Sanifit announces completion of enrollment in CaLIPSO – its Phase 2b Study for the Treatment of Cardiovascular Calcification in End-Stage-Renal-Disease Patients on Haemodialsis

Palma, Spain and San Diego, USA, August 6th, 2018 - Laboratoris Sanifit S.L., a clinical-stage biopharmaceutical company focused on treatments for calcification disorders, today announced the completion of enrollment of its Phase 2b CaLIPSO clinical trial investigating Sanifit's lead candidate SNF472, for the treatment of cardiovascular calcification (CVC) in end-stage-renal-disease (ESRD) patients on haemodialysis (HD).

Most ESRD patients, in the last stage of chronic kidney disease, suffer from accelerated cardiovascular calcification, which correlates with higher cardiovascular risk. Cardiovascular disease is the most common cause of death in patients with ESRD and there are currently no approved therapies for the treatment of CVC. SNF472 is being developed to address this significant medical challenge.

The CaLIPSO Study is a 52-week, double-blind, randomized, placebo-controlled trial evaluating the effects of 300mg and 600mg of SNF472 on the progression of CVC assessed by the coronary artery calcification score. The study is being conducted at 33 investigational sites in the US, Spain and the UK. The results of the study are expected in the second half of 2019.

Dr. Alex Gold, Chief Medical Officer of Sanifit, said: "We are pleased with the progress of the CaLIPSO Study and we are on track to meet the original timelines for study completion and final data communication in Q4, 2019. SNF472 is a selective blocker of CVC, with the potential to inhibit the progression of CVC for ESRD patients who have a high risk of cardiovascular events associated with this pathology with no approved treatments".

SNF472 is also in development for the treatment of calcific uraemic arteriolopathy (CUA), also known as calciphylaxis. Sanifit is currently in preparations for a pivotal phase 3 CUA study which will begin in Q4 2018.

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About SNF472

SNF472 is an intravenous formulation of myo-inositol hexaphosphate with a novel mechanism of action for the treatment of haemodialysis patients with cardiovascular diseases linked to calcification. SNF472 is being developed for two indications: calciphylaxis and cardiovascular disease in end stage renal disease (CV-ESRD) patients undergoing dialysis. SNF472 has orphan drug status for the treatment of calciphylaxis from both the EMA and FDA. SNF472 selectively blocks the progression of pathological cardiovascular calcification, and poses an innovative solution for these unmet medical needs.

About Sanifit

Sanifit is a biopharmaceutical company focused on calcification disorders. The company was founded in 2007 as a spin-off of the University of the Balearic Islands and expanded its activities in the USA in 2016 with the incorporation of a subsidiary with offices in San Diego. The company's lead asset, SNF472, has successfully completed a Phase 2 proof of concept study in calciphylaxis, with a Phase 3 pivotal study planned to initiate in 2H 2018. The company is also investigating SNF472 in a Phase 2b study in CV-ESRD, with results expected in Q4 2019. Sanifit has raised more than $50M, including a series C funding of $41.3M (€36.6M) in mid-2015. For more information please visit www.sanifit.com

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