Press Release

Sanifit Announces Initiation of First Clinical Trial of SNF472 in Patients with Calciphylaxis

San Diego, USA and Palma, Spain, October 20, 2016 - Laboratoris Sanifit S.L., a clinical-stage biopharmaceutical company focused on treatments for calcification disorders, today announced successful initiation of the first clinical trial of its lead candidate, SNF472, for the treatment of the orphan disease calciphylaxis (calcific uraemic arteriolopathy, CUA).

The recently initiated Phase II study is the first clinical investigation of SNF472 in patients with newly diagnosed calciphylaxis. Designed as an open-label investigation, eligible patients will be treated over three months to assess the effect of SNF472 on wound healing and pain. The trial is led by Prof Vincent Brandenburg, University Hospital RWTH Aachen, Germany, along with a team of internationally recognized calciphylaxis experts in the US, Spain and the UK. This multi-centre study plans to enroll a total of 15 adult patients with first data expected in Q2 2017.

Calciphylaxis is a serious and rare condition characterized by vascular calcification and thrombosis leading to necrosis (cellular death) of the skin and fatty tissue. Patients with calciphylaxis experience painful skin ulcers with a high risk of severe infection and a 50% rate of death within the first year after diagnosis. The condition is seen predominantly in patients receiving dialysis therapy due to end stage renal disease (ESRD) and is related to the abnormal deposition of calcium in small blood vessels and other tissues, a process known as ectopic calcification. Approximately 1-4% of patients with ESRD experience calciphylaxis and there is currently no US Food & Drug Administration (FDA) or European Medicines Agency (EMA) approved therapy to treat this disorder.

SNF472 is administered during hemodialysis in patients with ESRD. It selectively binds to hydroxyapatite and directly inhibits the initiation and progression of ectopic calcification. Preclinical models demonstrate that SNF472 reduces the progression of calcium deposition in blood vessels and cardiac tissue. SNF472 has received orphan drug designation for the treatment of calciphylaxis from both the EMA and FDA.

Vincent Brandenburg, University Hospital RWTH Aachen and Principal Investigator of the Study said: "Calciphylaxis is a rare and devastating disease for which there are currently no evidence-based treatment options available. This SNF472 trial is a prospective interventional study targeting unmet medical need in calciphylaxis and we are excited to understand more about the potential for this drug to benefit dialysis patients afflicted with this grievous condition."

Sanifit is also collaborating on this trial with Frenova Renal Research, a Fresenius Medical Care North America company, one of the world's largest providers of dialysis services with an extensive renal research network across the United States.

Joan Perelló, CEO of Sanifit said, "The enrollment of the first patients in this Phase II trial is a significant milestone in the clinical development of SNF472 for calcification disorders. We anticipate this trial will demonstrate SNF472's potential and build on the

strong Phase I data to support its continued clinical advancement and to ultimately benefit patients."

In addition to a calciphlyaxis program, SNF472 is being developed for the reduction in progression of cardiovascular calcification in dialysis patients. Preparations for a Phase IIb trial are currently underway for this separate indication.

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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 Ia studies with healthy volunteers and a Phase Ib/IIa study in haemodialysis patients. After a recent series C funding round of $41.3M (€36.6M), Sanifit will start a Phase IIb study in ESRD and extend the orphan program in calciphylaxis into Phase II/III clinical trials. For more information please visit www.sanifit.com.