



April 18, 2017

This announcement contains inside information

Motif Bio plc
("Motif Bio" or the "Company")

Motif Bio Announces Positive Results for Iclaprim, in the REVIVE-1 Phase 3 Study

- *Iclaprim met the primary endpoint*
- *Iclaprim was well tolerated in the study*
- *Data from the second Phase 3 ABSSSI Trial, REVIVE-2, expected in the second half of 2017*
- *NDA submission expected in the first half of 2018*

Company to host a conference call today at 1.00 pm BST, 8:00 am EDT

Motif Bio plc (AIM: MTFB), the clinical stage biopharmaceutical company specialising in developing novel antibiotics, today announced positive topline results from REVIVE-1, a global Phase 3 clinical trial of its investigational drug candidate iclaprim in patients with acute bacterial skin and skin structure infections (ABSSSI).

Iclaprim achieved the primary endpoint of non-inferiority (NI) (10% margin) compared to vancomycin at the early time point (ETP), 48 to 72 hours after the start of administration of the study drug, in the intent-to-treat (ITT) patient population. Iclaprim also achieved NI (10% margin) at the test of cure (TOC) endpoint, 7 to 14 days after study drug discontinuation, in the ITT patient population.

Time point	Endpoint	Iclaprim N=298	Vancomycin N=300	% Difference (95% CI)
ETP	Early Clinical Response (ECR)*	241 (80.9%)	243 (81.0%)	-0.13 (-6.42, 6.17)
TOC	Clinical cure	251 (84.2%)	261 (87.0%)	-2.77 (-8.39, 2.85)

* $\geq 20\%$ reduction of lesion area at 48-72 hours

In an analysis of a pre-specified secondary endpoint, 60.4% of patients receiving iclaprim demonstrated resolution or near resolution at end of therapy (EOT), compared to 58.3% of patients receiving vancomycin (treatment difference: 2.07%, 95% CI: -5.80% to 9.94%). In another pre-specified secondary endpoint analysis, using a modified clinical cure TOC endpoint defined by a $\geq 90\%$ reduction in lesion size at TOC, no increase in lesion size since ETP and no requirement for additional antibiotics, clinical cure was seen in 68.5% of patients receiving iclaprim and 73.0% of patients receiving vancomycin (treatment difference: -4.54%, 95% CI: -11.83% to 2.74%).

Graham Lumsden, Chief Executive Officer of Motif Bio commented: *"The successful completion of REVIVE-1 is a significant achievement for Motif Bio. I would like to thank the patients and physicians that participated in this important study. We believe that iclaprim, if approved, could be an important option for patients with ABSSSI, especially for patients with severe infections who may also have kidney disease with or without diabetes. Unlike current standard of care antibiotics, in clinical trials to date, nephrotoxicity has not been observed with iclaprim and dosage adjustment has not been required in renally impaired patients. It is estimated that up to 26% of the 3.6 million ABSSSI patients hospitalised*

annually in the U.S. have kidney disease.”

William D. O’Riordan M.D., FACEP, Chief Medical Officer, eStudySite commented: *“Following the positive outcome in this clinical trial, the differentiated mechanism, potency, spectrum, safety and efficacy of iclaprim, if approved, could provide a valuable new antibiotic treatment option that is urgently needed to offset the rising problem of bacterial resistance.”*

Data from REVIVE-2, the second Phase 3 trial, which uses an identical protocol to REVIVE-1 but has different trial centres, are expected in the second half of 2017 and submission of a New Drug Application (NDA) for iclaprim for the treatment of ABSSSI is anticipated in the first half of 2018.

Iclaprim has been designated as a Qualified Infectious Disease Product (QIDP) by the U.S. Food and Drug Administration (FDA) for the treatment of ABSSSI and hospital acquired bacterial pneumonia (HABP), which enables Priority Review following submission of a NDA. If approved, it is anticipated that iclaprim will be eligible to receive 10 years of market exclusivity in the U.S. from the date of approval. The FDA has also granted Fast Track designation for iclaprim.

REVIVE-1 Overview and Adverse Event (AE) Summary

REVIVE-1 is a 600-patient double-blinded, active-controlled, global, multicentre trial, in patients with ABSSSI that compares the safety and efficacy of an 80mg intravenous dose of iclaprim with a 15mg/kg intravenous dose of vancomycin. Treatments were administered every 12 hours for 5 to 14 days.

Iclaprim was well tolerated in the study, with most adverse events categorized as mild.

	Iclaprim N=293	Vancomycin N=297
TEAEs (Treatment Emergent Adverse Events)	151 (51.5%)	128 (43.1%)
Study drug related TEAEs	57 (19.5%)	53 (17.8%)
TEAEs leading to discontinuation of study drug	8 (2.7%)	13 (4.4%)
TEAE-related SAEs (Serious AEs)	8 (2.7%)	12 (4.0%)
Deaths	0 (0.0%)	1 (0.3%)

Motif Bio plans to present the full data from this study at an upcoming scientific forum.

Conference call details

Motif Bio management will host a conference call regarding this announcement at 1.00 pm BST, 8:00 am EDT on Tuesday, 18 April 2017. The call may be accessed by dialling +1-703-736-7410 for callers outside the U.S., (866) 219-5264 for callers in the U.S., using the conference ID number 6665100. A live webcast of the call will be available from the investor relations section of the company's website at www.motifbio.com, and will be archived there for 30 days.

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Notes to Editors

About iclaprim

Iclaprim is a potential novel antibiotic, designed to be effective against bacteria that have developed resistance to other antibiotics, including trimethoprim. Iclaprim exhibits potent *in vitro* activity against Gram-positive clinical isolates of many genera of staphylococci, including methicillin sensitive *Staphylococcus aureus* (MSSA) and methicillin resistant *Staphylococcus aureus* (MRSA). The MIC₉₀ of iclaprim was lower than most comparators including vancomycin and linezolid, standard of care therapies used in serious and life-threatening Gram-positive hospital infections. To date, iclaprim has been studied in over 900 patients and healthy volunteers. Iclaprim is administered intravenously at a fixed dose, with no dosage adjustment required in patients with renal impairment, or in obese patients. This may help reduce overall hospital treatment costs, especially in renally impaired patients.

About Motif Bio plc www.motifbio.com

Motif Bio is a clinical-stage biopharmaceutical company, engaged in the research and development of novel antibiotics designed to be effective against serious and life-threatening infections in hospitalised patients caused by multi-drug resistant bacteria. Our lead product candidate, iclaprim, is being developed for the treatment of acute bacterial skin and skin structure infections (ABSSSI) and hospital acquired bacterial pneumonia (HABP), including ventilator associated bacterial pneumonia (VABP), infections often caused by MRSA (methicillin resistant *Staphylococcus aureus*). Having completed the REVIVE-1 trial, patients are currently being enrolled and dosed in a second global Phase 3 clinical trial (REVIVE-2) with an intravenous formulation of iclaprim, for the treatment of ABSSSI. Data readout for REVIVE-2 is expected in the second half of 2017.

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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 commercialize its product candidates, (iv) Motif Bio’s ability to effectively market any product candidates that receive regulatory approval, (v) Motif Bio’s commercialization, 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, and (ix) Motif Bio’s estimates regarding the potential market opportunity for its product candidates and (x) the factors discussed in the section entitled “Risk Factors” in Motif Bio plc’s prospectus filed with the SEC in November 21, 2016, which is available on the SEC’s web site, www.sec.gov. Motif Bio plc undertakes no obligation to update or revise any forward-looking statements.