FDA grants QIDP and Fast Track Designations to MCB3837, Morphochem's novel intravenous antibacterial to treat *C. difficile* infections

Munich (Germany), July 25, 2016 — Morphochem, a clinical-stage pharmaceutical company, announced today that the U.S. Food and Drug Administration (FDA) has designated Morphochem's intravenous (IV) antibacterial product candidate MCB3837 as a Qualified Infectious Disease Product (QIDP) for the treatment of *Clostridium difficile* infection (CDI). At the same time, the FDA has granted Fast Track designation to the compound's development program for the treatment of CDI. MCB3837 is the IV prodrug of MCB3681, an antibacterial targeted at the treatment of CDI, which is a serious and potentially fatal disease regarded as an urgent healthcare threat.

Under the Generating Antibiotic Incentives Now (GAIN) title of the FDA Safety and Innovation Act, the QIDP designation provides certain incentives for the development of new antibacterial drug products, such as priority review and additional five years of marketing exclusivity granted at the time of marketing approval. The Fast Track designation enables more frequent interactions with the FDA, often leading to earlier drug approval and access for patients.

"After the U.S. FDA's acceptance of Morphochem's IND in June, we are glad to have now received both QIDP and Fast Track designation for MCB3837" says Thomas Kapsner, M.D., Morphochem's Chief Executive Officer. "These designations will help us to expedite the development of this promising IV compound for the many severely ill CDI patients who cannot be treated orally. By providing an effective IV therapy, we aim to improve the prospects and quality of life of these patients."

Morphochem is planning to initiate a proof-of-concept Phase 2 clinical trial of MCB3837/3681 in severe CDI patients in H2 2016.

About MCB3837/MCB3681

MCB3837 is a water-soluble injectable small-molecule prodrug of the active substance MCB3681, which is being developed for the IV treatment of CDI. Three Phase 1 clinical studies have proved MCB3837/MCB3681 to be safe and tolerable. In pre-clinical studies, MCB3681 demonstrated remarkable Gram-positive antimicrobial activity against *C. difficile* pathogens including the highly virulent BI/NAP1/027 strain, with no cross-resistance to any established class of antibacterial.

In a multiple-dose Phase 1b study with healthy volunteers, high fecal concentrations of MCB3681 were observed resulting in a pronounced effect on clostridia and other Gram-positive species while sparing Gram-negative species, including the bacteroides that protect the intestine against colonization with harmful pathogens potentially causing gastrointestinal infections. Due to this strong pharmacodynamic effect in humans, its narrow Gram-positive spectrum, and its favorable impact on the commensal flora, MCB3681 has the potential to target *C. difficile* pathogens selectively and effectively.

About *C. difficile* Infection

C*lostridium difficile (C. difficile)* is a Gram-positive bacterium that causes gastrointestinal infections. The toxins it produces lead to inflammation of the colon and severe diarrhea; in very serious cases the disease can be fatal. CDI incidence and severity have increased in recent years, as have related mortality rates. 500,000 to 700,000 cases are diagnosed annually in the US alone; up to 30,000 of these patients die. The situation in Europe is similar.

In 2013, the U.S. Centers for Disease Control classified *C. difficile* as an immediate and urgent public health threat requiring aggressive action. Mostly occurring in hospitals and long-term care facilities, the disease is estimated to have increased healthcare costs by $4.8 billion in 2008 in acute care alone.

Key risk factors for developing CDI include the use of antibiotics (as they suppress the normal bowel flora) and advanced age. Up to 40 percent of patients develop severe / severe and complicated CDI, associated with significantly higher morbidity and mortality rates. Treatment is currently dominated by oral therapies which, however, tend to prove ineffective for severely ill patients as they often have difficulties swallowing or digesting tablets, or problems retaining the oral medication in or moving it along the gastrointestinal tract. Alternatives are limited, as there is no approved IV therapy available at present.

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About Morphochem

Morphochem Aktiengesellschaft für kombinatorische Chemie is a private clinical-stage pharmaceutical company located in Munich, Germany. Morphochem is a 100-percent subsidiary of Biovertis AG, headquartered in Vienna, Austria. Biovertis's major shareholder is TVM Capital Life Science. Morphochem is fully dedicated to the development and

commercialization of MCB3837/MCB3681, which the company hopes to introduce as the first approved intravenous therapy for severe *Clostridium difficile* infections.
www.morphochem.de

About TVM Capital Life Science

TVM Capital Life Science is providing venture capital to the international pharmaceutical, biopharmaceutical, and medical technology industries with more than 30-years of transatlantic investment track record and in excess of US$1.3bn under management. TVM Capital Life Science currently invests from its 7th fund generation, TVM Life Science Ventures VII, with an integrated team of investment professionals from Munich and Montreal.
www.tvm-capital.com or www.tvm-lifescience.com

About TVM Capital Group

TVM Capital is a group of globally acting venture capital and private equity firms with an operating track record of 30 years. Investment teams have financed more than 250 emerging companies across several industries since 1984. Over the last 15 years the firm has increasingly specialized in the most attractive and fastest-growing verticals in the broader healthcare markets, with a specific focus on financing innovative products and technologies in the European and U.S. biopharmaceutical and medical device markets, as well as healthcare services in emerging markets. TVM Capital funds operate globally, with dedicated life science venture capital funds advised by group members TVM Life Science Management in Montréal and in Munich, and its healthcare private equity fund managed by TVM Capital Healthcare Partners out of Dubai.

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