

# Motif Bio REVIVE-2 Phase 3 Study Results with Iclaprim Published in Peer-reviewed Journal, Antimicrobial Agents and Chemotherapy

NEW YORK, May 01, 2018 (GLOBE NEWSWIRE) – Motif Bio plc (AIM:MTFB) (NASDAQ:MTFB), a clinical stage biopharmaceutical company specialising in developing novel antibiotics, today announced that the results from REVIVE-2, a global Phase 3 clinical trial evaluating the investigational drug candidate iclaprim in patients with acute bacterial skin and skin structure infections (ABSSSI), have been published in the peer-reviewed journal, Antimicrobial Agents and Chemotherapy. Positive results from this study were announced in October 2017 and presented at the recent 28th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID 2018).

The REVIVE-2 study was a global Phase 3 trial evaluating iclaprim in patients with ABSSSI. As previously reported, the study met its primary endpoint of non-inferiority (NI) (10% margin) compared to vancomycin, the current standard of care, at the early time point (ETP), 48 to 72 hours after the start of administration of the study drug, in the intent-to-treat (ITT) patient population. Iclaprim also achieved NI (10% margin) at the test of cure (TOC) endpoint, 7 to 14 days after study drug discontinuation.

The ITT study population included 600 patients from clinical trial sites in the U.S., Europe and Latin America. Patients were randomised 1:1 to receive either iclaprim 80mg IV or vancomycin 15 mg/kg IV. Treatments were administered every 12 hours for 5 to 14 days. Baseline and demographic

characteristics were comparable between the two groups. More than 40% of patients had wound infections, which are typically more difficult to cure than abscesses and cellulitis. The baseline mean lesion size of patients in the iclaprim arm was 372.3 cm<sup>2</sup> compared to 357.0 cm<sup>2</sup> in the vancomycin group. The median treatment time for both groups was 7 days (range, 5-14 days).

Iclaprim was well tolerated in the trial. There were no study-drug related treatment emergent adverse events related to nephrotoxicity (kidney toxicity) reported for patients treated with iclaprim, compared to 2 (0.7%) for vancomycin. There were no deaths in the iclaprim arm and one in the vancomycin arm.

Thomas L. Holland, M.D., MSc-GH, Assistant Professor of Medicine, Duke University School of Medicine, said: "An estimated 3.6 million patients in the U.S. are hospitalised annually with ABSSSI. Up to 26% have renal impairment, often with diabetes, putting them at increased risk for acute kidney injury. For this patient population, iclaprim, if approved, may provide advantages over standard of care vancomycin due to iclaprim's fixed dose regimen, with no dosage adjustment required in patients with renal impairment or in obese patients, and absence of kidney toxicity in the REVIVE trials."

Iclaprim has been designated as a Qualified Infectious Disease Product (QIDP) by the U.S. Food and Drug Administration (FDA). This designation includes Priority Review upon acceptance of a New Drug Application (NDA), and, if approved, it is anticipated that iclaprim will be eligible to receive 10 years of market exclusivity in the U.S. from the date of approval. The FDA has also granted Fast Track designation for iclaprim. Motif Bio has begun a rolling submission of an NDA, which is expected to be completed in the second quarter of 2018.

## **About Iclaprim**

Iclaprim is a novel investigational antibiotic that has a different and underutilised mechanism of action compared to other antibiotics. Iclaprim exhibits potent in vitro activity against Gram-positive clinical isolates of many genera of staphylococci, including methicillin-resistant *Staphylococcus aureus* (MRSA). Iclaprim is rapidly bactericidal, achieving 99.9% in vitro kill against MRSA within 4 to 6 hours of drug exposure versus 8 to 10 hours for vancomycin. To date, iclaprim has been studied in over 1,400 patients and healthy volunteers. In clinical studies iclaprim has been administered intravenously at a fixed dose with no dosage adjustment required in patients with renal impairment or in obese patients. The iclaprim fixed dose may, if approved, help reduce the resources required in hospitals since dosage adjustment by health care professionals is avoided and overall hospital treatment costs may be lower, especially in patients with renal impairment.

