Sanifit Presents Results from Phase 2 Clinical Trial of SNF472 at ERA-EDTA Congress

Palma, Spain and San Diego, USA 25th May 2018 – Laboratoris Sanifit S.L., a clinical-stage biopharmaceutical company focused on treatments for calcification disorders, announced that the results of its Phase 2 clinical trial of SNF472 were presented during an oral session earlier today at the 55th ERA-EDTA Congress taking place in Copenhagen, Denmark.

The presentation of *Results of a Phase 2 Open-Label Single-Arm Study to Assess the Effect of SNF472 on Wound Healing in Calciphylaxis (Calcific Uremic Arteriolopathy) Patients* was given on behalf of the investigators by Dr. Vincent Brandenburg, nephrologist, Associate Professor and Senior Consultant at the Department of Cardiology, Intensive Care Medicine and Vascular Medicine, University Hospital of the RWTJ Aachen, Germany.

This clinical trial assessed the effects of SNF472 for treating calciphylaxis (CUA) in patients with end stage renal disease (ESRD). SNF472 is an intravenous formulation of myo-inositol hexaphosphate, an agent that selectively inhibits formation and growth of hydroxyapatite crystals, the final common pathway in the etiology of vascular calcification. CUA is a rare condition characterised by painful necrotic skin ulcers and high mortality. The condition is predominantly observed in ESRD patients receiving dialysis therapy and has no approved therapies.

Fourteen subjects were treated with SNF472 400-900 mg during each hemodialysis session (3x/week) for up to 12 weeks. Clinically and statistically significant improvements were observed in wound healing and pain between baseline and Week 12. Wound healing was measured with the Bates-Jensen Wound Assessment Tool (BWAT), a validated, quantitative instrument ($p<0.001$, baseline vs Week 12). Consistent results were observed with independent blinded review of wound images. Pain, assessed on a visual analog scale, also improved during the treatment period ($p<0.02$, baseline vs Week 12). SNF472 was generally well tolerated with adverse events as expected for the hemodialysis study population and there were no clinically significant changes in any of the laboratory or ECG parameters.

Commenting on the announcement, Dr. Brandenburg said, "The results of this open-label, single-arm Phase 2 trial of SNF472 show that this agent has potential to improve wound healing and reduce pain in patients with CUA, who currently have no approved treatments for this severe disease. SNF472 was well tolerated by subjects enrolled in the trial and showed improvement across several important measures of effect."

The US Food & Drug Administration (FDA) and the European Medicines Agency (EMA) have granted SNF472 orphan drug designation for the treatment of CUA. Sanifit is currently in preparations for a Phase 3 clinical study.

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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 1 studies with healthy volunteers and haemodialysis patients and a Phase 2 program in the orphan space in calciphylaxis. After a series C funding round of $41.3M (€36.6M), Sanifit has launched a Phase 2 program in ESRD and is currently preparing the launch of a Phase 3 program in calciphylaxis. For more information please visit www.sanifit.com