



## Motif Bio Confirms Meeting Date with U.S. FDA regarding Iclaprim

July 26, 2019

NEW YORK, July 26, 2019 (GLOBE NEWSWIRE) -- 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 B meeting related to a proposed clinical study for the Company's lead product candidate, iclaprim. The in person meeting has been scheduled for September 19, 2019.

As previously announced, Motif Bio submitted a meeting request and clinical study proposal to the FDA based upon the minutes from a May 3, 2019, Type A meeting with the Agency, which indicated that an additional clinical trial will be required prior to granting marketing approval for iclaprim. The Company was encouraged by the FDA to put forth a proposal for such a study, and Motif Bio plans to discuss the proposed patient population and study design with the Agency at the upcoming meeting.

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.

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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. In February 2019, the Company received a Complete Response Letter (CRL) related to the New Drug Application (NDA) for iclaprim for the treatment of ABSSSI. Additional information regarding the CRL can be found in Motif Bio's Annual Report on Form 20-F filed with the SEC on April 15, 2019. Minutes from a meeting with the FDA to discuss the points raised in the CRL were received in June 2019 and indicated that an additional clinical trial will be required prior to granting marketing approval to address the Agency's continued concerns about potential liver toxicity. The Company was encouraged by the FDA to put forth a proposal for a future study and submitted such a proposal for review in July 2019. Motif Bio has been granted a meeting, scheduled for September 19, 2019, with the Agency to discuss the proposed patient population and study design.

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 pre-clinical development for this indication.

Iclaprim 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 15, 2019, which is available on the SEC’s web site, [www.sec.gov](http://www.sec.gov). Additionally, there can be no assurance that Motif Bio will regain compliance with Nasdaq rules or maintain its ADS listing on Nasdaq. Motif Bio undertakes no obligation to update or revise any forward-looking statements.



Source: Motif Bio plc