



## Motif Bio Receives Complete Response Letter from the FDA

February 14, 2019

NEW YORK, Feb. 14, 2019 (GLOBE NEWSWIRE) -- Motif Bio plc (AIM/NASDAQ: MTFB), a clinical-stage biopharmaceutical company specialising in developing novel antibiotics, announced today that the Company has received a Complete Response Letter (CRL) from the U.S. Food & Drug Administration (FDA) regarding the New Drug Application (NDA) for iclaprim for the treatment of acute bacterial skin and skin structure infections (ABSSSI). The CRL states that the FDA cannot approve the NDA in its present form and indicates that additional data are needed to further evaluate the risk for liver toxicity before the NDA may be approved. Motif Bio plans to request a meeting with the FDA as soon as possible to discuss potential options to address the deficiencies.

**Graham Lumsden, Chief Executive Officer of Motif Bio, said:** *"We are disappointed for patients and providers seeking an alternative antibiotic to treat ABSSSI. We intend to request a meeting with the FDA, which typically should occur within approximately 30-45 days, to discuss the CRL. We look forward to working with the Agency to discuss options to advance iclaprim towards approval."*

At 31 December 2018, the Company had cash of \$12.3 million and \$15 million of debt drawn from its Hercules loan facility. The Company is financed into the second quarter of 2019 but will need to raise capital in the near term.

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 addition, Motif is 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.

The person who arranged for the release of this announcement on behalf of Motif Bio plc was Jon Gold, Interim Chief Financial Officer.

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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. To date, iclaprim has been studied in nearly 1,500 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 the REVIVE Phase 3 clinical studies in patients with acute bacterial skin and skin structure infections (ABSSSI), iclaprim was 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 hospitalised 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 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](http://www.sec.gov). Motif Bio undertakes no obligation to update or revise any forward-looking statements.



Motif BioSciences Inc.