

# MGB Biopharma Announces Successful Outcome from Phase II Clinical Study on MGB-BP-3 for the treatment of *Clostridium difficile* Infection

## Study confirms MGB-BP-3 offers the potential for a new gold standard in treating *Clostridium difficile* Infection

MGB Biopharma, the Glasgow-based biopharmaceutical company developing a novel class of antiinfectives, today announces the successful conclusion of its Phase II clinical study into MGB-BP-3, for the treatment of *Clostridium difficile Infection* (CDI). The study confirms that the drug has the potential to become the new gold standard, first-line treatment for CDI.

CDI is a serious and often life-threatening infection of the large intestine and is the most frequent cause of diarrhoea in hospitals and care homes. In the US alone, there are almost half a million cases every year associated with around 30,000 deaths; three people die of uncontrolled CDI each hour in the United States.

The study, which was conducted at sites in the United States and Canada, was designed to determine the optimum dose of the product for use in further studies, recorded initial cure and sustained cure of 100% at the 250mg twice daily dosage level. The drug has met its endpoints of safety, efficacy and dose selection in the Phase II study.

The most important goal in developing a new medicine for the treatment of CDI is to prevent recurrent disease by providing a sustained cure. MGB-BP-3 achieves this goal by its unique rapid bactericidal activity, a feature shared by no other treatment available. Recurrence is unacceptably high with current treatments, occurring in up to one third of patients. At the 250mg twice daily dose level, MGB-BP-3 recorded no disease recurrence measured four weeks after therapy.

MGB Biopharma is backed by a range of investors, led by Edinburgh-based business angel investment syndicate, Archangels. Other investors include Barwell, TRICAPITAL, Syndicate Room and the Scottish Investment Bank. The company has also received support for its clinical programme from Innovate UK.

CDI has been recognised as an urgent threat pathogen by the Centers for Disease Control and Prevention in the US and is a common consequence of antibiotic treatment in hospitalised patients. MGB-BP-3 has received Qualified Infectious Disease Product (QIDP) status from the FDA, enabling Fast Track submission and 5 years of extended marketing exclusivity. In contrast to vancomycin and fidaxomicin, MGB-BP-3 will be eligible to participate in the DISARM programme of prescribing incentives being considered in the United States which will increase patient access to new and innovative treatments.

**Dr Miroslav Ravic, CEO of MGB Biopharma**, said: "We are delighted to have succeeded in meeting our endpoints in this Phase II trial, which is a significant milestone for MGB Biopharma. This study managed to identify a dose that provides a fine balance between maximal killing effects against *C. difficile* whilst having a minimal effect on the remaining normal gut flora. This results in a very high initial cure rate and reduction of disease recurrence.



"As the recent COVID-19 pandemic has demonstrated, the world urgently needs new anti-infective treatments so we can be better prepared for new threats. MGB-BP-3 would bring a new, vastly improved paradigm to the treatment of CDI which would reduce the morbidity and mortality caused by this dreadful infection."

### Dr Sarah Hardy, Director, Archangels, said:

"Developing new treatments is a key part of the global effort against superbugs. We're proud to have supported MGB Biopharma to take on this debilitating disease and we look forward to watching its performance in Phase III trials ahead of it being made available to the clinicians who are battling CDI on a daily basis."

#### Kerry Sharp, Director, Scottish Investment Bank, said:

"This is great news for MGB Biopharma and a significant development in the ongoing global fight against antibiotic-resistant infections. It's never been more important to support pioneering companies developing new and better medicines with the potential to save lives."

#### About MGB Biopharma

MGB Biopharma is a clinical stage company developing a novel class of anti-infectives. Its lead candidate, MGB-BP-3, is an antibacterial which is active against a broad range of important multi-resistant and susceptible Gram-positive pathogens. The Company is developing an oral formulation of MGB-BP-3 for the treatment of *Clostridium difficile* Infection (CDI).

In addition to its *C. difficile* programme, MGB Biopharma has a pipeline of early preclinical compounds against Gram-positive, Gram-negative, anti-fungal, anti-viral and anti-parasitic pathogens.

MGB Biopharma acquired rights to the proprietary minor groove binder (MGB) platform, developed at the University of Strathclyde, Glasgow, with exclusive worldwide licensing rights for all antiinfective fields. This platform provides an opportunity to develop various compounds with a completely new mode of action which are distinct from the antimicrobial drugs used in clinical practice today. As a result, many MGB-based drugs could have the potential to offer significant advantages over existing anti-infectives.

The Company is currently looking for partners to fully capitalise on the multiple value creating opportunities offered by its broad and innovative anti-infectives platform.

The Company, founded in 2010 and headquartered in Glasgow, Scotland, is backed by Scottish investors including Archangel Investors Limited, Barwell, TRI Cap, Syndicate Room and the Scottish Investment Bank, Scottish Enterprise. The company also received support for its clinical programme from Innovate UK.

For more information please visit <u>www.mgb-biopharma.com</u> Or follow MGB Biopharma on Twitter @MGB\_Biopharma

#### Further media enquiries:

Callum Spreng Spreng Thomson Mob: 07803 970103 Email: <u>callum@sprengthomson.com</u>



#### Notes to Editors

#### **About Archangels**

<u>Archangels</u> is a prominent business angel syndicate which has been at the forefront of early stage investing in Scotland for more than a quarter of a century.

Originally formed in 1992 and based in Edinburgh, the syndicate now comprises around 100 investor members and leads investment of around £15m per year in early stage Scottish companies, including leverage from partners, the largest being the Scottish Investment Bank.

Archangels is interested in Scottish technology companies that are looking for initial funding of £50,000 to £2m. In addition, Archangels is keen to welcome new investors to its syndicate.

#### **About Barwell**

Barwell is a privately-funded venture capital company that is based in Glasgow, Scotland.

#### About TRICAPITAL

TRI CAPITAL LIMITED ("TRICAPITAL") is a group of 40-50 angel investors and business men and women who invest in innovative businesses. Most are based in the south of Scotland and north of England, with some members also coming from the rest of the UK and abroad. TRICAPITAL was established in 2004 and its members have invested over £14 million in a number of businesses mainly located in Scotland and the Borders.

#### About SyndicateRoom:

We're a fintech company made up of data-scientists, investment professionals, software developers and marketers with one mission: *to fund every single British startup success story*.

To achieve this, our fund – <u>Access EIS</u> – tracks over 1,000 startup investors. It then selects and coinvests with the best-performing super angels with the aim of replicating their collective success." room.