Motif Bio Presents New Iclaprim Data at ECCMID 2019

April 16, 2019

NEW YORK, April 16, 2019 (GLOBE NEWSWIRE) -- Motif Bio plc (AIM/NASDAQ: MTFB), a clinical-stage biopharmaceutical company specialising in developing novel antibiotics, announced today that new iclaprim data are being presented at the 28th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID 2019) in Amsterdam, The Netherlands.

Efficacy analysis by lesion size demonstrates iclaprim had comparable efficacy to vancomycin across broad range of lesion sizes in REVIVE Phase III study patients

Larger-size acute bacterial skin and skin structure infection (ABSSSI) lesions may be more difficult to treat. A post-hoc analysis by lesion size of the pooled data from the REVIVE-1 and REVIVE-2 Phase III trials evaluating iclaprim versus vancomycin for the treatment of ABSSSI patients showed that fixed dosing of iclaprim had similar efficacy results compared to weight/renal function-based dosing of vancomycin across a broad range of lesion sizes, including lesions 800 cm^2 or greater.

Clearance of bacteremia comparable in patients treated with iclaprim versus vancomycin in pooled analysis of REVIVE Phase III study results

Secondary bacteremia is a complication among patients with ABSSSI and is associated with increased morbidity and mortality. A post-hoc analysis evaluated bacteremia outcomes in patients in the REVIVE trials. There were 12/592 patients in the iclaprim arm and 12/606 patients in the vancomycin arm with secondary bacteremia. In each group, 83% of patients cleared their bacteremia by the test of cure visit (7 to 14 days after end of therapy).

Pharmacokinetics of iclaprim support use of fixed dosing regimen in ABSSSI patients

A pharmacokinetic analysis of iclaprim-treated patients in the REVIVE Phase III trials evaluated iclaprim clearance and concentration. Age had a small effect on clearance and with it on AUC[i]. Clearance decreased by about 10% for each decade over 50 years. Clearance was not affected by weight, gender, renal function, hepatic function or race. There were modest increases related to drug concentration (as measured by AUC and Cmax[ii]) in patients 65 years and older compared to younger patients, likely due to slower clearance. These differences were not considered clinically meaningful. The results support that no iclaprim dose adjustments are required for elderly patients, nor for obese or renally impaired patients, in this patient population.

Recent in vitro data support iclaprim activity against Gram-positive bacteria collected from patients with skin and skin structure infections

Data are being presented that show that iclaprim continues to be active against a variety of antibiotic-resistant pathogens like methicillin-resistant (MRSA), methicillin–susceptible (MSSA) *Staphylococcus aureus*, and other Gram-positive skin and soft structure pathogens collected during 2017 from Europe and the U.S.

"It is important to see that these subgroup analyses in the REVIVE Phase III trials show that results with iclaprim were comparable to vancomycin, even in patients with more challenging-to-treat skin infections, such as those with large lesions or with bacteremia," **said Thomas L. Holland, M.D., MSc-GH, Assistant Professor of Medicine, Duke University School of Medicine.** *"We continue to need new options to treat patients with ABSSSI, particularly those at risk of vancomycin-associated kidney injury."*

Real-world incidence of vancomycin-associated nephrotoxicity in hospitalised patients with ABSSSI shown to be >3-fold higher than in recent trials

Michael J. Rybak, Pharm.D., MPH, Ph.D., Professor of Pharmacy and Medicine, Director, Anti-Infective Research Laboratory, Eugene Applebaum College of Pharmacy and Health Sciences, Wayne State University, Detroit, Michigan, USA led a retrospective, cohort study at two medical centers in Detroit from February to June 2018. A total of 82 hospitalised adults treated with vancomycin (≥72 hours) for ABSSSI and with ≥1 baseline acute kidney injury (AKI) risk factors were evaluated. Patients with severe renal impairment or AKI prior to vancomycin treatment were excluded. The study found that the incidence of nephrotoxicity in patients with ≥1 AKI risk factor was >3-fold higher than in recent trials, underscoring the importance of close monitoring and/or selection of an alternative agent in at-risk ABSSSI patients.

For further information please contact:

Motif Bio plc ir@motifbio.com
Graham Lumsden (Chief Executive Officer)

Walbrook PR Ltd. (UK FINANCIAL PR & IR) +44 (0)20 7933 8780
Paul McManus/Helen Cresswell/Lianne Cawthorne motifbio@walbrookpr.com

MC Services AG (EUROPEAN IR) +49 (0) 89 210 2280
Raimund Gabriel raimund.gabriel@mc-services.eu

Russo Partners (U.S. PR) +1 (858) 717-2310 or +1 (212) 845 4272
David Schull 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.

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.

[i] AUC – Area under the curve: Mathematical method for measuring drug concentrations.

[ii] Cmax – Maximum concentration: The peak concentration that a drug achieves in the body after the drug has been administered and before administration of a second dose.

Motif Bio plc