



## Motif Bio Submits Meeting Request and Package to the U.S. FDA for Iclaprim

July 15, 2019

NEW YORK, July 15, 2019 (GLOBE NEWSWIRE) -- Motif Bio plc (AIM/Nasdaq: MTFB), a clinical-stage biopharmaceutical company specialising in developing novel antibiotics, today announced that it has submitted a meeting request and package to the U.S. Food & Drug Administration (FDA) related to the Company's lead product candidate, iclaprim. In the minutes from a May 3, 2019, Type A meeting, the FDA indicated that an additional clinical trial will be required prior to granting marketing approval of iclaprim. The Company has been encouraged by the FDA to put forth a proposal for such a study. Motif Bio has requested a Type B meeting with the Agency to discuss the proposed study population and design. The Company will provide guidance on when such a meeting will occur once FDA issues the meeting granted letter. The FDA typically schedules a Type B meeting within 60 days of request, although it can take longer.

**Graham Lumsden, Chief Executive Officer, said:** "As we take this next step towards potential regulatory approval for iclaprim in the U.S., I want to recognize the efforts of our dedicated team and our clinical advisors in producing a well-considered submission package to advance our dialogue with the FDA in an expeditious manner. As we continue our discussions with potential U.S. commercial partners and evaluate potential funding options for the iclaprim clinical programme, we expect to gain greater clarity from the Agency during the Type B meeting on the pathway forward for iclaprim."

**Dr. Lumsden continued:** "Our strategic goal of building long-term shareholder value by establishing a robust pipeline of product candidates continues to be our priority. In addition to exploring the use of iclaprim in other disease areas through our recently announced collaborations for cystic fibrosis and chorioretinitis, we are actively evaluating additional in-licensing and asset acquisition opportunities."

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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 hospitalised 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 requested a meeting with the Agency to discuss the proposed study population and 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). Motif Bio undertakes no obligation to update or revise any forward-looking statements.



Source: Motif Bio plc