Sanifit Announces Enrollment of First Patient in CaLIPSO – a Phase IIb Study for the Treatment of Cardiovascular Calcification in End-Stage-Renal-Disease Patients on Haemodialsis

San Diego, USA and Palma, Spain, January 23, 2016 - Laboratoris Sanifit S.L., a clinical-stage biopharmaceutical company focused on treatments for calcification disorders, today announced that the first patient has been enrolled in the Phase IIb "CaLIPSO Study" clinical trial of 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 which will evaluate the effects of 300 and 600mg of SNF472 on the progression of cardiovascular calcification (CVC). The study will be conducted at approximately 75 investigation sites across the US, Spain, Italy and the UK. It is the largest trial ever in the field of cardiovascular calcification with plans to enrol 400 patients and results expected in 2019.

Joan Perelló, CEO of Sanifit, said: "SNF472 selectively blocks the pathological cardiovascular calcification progression and we are delighted to initiate this trial. We believe SNF472 has significant potential as a novel treatment of cardiovascular calcification for ESRD patients suffering from this life-threatening clinical condition. We have assembled a strong management team and look forward to progressing the development of our lead compound for this high unmet medical need."

Sanifit has also initiated a Phase II clinical trial to evaluate SNF472 for the treatment of calciphylaxis, the most severe form of cardiovascular calcification. SNF472 has received orphan drug designation from both the EMA in June 2012 and the FDA in December 2012.

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About SNF472
SNF472 is an intravenous formulation with a novel mechanism of action for haemodialysis patients with cardiovascular diseases linked to calcification. SNF472 is being developed for

two indications: reduction of cardiovascular events in dialysis patients and for the treatment of calciphylaxis. SNF472 has orphan drug status for the treatment of calciphylaxis from both the EMA and FDA. SNF472 selectively blocks the pathological cardiovascular calcification progression and poses an innovative solution for these unmet medical needs.

About Sanifit

Sanifit is a biopharmaceutical company focused on the development of SNF472. 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. SNF472 is an experimental drug for the treatment of cardiovascular diseases linked to calcification in the End Stage Renal Disease population undergoing haemodialysis. Sanifit has completed Phase I studies with healthy volunteers and haemodialysis patients, and after a recent series C funding round of $41.3M (€36.6M), Sanifit has launched two Phase II programs in ESRD and in the orphan space in calciphylaxis. For more information please visit www.sanifit.com