



Motif Bio plc

("Motif Bio" or the "Company")

Motif Bio Announces New Iclaprim Data being Presented at ECCMID 2018

- Positive efficacy and safety highlights from Phase 3 REVIVE-2 trial in ABSSSI
- Potential to avoid costs related to vancomycin-associated acute kidney injury in ABSSSI
- Data continue to support iclaprim activity against MRSA and other drug-resistant pathogens

Motif Bio plc (AIM/NASDAQ: MTFB), a clinical-stage biopharmaceutical company specialising in developing novel antibiotics, announced that new clinical and pre-clinical data with its investigational drug candidate iclaprim are being presented at the 28th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID 2018).

Positive efficacy and safety results from REVIVE-2 Phase 3 trial in ABSSSI

The REVIVE-2 study was a global Phase 3 trial evaluating iclaprim in patients with acute bacterial skin and skin structure infections (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, in the ITT patient population.

More detailed safety results are being presented at the conference. Iclaprim was well tolerated in the trial, and 75% of adverse events in the study were categorized as mild. Levels of serum creatinine, a blood test that measures kidney function, were not affected in patients using iclaprim compared to vancomycin. 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, who is presenting the data, said: "The results from this study show that iclaprim was efficacious and well tolerated and did not appear to cause kidney injury. Based on these findings, I believe that iclaprim has the potential to be a useful addition to the treatment armamentarium for patients with ABSSSI suspected or confirmed to be due to Gram-positive pathogens, particularly those at high risk of kidney injury."

Iclaprim potential to avoid costs related to vancomycin-associated acute kidney injury (VA-AKI) in patients hospitalized for ABSSSI

Data are also being presented on potential cost savings opportunities for hospitals by using iclaprim to treat ABSSSI and so avoiding costs related to VA-AKI. Patients who are obese, diabetic or who have renal impairment are at particular risk for VA-AKI. Vancomycin is the most frequently prescribed antibiotic for adults hospitalized with ABSSSI.

In a separate study, also conducted by Tom Lodise, Ph.D., PharmD, Professor at Albany College of Pharmacy and Health Sciences, and his colleagues, evaluating the frequency of VA-AKI and healthcare utilization among Veterans' Affairs patients hospitalized with skin and skin structure infections, VA-AKI incidence was 9.2%. Hospital length of stay was extended by five days for patients with VA-AKI, and many patients with VA-AKI required a nephrology physician consultation and acute dialysis.

Recent in vitro data support iclaprim activity against MRSA and other drug-resistant pathogens

Data are being presented that show that iclaprim continues to be active against a variety of antibiotic-resistant pathogens like methicillin-resistant (MRSA) and methicillin-susceptible (MSSA) *Staphylococcus aureus*. Iclaprim and the comparator antibiotics were tested against MRSA, MSSA and other skin and soft tissue pathogens collected during 2015-2016 from Europe.

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Note to Editors:

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/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 (<2% of the administered dose was recovered unchanged in the urine). No nephrotoxicity was observed with iclaprim in the REVIVE Phase 3 trials and dosage adjustment has not been required in patients with renal impairment.

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. Motif Bio undertakes no obligation to update or revise any forward-looking statements.