FDA in May
- Phase 2 study to start in Q2/3 2016



Antibacterial	Routes	Phase	MIC range mg/L
MCB3681	**IV**	**Phase 1**	**0.008 – 0.5**
Metronidazole	IV / oral	off-label	0.125 – 2
Vancomycin	oral	Market	0.125 – 1
Fidaxomicin	oral	Market	0.008 – 0.125
Tigecycline	IV	off-label	0.032 – 0.1
Cadazolid	oral	Phase 3	0.064 – 0.5
Ridinilazole	oral	Phase 2	0.125 – 0.5
CRS3123	oral	Phase 1	0.5 – 1