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

Motif Bio Initiates NDA Rolling Submission for Iclaprim and Provides Business Update

Motif Bio plc (AIM/NASDAQ: MTFB), a clinical-stage biopharmaceutical company specialising in developing novel antibiotics, today announced the initiation of a rolling submission of a New Drug Application (NDA) to the U.S. Food & Drug Administration (FDA) for iclaprim, a targeted, Gram-positive investigational antibiotic, for the treatment of acute bacterial skin and skin structure infections (ABSSSI). The NDA submission is expected to be completed during the second quarter of 2018.

Iclaprim has received Qualified Infectious Disease Product (QIDP) designation from the FDA together with Fast Track Designation. A candidate granted Fast Track Designation is eligible for a rolling NDA submission, which means that a company can submit completed sections of its NDA, rather than waiting until every section of the NDA has been finalised. Upon acceptance for filing by the FDA of a complete NDA, iclaprim will receive Priority Review status which will result in a review period of up to six months. Upon NDA approval as a new chemical entity with QIDP designation, iclaprim will be eligible for 10 years of market exclusivity in the U.S. starting from the date of first approval.

The Company has also received correspondence from the FDA that a small business waiver has been granted for the NDA application fee which is due upon submission of an NDA under the Prescription Drug User Fee Act (PDUFA). As a result, Motif did not have to pay the \$2.4 million application fee for this NDA submission.

Motif Bio continues to evaluate commercialisation strategies for bringing iclaprim, if approved, to patients in the U.S. and elsewhere. The Company is in continuing discussions with potential regional partners, in line with its stated strategy. For the U.S. market, the Company's strategy is to continue to evaluate its options, which include partnering with a revenue-generating company or a late development-stage company in the hospital space, employing a commercial outsourcing company or building its own commercialisation organisation. The Company is in discussions with several potential partners and views partnering as its preferred strategy. However, it is noted that there can be no certainty given as to the prospect of entering into an agreement with a partner, nor in relation to the timing or terms on which any such agreement may be made.

Motif Bio also announced that the Company plans to issue its 2017 full year financial results by April 10, 2018, including filing its U.S. Annual Report on Form 20-F and its UK Annual Report and Accounts.

Graham Lumsden, Chief Executive Officer, said: *"We are delighted to announce this major milestone of beginning our NDA submission for iclaprim in the treatment of ABSSSI by the end of the first quarter of 2018. We remain on track to be able to complete the submission in the second quarter and will confirm when this has been done. We are also pleased to confirm the waiver for the NDA PDUFA application fee. We remain focused on completing the NDA submission, advancing our pre-commercialisation activities and driving discussions with potential partners as we move closer to our goal of bringing iclaprim to market for the benefit of patients."*

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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 1,400 patients and healthy volunteers. In clinical studies iclaprim has been administered intravenously at a fixed dose with no dosage adjustments 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 ABSSSI, 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.

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 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 for the ABSSSI and HABP indications. Upon acceptance by the FDA of a New Drug Application (NDA) for ABSSSI or HABP, 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 May 1, 2017, 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.