



14 June 2018

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

Motif Bio Submits NDA for Iclaprim

Motif Bio plc (AIM/NASDAQ: MTFB), a clinical-stage biopharmaceutical company specialising in developing novel antibiotics, today announced the completion of its 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 for iclaprim is a major milestone for Motif Bio. Our team of experts has worked tirelessly to achieve this important goal," said **Graham Lumsden, Chief Executive Officer.** "We look forward to working with the FDA with the goal of bringing this antibiotic candidate to patients as expeditiously as possible."*

Iclaprim has received Qualified Infectious Disease Product (QIDP) designation from the FDA together with Fast Track Designation. Upon acceptance of the filing of the NDA by the FDA, iclaprim will receive Priority Review, a review period of six months instead of the standard ten months. If iclaprim is approved as a new chemical entity with QIDP designation, it will be eligible for 10 years of market exclusivity in the U.S. starting from the date of approval.

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Note to Editors:

About Iclaprim

Iclaprim is a novel investigational antibiotic with a targeted Gram-positive spectrum of activity. In contrast to commonly used broad-spectrum antibiotics, this “precision medicine approach” is consistent with antibiotic stewardship principles which, among other things, seek to reduce the inappropriate use of broad-spectrum products to avoid the build-up of resistance and to lessen the impact on the microbiome of the patient.

Iclaprim has a different and underutilised mechanism of action compared to most other antibiotics. Following positive results from two Phase 3 trials (REVIVE-1 and REVIVE-2), a New Drug Application (NDA) has been submitted to the U.S. Food & Drug Administration (FDA) for the treatment of acute bacterial skin and skin structure infections (ABSSSI). To date, iclaprim has been studied in over 1,400 patients and healthy volunteers. Clinical and microbiological data indicate that iclaprim has a targeted Gram-positive spectrum of activity, low propensity for resistance development and favourable tolerability profile. 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. Many standard of care Gram-positive antibiotics are not suitable for hospitalized ABSSSI patients with renal impairment due to efficacy and/or safety issues.

About Motif Bio

Motif Bio plc (AIM/NASDAQ: MTFB) is a clinical-stage biopharmaceutical company focused on developing novel antibiotics for hospitalised patients and designed to be effective against serious and life-threatening infections caused by multi-drug resistant bacteria, including MRSA. The Company’s lead product candidate is iclaprim. Following positive results from two Phase 3 trials (REVIVE-1 and REVIVE-2), an NDA has been submitted to the U.S. FDA for the treatment of acute bacterial skin and skin structure infections (ABSSSI). More than 3.6 million patients with ABSSSI are hospitalised annually in the U.S. It is estimated that up to 26% of hospitalized ABSSSI patients have renal impairment. The Company believes, based on the data from the Phase 3 REVIVE studies, that iclaprim may be suitable for first-line empiric therapy in ABSSSI patients, including those with renal impairment, with or without diabetes.

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 in patients with HABP has been successfully completed and a Phase 3 trial is being planned. Additionally, iclaprim has been granted orphan drug designation by the FDA for the treatment of *Staphylococcus aureus* lung infections in patients with cystic fibrosis and is in preclinical development for this indication.

Iclaprim has received Qualified Infectious Disease Product (QIDP) designation from the FDA together with Fast Track status. Upon acceptance by the FDA of an 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.