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The information contained within this announcement is deemed by the Company 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 Granted Meeting with U.S. FDA regarding Iclaprim

Motif Bio plc (AIM/NASDAQ: MTFB), a clinical-stage biopharmaceutical company specialising in developing novel antibiotics, announced today that the U.S. Food & Drug Administration (FDA) has granted the Company’s request for a Type A meeting to discuss the points raised in the Complete Response Letter received from the FDA related to the New Drug Application (NDA) for iclaprim for the treatment of acute bacterial skin and skin structure infections. The meeting is scheduled to take place on May 3, 2019.

Graham Lumsden, Chief Executive Officer of Motif Bio, said: “We are pleased that the FDA has granted our meeting request and that critical personnel from the FDA have been invited to attend the upcoming meeting with our internal and external experts. We look forward to a collaborative meeting and to discussing with the Agency the best way to move iclaprim towards marketing approval.”

Official meeting minutes are received from the FDA typically within 30 days of a meeting. After this, Motif Bio will be in a position to provide an update to the market on the path forward for iclaprim.

As previously announced, the Company needs to raise additional capital in the near term. A further update regarding financing will be made in due course.

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Note to Editors:

About Motif Bio
Motif Bio plc (AIM/NASDAQ: MTFB) is a clinical-stage biopharmaceutical company focused on developing novel antibiotics designed to be effective against serious and life-threatening infections caused by multi-drug resistant Gram-positive bacteria, including MRSA. The Company’s lead product candidate is iclaprim. Motif Bio is seeking approval of iclaprim from the U.S. Food & Drug Administration (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 also has 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 for the ABSSSI indication. If approved for the ABSSSI indication as a New Chemical Entity, iclaprim 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. Motif is also building a patent estate to provide additional protection for iclaprim and has two U.S. method of use patents issued that will expire in 2037.

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, (x) Motif Bio’s ability to raise additional capital to sustain its operations and pursue its strategy and (xi) 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.