MCB3681 – the only intravenous treatment in clinical development for Clostridium difficile infections

Morphochem AG  Gmunderstr. 37 A  81374 Munich  Germany

Company: Morphochem AG
- Private company based in Munich, Germany
- 100% subsidiary of Biovertis AG, Austria, backed by TVM Capital

Focus: Clinical Development of MCB3681
- Active substance of intravenous (iv.) prodrug MCB3837
- Small-molecule antibacterial of novel quinolonyl-oxazolidinone class
- Strong activity against C. difficile (over 314 clinical isolates tested; see ECCMID 2016 ePoster #EV0627 / Abstract #2165)
- Safety and tolerability demonstrated in three Phase I studies with approximately 90 healthy volunteers
- Aerobic and anaerobic Gram-negative species in humans not affected – including intestinal bacteroides providing resistance to colonization

Lead Indication: Intravenous Treatment of CDI
- C. difficile was assigned an urgent threat level by U.S. CDC
- Incidence of CDI in hospitalized patients estimated to reach >1 million in the U.S. and EU by 2021
- Up to 40% of hospitalized C. difficile patients diagnosed with severe/severe-complicated CDI (see graph)
- No approved iv. treatment available for severely ill patients who cannot be treated orally, iv. metronidazole and iv. tigecycline used off-label (see table)

Next steps: IND and Phase II study
- Successful Pre-IND meeting with FDA in 2015
- Submission of IND for a Phase II clinical study in patients with severe CDI underway
- Phase II clinical study to start in Q2/3 2016

Contact: thomas.kapsner@biovertis.de

Sources and Publications
2 Wilcox MH et al., Comparative in vitro activities of MCB3681 and 8 comparators against 200 C. diff. isolates with known ribotypes and diverse geographical spread, ECCMID 2016 ePoster #EV0627 / Abstract #2165
3 Rashid M et al., Nord CE: Ecological impact of MCB3837, IJAA 44 (2014) 44, 125-130
5 Decision Resources: Treatment Trends C. diff. Infections, 2013