



Motif Bio Presents New Iclaprim Data at ASM Microbe 2019

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NEW YORK, June 24, 2019 (GLOBE NEWSWIRE) -- Motif Bio plc (AIM/NASDAQ: MTFB), a clinical-stage biopharmaceutical company specialising in developing novel antibiotics, today reported that new iclaprim data were presented at the American Society For Microbiology (ASM) Microbe 2019 meeting held in San Francisco, CA, USA, June 20-24, 2019.

David Huang, MD, PhD, Chief Medical Officer of Motif Bio, said: “The posters presented at ASM Microbe include additional data from the Phase 3 clinical trials with iclaprim in bacterial skin and skin structure infections, notably improvements in efficacy parameters and C_{max} with the fixed dosing regimen compared to the weight-based dose regimen, and analysis of subpopulations who had co-morbidities such as obesity, diabetes and renal impairment, or were elderly.”

1. Pharmacokinetic analysis shows improvement in efficacy parameters and C_{max}¹ with iclaprim fixed dose versus weight-based dose

Data presented included an analysis of the pharmacokinetics of the iclaprim fixed dose used in the REVIVE Phase 3 trials in acute bacterial skin and skin structure infections (ABSSSI) compared to the weight-based dose used in the earlier ASSIST trials with iclaprim for complicated skin and skin structure infections (cSSSI) (*Population Pharmacokinetic (PK) Analysis of the Fixed Dose of Iclaprim in the Phase 3 REVIVE Studies for the Treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI)*). The analysis showed that two efficacy parameters (AUC/MIC and T>MIC²) were improved with the fixed two-hour 80mg dose by 54% and 67%, respectively. C_{max} was improved by 7% with the fixed dose compared to the 30-minute weight-based dose. The fixed dose regimen may help reduce the resources required in hospitals, since dosage adjustment by clinicians is avoided, and overall treatment costs may be lower, especially in patients with obesity or renal impairment.

2. Iclaprim subpopulation analysis shows iclaprim used to treat patients with variety of co-morbidities in Phase 3 trials

Motif Bio also presented an analysis of the patient populations treated with iclaprim in the REVIVE and earlier ASSIST Phase 3 trials (*Iclaprim Use across Various Subpopulations Treated for Bacterial Skin and Skin Structure Infections*). Overall, 1,093 patients with ABSSSI/cSSSI were exposed to iclaprim in these studies. Older patients and patients with co-morbidities such as obesity, diabetes, and renal impairment were well represented across the trials. In the REVIVE and ASSIST trials, respectively: 12% and 16% of patients treated with iclaprim were 65 years of age or older; 15% and 8% were obese (body mass index >35 kg/m²); 9% and 12% had diabetes; and 15% and 41% had renal impairment. The median treatment duration was seven days in the REVIVE studies and ten days in the ASSIST trials.

3. Iclaprim is active against various Gram-positive multi-drug resistant bacteria in updated surveillance analysis, including those resistant to other antibiotics

Iclaprim demonstrated potent activity against various Gram-positive multi-drug resistant streptococci that were collected from patients with ABSSSI between 2013 and 2017 in locations around the world (*Surveillance of Iclaprim Activity against Multi-Drug Resistant Streptococci Collected from Patients with Skin and Skin Structure Infections from 2013-2017 from Locations Worldwide*). This included isolates that had multi-drug resistance to azithromycin, clindamycin and tetracycline. Given the growing public health concern about antibiotic resistance, it is important to continue to monitor the activity of iclaprim against these bacteria.

¹ C_{max}: Maximum concentration that a drug achieves in a tested area after the drug has been administered and prior to the administration of a second dose.

² AUC/MIC: Area under the curve/minimum inhibitory concentration – AUC = The total exposure of an antibiotic to an organism. MIC = The lowest concentration of an antibiotic that will inhibit the growth of an organism.

T>MIC: Time the concentration of an antibiotic remains above MIC.

The iclaprim-related posters will be available shortly on the Motif Bio website (www.motifbio.com).

For further information please contact:

Motif Bio plc

Graham Lumsden (Chief Executive Officer)

ir@motifbio.com

Walbrook PR Ltd. (UK FINANCIAL PR & IR)

Paul McManus/Lianne Cawthorne

+44 (0)20 7933 8780

motifbio@walbrookpr.com

MC Services AG (EUROPEAN IR)

Raimund Gabriel

+49 (0)89 210 2280

raimund.gabriel@mc-services.eu

LifeSci Advisors (U.S. IR)

Bob Yedid

+1 (646) 597 6989

bob@lifesciadvisors.com

Russo Partners (U.S. PR)

David Schull

+1 (858) 717 2310 or +1 (212) 845 4272

david.schull@russopartnersllc.com

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 has been encouraged by the FDA to put forth a proposal for a future study and to submit it for review and plans to request a meeting with the Agency to discuss the design of the study, including the appropriate patient population to be evaluated.

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 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.



Source: Motif Bio plc