Motif Bio Signs Agreement with Lamellar Biomedical

May 1, 2019

Evaluation of Iclaprim in Combination with LMS-611 for Cystic Fibrosis Lung Infections

NEW YORK, May 01, 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 signed an agreement with Lamellar Biomedical Limited (Lamellar) under which Motif Bio will conduct an *in vivo* pre-clinical study evaluating iclaprim in combination with Lamellar's patented LAMELLASOME™ technology. Iclaprim has been granted U.S. orphan drug designation for *Staphylococcus aureus* pneumonia in patients with Cystic Fibrosis (CF). Lamellar's LAMELLASOME™ candidate LMS-611, which has mucokinetic (mucus clearing) properties, has demonstrated antibiotic potentiation (the enhancement of certain properties of antibiotics) and has European orphan drug designation for CF.

The companies believe that, based on pre-clinical data with the two individual components, the combination could be a promising potential treatment for lung infections in patients with CF.

Dr. Graham Lumsden, Chief Executive Officer of Motif Bio, said: *"We have been looking for a way to optimise the development of iclaprim in patients with CF. We are excited about the preliminary data we have seen with Lamellar's technology and look forward to evaluating it in combination with iclaprim."*

Dr. Alex McLean, Chief Executive Officer of Lamellar Biomedical, said: "*CF is a key area of interest for Lamellar. We are delighted to announce this partnership with Motif Bio, which will evaluate the antibiotic potentiation properties of our LAMELLASOME ™ technology in combination with iclaprim. This collaboration augments our own work in this orphan indication, which is focused on a novel nucleic acid-based therapeutic, as we strive to develop a range of highly effective treatment options for patients with CF."*

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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.

About Lamellar Biomedical

Lamellar Biomedical Limited (Lamellar) is an innovative biotechnology company pioneering new approaches for the transfer of functional nucleic acids. The Company's unique and versatile LAMELLASOME™ platform has been designed for the safe and effective delivery of nucleic acid-based therapeutics and for the potentiation of antibiotics. Lamellar believes that its LAMELLASOME technology will play a key role in realising the potential of mRNAs, siRNAs, miRs, plasmids and other nucleic acids in development offering the potential to revolutionise the treatment of many rare and intractable diseases. It also believes that its technology could be used to improve the utility of antibiotics in a range of indications including Cystic Fibrosis.

LAMELLASOME™ formulations have been shown to be effective in delivering functional nucleic acids to a range of cell types including macrophages, human pulmonary fibroblasts and human dendritic cells. The technology has also been successfully used for the in vivo delivery of functional nucleic acids. LAMELLASOME monotherapy formulations have excellent preclinical safety, a very high NOAEL (taken from inhalation toxicology) and excellent clinical safety and tolerability profile.

Lamellar is developing its own pipeline of nucleic acid-based therapeutics, the most advanced of which target two areas of unmet clinical need: Idiopathic Pulmonary Fibrosis and Cystic Fibrosis.

Founded in 2007, Lamellar is backed by both institutional and private investors, including Invesco, Scottish Enterprise, Barwell Plc, TRI Capital and has multiple research collaborations with world renowned institutions and universities.

Forward-Looking Statements for Motif Bio

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.

Motif Bio plc