

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



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## 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<sup>1,2</sup>; see ECCMID 2016 ePoster #EV0627 / Abstract #2165<sup>2</sup>)
- 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<sup>3</sup>

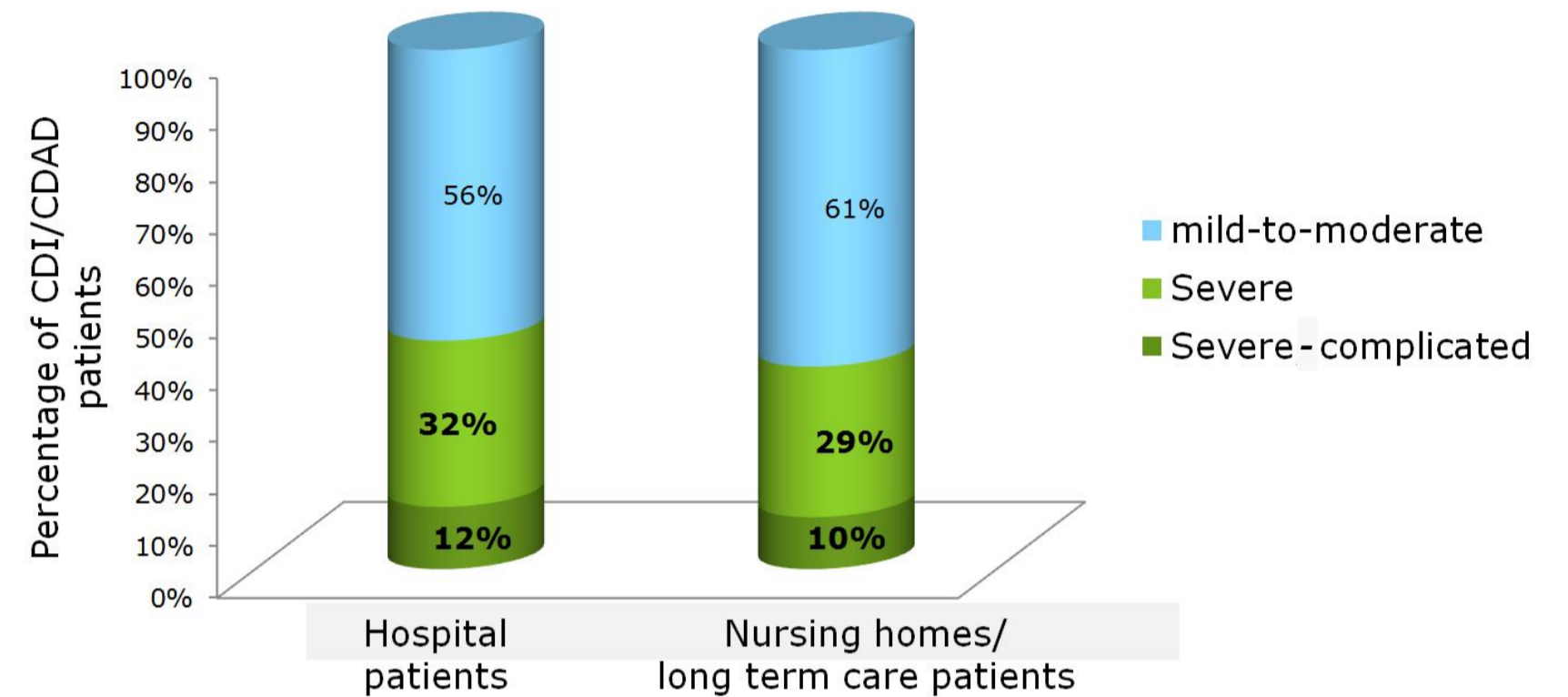
## Lead Indication: Intravenous Treatment of CDI

- *C. difficile* was assigned an urgent threat level by U.S. CDC<sup>4</sup>
- Incidence of CDI in hospitalized patients estimated to reach >1 million in the U.S. and EU by 2021<sup>5</sup>
- Up to 40% of hospitalized *C. difficile* patients diagnosed with severe/severe-complicated CDI<sup>5</sup> (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

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***Clostridium difficile* infections by disease severity**

Antibacterial	Routes	Phase	MIC range mg/L
<b>MCB3681</b>	<b>iv.</b>	<b>Phase I</b>	<b>0.008 – 0.5</b>
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 III	0.064 – 0.5
Ridinilazole	oral	Phase II	0.125 – 0.5
CRS3123	oral	Phase I	0.5 – 1

**Overview of antibacterial treatments marketed and in development for CDI**

## Sources and Publications

- <sup>1</sup> Rashid M et al., Nord CE: In vitro activity of MCB3681 against *C. diff.*, Anaerobe 28 (2014) 216-219
- <sup>2</sup> 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
- <sup>3</sup> Rashid M et al., Nord CE: Ecological impact of MCB3837, IJAA 44 (2014) 44, 125-130
- <sup>4</sup> CDC (U.S.A.): Antibiotic Resistance Threats in the U.S., 2013
- <sup>5</sup> Decision Resources: Treatment Trends *C. diff.* Infections, 2013