



Motif Bio Announces Path Forward for Iclaprim following Receipt of FDA Meeting Minutes

June 6, 2019

Conference call scheduled for Thursday, June 6, 2019 at 8:00 AM EDT/1:00 PM BST/2:00 PM CET

NEW YORK, June 06, 2019 (GLOBE NEWSWIRE) -- Motif Bio plc (AIM/Nasdaq: MTFB), a clinical-stage biopharmaceutical company specialising in developing novel antibiotics, today announced that the Company has received the official minutes of the Type A meeting the Company held with the U.S. Food & Drug Administration (FDA or Agency) on May 3, 2019, to discuss the points raised in the Complete Response Letter (CRL) related to the New Drug Application (NDA) for iclaprim, for the treatment of acute bacterial skin and skin structure infections (ABSSSI). The minutes indicate 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 has been encouraged by the FDA to put forth a proposal for a future study and to submit it for review. The Company plans to request a meeting with the Agency to discuss the design of the study, including the appropriate patient population to be evaluated.

Dr. Graham Lumsden, Chief Executive Officer, said: "We now have confirmation of what will be required for a path forward for iclaprim. We intend to meet with the Agency to agree on the specific requirements of the trial, which will enable us to estimate its size and scope and, therefore, the costs and funding requirements. In parallel, we expect to continue our discussions with potential commercial partners and will determine the best options for funding the trial once we have clarity from the FDA."

"We continue to believe that iclaprim has the potential to be an important new treatment option for hospitalised patients with ABSSSI and potentially also in patients with hospital-acquired bacterial pneumonia, including ventilator-associated bacterial pneumonia. In addition, we are exploring the use of iclaprim in other disease areas, including orphan indications such as Staphylococcus aureus lung infections in patients with cystic fibrosis and in ophthalmology, as evidenced by recently announced collaborative agreements. Completing the steps necessary to provide the additional trial data to respond to the Complete Response Letter is our top priority. We are also continuing our business development activities to position Motif Bio for long-term growth by building a robust development pipeline. In parallel with our focus on iclaprim, we continue to pursue a variety of attractive opportunities in the anti-infectives space, as well as in other key therapeutic areas."

As of May 31, 2019, the Company had a cash balance of \$2.3 million and \$7.1 million of outstanding debt drawn from the Hercules Loan Facility. The Company believes the current cash position can support continued operations into September 2019 with diligent cash management. The Company will need to raise additional capital, which may be through equity financing and/or from non-dilutive sources. The Company is evaluating options to determine the funding strategy that will be most favourable for shareholders and will provide an update to the market in due course.

Conference call scheduled

Motif Bio will hold a conference call on **Thursday, June 6, 2019 at 8:00 AM EDT/1:00 PM BST/2:00 PM CET**.

You may pre-register for the call here <http://dpreregister.com/10131464>. Callers who pre-register will be given a conference passcode and unique PIN to gain immediate access to the call and bypass the live operator. Participants may pre-register at any time, including up to and after the call start time.

If you have not pre-registered, please dial in at least 10 minutes in advance of the call and refer to the Motif Bio call.

The dial-in details are as follows:

United Kingdom: +44 (0)20 3514 3188
Germany: +49 (0)69-22221534
United States: +1 412-317-5413

The call will also be webcast. Please visit the Investors - Events and Presentations section of Motif Bio's website at <http://ir.motifbio.com/phoenix.zhtml?c=254416&p=irol-calendar> for a link to the webcast.

The person who arranged for the release of this announcement on behalf of Motif Bio plc was Graham Lumsden, Chief Executive Officer.

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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 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. Motif Bio undertakes no obligation to update or revise any forward-looking statements.

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Source: Motif Bio plc