4 October 2017

The information contained within this announcement is deemed by Motif Bio plc to constitute inside information as stipulated under the Market Abuse Regulation (EU) No. 596/2014. Upon the publication of this announcement via the Regulatory Information Service, this inside information is now considered to be in the public domain.

Motif Bio plc
("Motif Bio" or the "Company")

Motif Bio Announces Positive Topline Results for iclaprim in the REVIVE-2 Phase 3 Study

- *Iclaprim met the primary endpoint*
- *Iclaprim was well tolerated in the study*
- *NDA submission expected in the first quarter of 2018*

Company to host a conference call today at 2.00 pm CET/1.00 pm BST/8:00 am EDT

Motif Bio plc (AIM/NASDAQ: MTFB), the clinical stage biopharmaceutical company specialising in developing novel antibiotics, today announced positive topline 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).

Iclaprim achieved the 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.

Timepoint	Endpoint	Iclaprim N=295	Vancomycin N=305	% Difference (95% CI)
ETP *(primary endpoint)*	Early Clinical Response (ECR)*	231 (78.3%)	234 (76.7%)	1.58 (-5.10, 8.26)
TOC	Clinical cure	230 (78.0%)	237 (77.7%)	0.26 (-6.39, 6.91)

*≥20% reduction of lesion area at 48-72 hours

In an analysis of a pre-specified secondary endpoint, 54.6% of patients receiving iclaprim demonstrated resolution or near resolution at end of therapy (EOT), compared to 55.4% of patients receiving vancomycin (treatment difference: -0.83%, 95% CI: -8.80% to 7.13%). In another pre-specified secondary endpoint analysis, using a modified clinical cure TOC endpoint defined by a ≥90% reduction in lesion size at TOC, no increase in lesion size since ETP and no requirement for additional antibiotics, clinical cure was seen in 71.9% of patients receiving iclaprim and 70.5% of patients receiving vancomycin (treatment difference: 1.37%, 95% CI: -5.88% to 8.62%).

Graham Lumsden, Chief Executive Officer of Motif Bio commented: *"With the positive results announced today from REVIVE-2, we have now successfully completed the two required Phase 3 trials in ABSSSI and plan to submit an NDA to the U.S. FDA by the end of the first quarter of 2018. This is a testament to the incredible efforts of our team at Motif who have worked tirelessly to get us to this stage. We believe that these results validate our belief in iclaprim as a potential new antibiotic candidate for patients with serious and life-threatening infections. I thank the patients and clinicians who participated in this important study.*
"We believe that iclaprim, if approved, could be an important option for patients with ABSSSI, especially for those patients who may also have kidney disease, with or without diabetes. It is estimated that up to 26% of the 3.6 million ABSSSI patients hospitalised annually in the U.S. have kidney disease. Unlike current standard of care antibiotics, in clinical trials to date, kidney toxicity has not been observed with iclaprim and dosage adjustment has not been required in patients with renal impairment. Iclaprim may be an important option for the growing population of patients with ABSSSI and kidney disease who need a safe and effective antibiotic targeting Gram-positive bacteria, including MRSA."

G. Ralph Corey, MD, Vice Chair for Education and Global Health, School of Medicine Gary Hock Professor, Global Health Director, Hubert-Yeargan Center for Global Health, Duke University School of Medicine and principal investigator of the REVIVE-2 study, said: *"ABSSSI is a serious infection for which patients are frequently hospitalized for several days. Many of these patients have co-morbidities, such as renal impairment and diabetes. For these patients in particular, there is an urgent need for better treatment options. With the strong efficacy and safety results from REVIVE-2, including no renal toxicity, as well as fixed dosing, iclaprim, if approved, could be an important new treatment option for these patients."*

REVIVE-2 Overview and Adverse Event (AE) Summary

REVIVE-2 was a 600-patient double-blinded, active-controlled, global trial in patients with ABSSSI that compared the safety and efficacy of an 80mg intravenous dose of iclaprim with a 15mg/kg intravenous dose of vancomycin. Treatments were administered every 12 hours for 5 to 14 days. The trial involved over 40 clinical centres in the U.S., South America and Europe.

Iclaprim was well tolerated in the study, with most adverse events categorized as mild.

	Iclaprim N=299	Vancomycin N=302
TEAEs (Treatment Emergent Adverse Events)	140 (46.8%)	133 (44.0%)
Study drug related TEAEs	42 (14.0%)	39 (12.9%)
TEAEs leading to discontinuation of study drug	16 (5.4%)	17 (5.6%)
TEAE-related SAEs (Serious AEs)	14 (4.7%)	12 (4.0%)
Deaths	0	1

Motif Bio plans to present more detailed data from this study at an upcoming scientific forum.

Iclaprim has been designated as a Qualified Infectious Disease Product (QIDP) by the U.S. Food and Drug Administration (FDA) for the treatment of ABSSSI and hospital acquired bacterial pneumonia (HABP), which enables Priority Review following submission of an NDA. 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.

Conference call details

Motif Bio management will host a conference call regarding this announcement at 8:00 am EDT/1.00 pm BST/2.00 pm CET on 4 October 2017. The call may be accessed as follows:

UK: +44 08000288438 (toll free) or +44 02031070289

US: 1 -866-219-5264 (toll free) or 1-703-736-7410

Germany: +49 08001815287 (toll free) or +49 06922224710

Conference passcode: 95686039

A live webcast of the call will be available in the Investors section of the company's website at www.motifbio.com, and will be archived there for 30 days.

The person responsible for the release of this announcement on behalf of Motif Bio plc is Robert Dickey IV, Chief Financial Officer.

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Notes 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 1,300 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. The first proposed indication, and near-term commercial opportunity, is for the treatment of acute bacterial skin and skin structure infections (ABSSSI), one of the most common bacterial infections, with 3.6 million patients hospitalised annually in the US. 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 current standard of care antibiotics, in clinical trials to date, nephrotoxicity has not been observed with iclaprim and dosage adjustment has not been required in patients with renal impairment.

Iclaprim has an underutilised mechanism of action compared to other antibiotics. 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. Additionally, data support that the inactive metabolites of iclaprim clear through the kidneys. 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 chronic pulmonary MRSA infection which mimics the pathophysiology observed in patients with cystic fibrosis. Results from this study will be presented at IDWeek 2017™ on October 6, 2017 in San Diego, CA. 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 US from the date of first approval, under the Generating Antibiotic Incentives Now Act (the GAIN Act). In Europe, 10 years of data 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 plc’s Annual Report on Form 20-F filed with the SEC on May 1, 2017, which is available on the SEC’s web site, www.sec.gov. Motif Bio plc undertakes no obligation to update or revise any forward-looking statements.