



22 May 2019

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

### **AGM Statement**

Motif Bio plc (AIM/Nasdaq: MTFB), a clinical-stage biopharmaceutical company specialising in developing novel antibiotics, announces that at the Company's AGM held earlier today the Company provided the following review of key aspects of its business and growth strategy.

#### **Iclaprim for treating ABSSSI (acute bacterial skin and skin structure infections)**

- Type A meeting held with the U.S. FDA on 3<sup>rd</sup> May to discuss the path forward
- Additional data likely will be required to address the Agency's concern about a risk of liver toxicity, the size and scope of which will determine the specific next steps
- Motif Bio to provide an update once the minutes of the meeting are received
- Intention remains to partner Iclaprim upon marketing approval for commercialisation in the U.S. and other global markets
- Strengthen IP portfolio and partnering position in ex-U.S. markets by filing method-of-use patents covering fixed dose of Iclaprim

#### **Near-term expansion opportunities for Iclaprim**

- Cystic fibrosis (Agreement with Lamellar Biomedical Limited)
  - To conduct *in vivo* preclinical studies evaluating Iclaprim in combination with LBL's LMS-611
  - Complementary mechanisms of action: LMS-611 breaks down mucus in the lungs of CF patients, enabling greater penetration and enhanced activity of antibiotics; Iclaprim accumulates in the lung alveolar macrophages and has activity against CF-relevant bacteria, including *Staphylococcus aureus*
  - Iclaprim was granted U.S. orphan drug designation for *S. aureus* pneumonia in patients with CF and LMS-611 has European orphan drug designation for CF
  - Lamellar also has a disease-modifying gene therapy product candidate
- Toxoplasma chorioretinitis (Agreement with Otto-von-Guericke University, Magdeburg)
  - To evaluate Iclaprim in an *in vitro* model for ocular toxoplasmosis, a parasitic disease that may result in severe life-threatening infections and/or blindness
  - Iclaprim has shown promising activity against toxoplasma *in vitro*
  - Study is planned to focus on toxoplasma chorioretinitis, a progressive and recurring necrotizing retinitis
  - To be led by Prof. Dr. Ildiko Rita Dunay, a toxoplasmosis expert and Director of the Institute of Inflammation and Neurodegeneration at Otto-von-Guericke University

#### **Additional business development initiatives**

- A concerted business development effort has been ongoing
- Proactively sought and will continue to seek to license or acquire assets that could enhance and/or broaden the Company's development pipeline
- Continue to be approached and presented with opportunities based on Motif Bio's demonstrated ability to execute successful late-stage clinical studies
- Currently evaluating a number of licensing and partnering opportunities
- Look forward to discussing additional pipeline developments at the appropriate time

## Additional updates

- Sufficiently funded to reach a decision point regarding Iclaprim based on the outcome of interactions with the FDA
  - As in the past, Motif Bio will continue to evaluate options to determine the funding strategy that is most favorable for shareholders and provides flexibility to execute on our clinical and business development activities
- Enhanced Board of Directors with the appointment of Andrew Powell, J.D. as Non-executive Director
  - Extensive experience in the life sciences industry and strong expertise in commercialization strategy, corporate expansion, governance and M&A
- Continued to establish Motif Bio within the anti-infectives industry
  - April 2019: Presented new Iclaprim data at ECCMID 2019
  - Announced yesterday three poster presentations at upcoming ASM Microbe 2019

**Summarising Dr. Graham Lumsden, Chief Executive Officer of Motif Bio, said:** *“We are very confident in our lead compound Iclaprim’s broad potential as a differentiated and targeted anti-infective agent, based on the strong clinical safety and efficacy data we have generated and the important unmet medical and health-economic needs we believe Iclaprim may fulfill within the hospital-based antibiotic landscape and other indications. In addition to pursuing our first potential approval and commercial partnership for Iclaprim, we are committed to maximizing opportunities to further expand the value of this asset. We recently announced two collaborative agreements to evaluate Iclaprim’s ability to address high-need orphan diseases within lung disease and ophthalmology.*

*“In parallel, we’re continuing our broader business development efforts to in-license or acquire additional assets. Multiple opportunities are currently under evaluation based on our proactive efforts as well opportunities that have been presented to us based on our demonstrated ability to execute successful late-stage clinical studies. Our goal is to position Motif Bio for long-term growth by building a robust development pipeline, both within the anti-infectives space and potentially other high-growth areas that we believe have significant therapeutic and commercial potential. Based on our current pipeline and future opportunities, we believe there are several exciting pathways for continued value creation.”*

No new material information was disclosed during the meeting.

The AGM was adjourned until 1 PM BST on Friday 31 May 2019 at the offices of DLA Piper UK LLP at 160 Aldersgate Street London EC1A 4HT, United Kingdom. The decision to adjourn the AGM follows consultation with certain of the Company's shareholders relating to their ability to attend the meeting and the Company has adjourned the meeting in order to facilitate their participation at the adjourned AGM.

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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](http://www.sec.gov). Motif Bio undertakes no obligation to update or revise any forward-looking statements.*