PRESS RELEASE

Debiopharm International SA Initiates a Clinical Trial Phase II study evaluating afabicin in Bone and Joint Infections

Lausanne, Switzerland – February 26, 2019 – Debiopharm International SA (Debiopharm – www.debiopharm.com/debiopharm-international/), part of Debiopharm Group™, a Swiss-based global biopharmaceutical company, today announced the start of a clinical phase II study to evaluate its antibiotic afabicin (Debio 1450) for the treatment of staphylococcal bone and joint infections (NCT03723551).

This study, a randomized open-label active-controlled trial, will assess the safety, tolerability, and efficacy of afabicin IV/oral in the treatment of patients with bone or joint infection (BJI). In this global clinical study with sites in Ukraine and the US, 60 patients will be treated with afabicin or comparator up to 12 weeks. The primary endpoints of the study are safety and tolerability. A range of efficacy measures such as number of responders, resolution of disease specific signs and symptoms, improvement of inflammation and microbiological eradication of the baseline pathogen will be assessed as secondary endpoints. As this is an open label study, data will be available as the study progresses. Depending on recruitment completion is expected mid-2020.

"This trial is a key step forward for afabicin clinical development, but even more for patients suffering from severe bone and joint infections who are left with too few treatment options. Remember that afabicin is a first in class selective Staphylococcus aureus antibiotic and that Staphylococcus aureus is responsible for most of the BJI infections. So specifically targeting the responsible bug is not only providing a new ammunition against a well-known high priority pathogen, but it is also embracing latest stewardship program and treatment trends that all point to a better use of antibiotics."
- Mahdi Farhan, Medical Director at Debiopharm International

About afabicin

afabicin (Debio 1450) is a first-in-class new antibiotic benefiting from both oral and intravenous (IV) formulations. It is a highly potent, *Staphylococcus*-selective antibiotic with a low propensity to develop resistance. This FabI inhibitor is also active against staphylococci strains which are resistant to the current standard-of-care antibiotics such as beta- lactams, vancomycin, daptomycin or linezolid. Debio 1450, perfectly suited to tackle several hard-to-treat infections, is now studied in Bone & Joint infections (BJIs) caused by staphylococci.

For more information: patients.debiopharm.com/bone-joint-infection/

About Debiopharm International SA

Part of Debiopharm Group™, Debiopharm International SA is focused on the development of prescription drugs that target unmet medical needs. The company in-licenses and develops promising drug candidates. The products are commercialized by pharmaceutical out-licensing partners to give access to the largest number of patients worldwide.
For more information, please visit www.debiopharm.com/debiopharm-international/

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