Sanifit Announces Last Patient Last Visit completed in Clinical Trial of SNF472 in Patients with Calciphylaxis

Last Patient Last Visit (LPLV) completed in Phase II Study for the Treatment of Calcific Uraemic Arteriolopathy in End Stage Renal Disease Patients

Palma, Spain and San Diego, USA, December 21, 2017 - Laboratoris Sanifit S.L., a clinical-stage biopharmaceutical company focused on treatments for calcification disorders, announced today that the Last Patient's Last Visit (LPLV) occurred in the Phase II study of SNF472, its lead candidate for the treatment of the orphan disease calciphylaxis (calcific uraemic arteriolopathy, CUA) for which there is currently no approved agent.

Calciphylaxis is a rare, but devastating condition characterised by vascular calcification and thrombosis leading to necrosis (cellular death) of the skin and fatty tissues. The condition is predominantly seen in end stage renal disease (ESRD) patients receiving dialysis therapy and is linked to ectopic calcification, the abnormal deposition of calcium in small blood vessels and other tissues. Patients suffering from calciphylaxis experience painful skin ulcers leading to a high risk of infection and a mortality rate of 50% in the first year after diagnosis.

In the absence of any approved treatment for this condition, the US Food & Drug Administration (FDA) and the European Medicines Agency (EMA) have granted SNF472 orphan drug designation for the treatment of calciphylaxis. Preclinical models have already demonstrated that SNF472 reduces the progression of calcium deposition in blood vessels and cardiac tissue.

The trial was done in collaboration with internationally recognised calciphylaxis experts in the US, Spain, Germany and the UK. Sanifit expect to present and publish the data from the trial on healing of skin ulcers in early 2018.

Commenting on the announcement, Dr Alex Gold, Chief Medical Officer of Sanifit said, "We are pleased with the progress of the study. SNF472 has considerable potential for ESRD patients suffering from life-threatening calciphylaxis and currently do not have an approved treatment of this disease. Calciphylaxis is a rare and serious condition with high morbidity and mortality, and we believe that SNF472 has significant potential to benefit these patients."

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

For media enquiries:

Sanifit
Joan Perelló, CEO
Antonio Jiménez, VP Operations

Hume Brophy
Conor Griffin, Alexander Protsenko, Jonothan Blackbourn
Tel: +44 (0) 20 7862 6475
Email: sanifit@humebrophy.com

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: cardiovascular disease 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. The intravenous route is promising for dialysis patients as it assures 100% compliance.

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