Sanifit Announces Results of the Phase II Clinical Trial of SNF472 in Patients with Calciphylaxis

Palma, Spain and San Diego, USA March 06, 2018 - Laboratoris Sanifit S.L., a clinical-stage biopharmaceutical company focused on treatments for calcification disorders, announced today the completion of its Phase II clinical trial of SNF472, its lead candidate for the treatment of the orphan disease calciphylaxis (calcific uraemic arteriolopathy, CUA), with both primary and secondary endpoints being successfully met. Full trial results will be presented at a scientific meeting in mid-2018.

The Phase II clinical trial was an open label, single arm, repeat dose study which assessed the effect of 12 weeks of treatment with SNF472 on wound healing in Calciphylaxis patients receiving dialysis. The results of the study showed that both the primary endpoint, wound healing, and the secondary endpoint, reduction of pain, were successfully met. The study was conducted in the USA, Spain and the UK.

Calciphylaxis is a rare 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. Patients suffering from calciphylaxis experience painful skin ulcers leading to a high risk of infection and a mortality rate of 55% in the first year after diagnosis. SNF472 has been granted orphan drug designation by both the US Food & Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of calciphylaxis.

Commenting on the announcement, Dr Alex Gold, Chief Medical Officer of Sanifit said, "We are very pleased with the results of the study. There is a high unmet medical need for treatment of calciphylaxis and the Phase II results demonstrate that SNF472 has considerable potential for ESRD patients suffering from calciphylaxis. This is a devastating condition with high morbidity and mortality and no approved treatment options. We plan to confirm the therapeutic potential of SNF472 in a Phase III clinical study."

Sanifit is preparing to initiate a Phase III trial in 2018 after finalizing the ongoing dialogue on its design with the US Food & Drug Administration (FDA) and the EMA.

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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: 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