## **About Motif Bio**

Motif Bio plc (AIM:MTFB) (NASDAQ:MTFB) is a clinical-stage biopharmaceutical company engaged in the research and development of novel antibiotics designed to be effective against serious and life-threatening infections in hospitalised patients caused by multi-drug resistant bacteria, including MRSA. The Company's lead product candidate, iclaprim, is being developed for high-risk MRSA patient populations. Following positive results from two Phase 3 trials (REVIVE-1 and REVIVE-2), a rolling submission of a New Drug Application (NDA) with the U.S. Food & Drug Administration (FDA) for the treatment of acute bacterial skin and skin structure infections (ABSSSI) has been initiated and is expected to be completed in the second quarter of 2018. ABSSSI is one of the most common bacterial infections, with

3.6 million patients hospitalised annually in the U.S. The Company believes that iclaprim may be suitable for first-line empiric therapy in ABSSSI patients, especially those with renal impairment, with or without diabetes. Unlike many standard of care antibiotics, iclaprim is only minimally cleared via the kidneys (

Clinical and microbiology data indicate iclaprim has a targeted Gram-positive spectrum of activity, low propensity for resistance development, fixed dose administration and favourable tolerability profile. The Company also plans to develop iclaprim for hospital acquired bacterial pneumonia (HABP), including ventilator associated bacterial pneumonia (VABP), as there is a high unmet need for new therapies in this indication. A Phase 2 trial was conducted to study iclaprim in patients with HABP. Iclaprim has been studied in an animal model of pulmonary MRSA infection which mimics the pathophysiology observed in patients with cystic fibrosis. Iclaprim has been granted orphan drug designation by the U.S. FDA for the treatment of Staphylococcus aureus lung infections in patients with cystic fibrosis.

Iclaprim has received Qualified Infectious Disease Product (QIDP) designation from the FDA together with Fast Track status. Upon acceptance by the FDA of a New Drug Application (NDA), iclaprim will receive Priority Review status and, if approved as a New Chemical Entity, will be eligible for 10 years of market exclusivity in the U.S. from the date of first approval, under the Generating Antibiotic Incentives Now Act (the GAIN Act). In Europe, 10 years of market exclusivity is anticipated.

### ***Forward-Looking Statements***

*This press release contains forward-looking statements. Words such as “expect,” “believe,” “intend,” “plan,” “continue,” “may,” “will,” “anticipate,” and similar expressions are intended to identify forward-looking statements. Forward-*

looking statements involve known and unknown risks, uncertainties and other important factors that may cause Motif Bio's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Motif Bio believes that these factors include, but are not limited to, (i) the timing, progress and the results of clinical trials for Motif Bio's product candidates, (ii) the timing, scope or likelihood of regulatory filings and approvals for Motif Bio's product candidates, (iii) Motif Bio's ability to successfully commercialise its product candidates, (iv) Motif Bio's ability to effectively market any product candidates that receive regulatory approval, (v) Motif Bio's commercialisation, marketing and manufacturing capabilities and strategy, (vi) Motif Bio's expectation regarding the safety and efficacy of its product candidates, (vii) the potential clinical utility and benefits of Motif Bio's product candidates, (viii) Motif Bio's ability to advance its product candidates through various stages of development, especially through pivotal safety and efficacy trials, (ix) Motif Bio's estimates regarding the potential market opportunity for its product candidates, and (x) the factors discussed in the section entitled "Risk Factors" in Motif Bio's Annual Report on Form 20-F filed with the SEC on April 10, 2018, which is available on the SEC's web site, [www.sec.gov](http://www.sec.gov). Motif Bio undertakes no obligation to update or revise any forward-looking statements.

i Holland, TL et al. A Phase 3, Randomized, Double-Blind, Multicenter Study To Evaluate the Safety and Efficacy of Intravenous Iclaprim versus Vancomycin for Treatment of Acute Bacterial Skin and Skin Structure Infections Suspected or Confirmed To Be Due to Gram-Positive Pathogens (REVIVE-2 Study). *Antimicrob Agents Chemother.* May 2018 62:e02580-17.

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