



Data from first in-human clinical trial of SNF472 in haemodialysis patients published in British Journal of Clinical Pharmacology

Palma, Spain and San Diego, USA, 23 October, 2018 – Laboratoris Sanifit S.L., a clinical-stage biopharmaceutical company focused on treatments for calcification disorders, today announces that data from a phase I study assessing the safety and tolerability of its lead drug candidate SNF472 in haemodialysis patients has been published in the *British Journal of Clinical Pharmacology*.

SNF472 is a novel calcification inhibitor being developed for the treatment of cardiovascular disease linked to calcification in haemodialysis (HD), a major factor in morbidity and mortality among the HD patient population. This double-blind, randomized, placebo-controlled study investigated the safety, tolerability and pharmacokinetics of intravenously administered SNF472 in 28 healthy volunteers and HD patients.

Data from this study demonstrated acceptable safety and tolerability with no significant adverse events, as well as a lack of significant removal of IV SNF472 drug during dialysis at the selected doses. Pharmacodynamic analyses also demonstrated that SNF472 administration reduced hydroxyapatite crystallization potential in HD patients.

“We are pleased with the promising results of this first-in-human study,” commented Dr. Joan Perelló, Chief Executive Officer of Sanifit “These data clearly show that SNF472 has strong potential as a novel treatment for cardiovascular calcification in end-stage renal disease; a significant, underserved market with no approved therapies. This provides us with further validation as we progress SNF472 through the clinic.”

The full article; *First-time-in-human randomized clinical trial in healthy volunteers and haemodialysis patients with SNF472, a novel inhibitor of vascular calcification*, published in the *British Journal of Clinical Pharmacology* can be accessed [here](#).

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SNF472 is currently being assessed in the Phase 2b CaLIPSO clinical trial, for the treatment of cardiovascular disease linked to calcification in end-stage-renal-disease patients on haemodialysis and completed enrolment in July 2018 and final data will be available in Q4 2019. SNF472 is also in development for the treatment of calcific uraemic arteriopathy (CUA), also known as calciphylaxis. Sanifit is currently in preparations for a pivotal phase 3 CUA study which will begin in H1 2019.

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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 H1 2019. 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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