Positive data from Sanifit's Phase 2b CaLIPSO trial of SNF472 published in *Circulation*

SNF472 significantly reduced progression of cardiovascular calcification in patients with end stage kidney disease (ESKD) receiving hemodialysis

SNF472 treated patients had coronary artery calcium (CAC) volume score progression of 11% from baseline versus 20% in patients receiving placebo (P=0.016)

SNF472 was well tolerated

Results are remarkable as they have been achieved in patients who continued to be treated with modern adjunct therapy for the management of cardiovascular disease and disorders of mineral metabolism in ESKD

Data to be presented at AHA Scientific Sessions 2019 on Saturday 16 November

Webcast to discuss these data to be held on Monday 18 November at 11.00am ET, 5.00pm CET, 4.00pm GMT

Palma, Spain and San Diego, USA, 12 November 2019 – Sanifit today announced that the positive topline results from the CaLIPSO phase 2b international clinical trial of SNF472 have been published in *Circulation*, the journal of the American Heart Association. The trial met its primary endpoint, demonstrating significantly reduced progression of coronary artery calcium (CAC) volume in patients treated with SNF472 compared to placebo.

The CaLIPSO trial was a 52-week, double-blind, randomized, placebo-controlled trial assessing SNF472, a selective inhibitor of the formation and growth of hydroxyapatite crystals, in patients with ESKD on hemodialysis. The trial compared progression of CAC volume score and other measurements of cardiovascular calcification (CVC) by CT scan during 52 weeks of treatment with SNF472 or placebo, in addition to standard therapy, in adult patients with ESKD receiving hemodialysis. Patients were randomized 1:1:1 to SNF472 300 mg (n=92), SNF472 600 mg (n=91), or placebo (n=91) thrice weekly during hemodialysis sessions.

The primary endpoint was change in CAC volume score from baseline to week 52. The primary analysis combined the SNF472 treatment groups and included all patients who received at least one dose of SNF472 or placebo and had a post-randomization evaluable CT scan. The study was conducted at 65 investigational sites in the US, Spain and the UK.

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The topline results include:

- For the primary end point, SNF472 (combined dosing groups) significantly attenuated the progression of CAC compared with placebo: the mean change in CAC volume score from baseline to week 52 was 11% and 20%, respectively (P=0.016).
- The mean change from baseline to week 52 in CAC volume score was 12% for the 300 mg dose group (P=0.052 vs placebo) and 10% for the 600 mg dose group (P=0.029 vs placebo).
- Changes from baseline to week 52 in calcium volume scores in the aortic valve were 14% for SNF472 combined dosing groups and 98% for placebo (P<0.001). The mean change from baseline to week 52 was 28% for the 300 mg dose group (P<0.001 vs placebo) and 1% for the 600 mg dose group (P<0.001 vs placebo).
- Changes from baseline to week 52 in calcium volume scores in the thoracic aorta were 23% for SNF472 combined dosing groups and 28% for placebo (P=0.40). The mean change from baseline to week 52 was 25% for the 300 mg dose group (P=0.63 vs placebo) and 21% for the 600 mg dose group (P=0.34 vs placebo).
    - Due to the size of the arterial territory in the thoracic aorta, the precision of quantification of calcium may be more limited.
- These results are remarkable as they have been achieved in patients who continued to be treated with modern adjunct therapy for the management of cardiovascular disease and disorders of mineral metabolism in ESKD.

Safety

- Adverse events occurred in 79 of 92 patients (86%) in the SNF472 300 mg group, 84 of 91 patients (92%) in the SNF472 600 mg group, and 78 of 90 patients (87%) in the placebo group.
- Serious adverse events occurred in 38 patients (41%) in the SNF472 300 mg group, 55 patients (60%) in the SNF472 600 mg group, and 49 patients (54%) in the placebo group. Safety was monitored during the trial by the independent data safety and monitoring board. No safety signals were identified.
- No clinically significant abnormalities were identified from analyses of clinical laboratory values (hematology and chemistry) with SNF472 compared with placebo.

Dr. Paolo Raggi, Principal Investigator of the trial, commented: *"Patients with end-stage kidney disease requiring dialysis, have a five to 30 times higher risk of death due to cardiovascular causes than the general population. The potential for SNF472 to attenuate cardiovascular calcification and thereby reduce this risk, is incredibly exciting. I look forward to further investigation of SNF472 in this area."*

Dr. Alex Gold, Chief Medical Officer of Sanifit, said: *"We are pleased to have further demonstrated SNF472's potential as a novel treatment for disorders related to cardiovascular calcification in dialysis patients, an important factor in the morbidity and mortality for these patients with no currently approved treatment."*

Joan Perelló, Chief Executive Officer of Sanifit, commented: *"We are delighted with these positive topline trial results, which show the clear promise of SNF472 in directly targeting the final common pathway in cardiovascular calcification. We believe this could lead to meaningful improvements in the treatment of patients with end stage kidney disease. We look forward to reviewing the data further as we continue clinical development of SNF472."*

The topline CaLIPSO results will be presented at the Featured Science Session of the 2019 Scientific Sessions of the American Heart Association (AHA) on 16 November 2019 in Philadelphia, Pennsylvania. Dr. Paolo Raggi, Professor of Medicine, Division of Cardiology, at the University of Alberta, will deliver the presentation titled, *Effect of SNF472 On Progression of Cardiovascular Calcification In Patients On Hemodialysis (results Of A Phase 2 Randomized Controlled Study: CaLIPSO)* at 5.52pm EST in Room 103A.

Webcast

A webcast to discuss these data will take place on **Monday, 18 November at 11.00am ET, 5.00pm CET, 4.00pm GMT**. Joan Perelló, PhD, Chief Executive Officer and Alexander M. Gold, MD, Chief Medical Officer of Sanifit will be joined by Dr. Glenn M. Chertow, Professor of Medicine (nephrology) and Health Research and Policy at Stanford University, on behalf of the CaLIPSO Steering Committee. Slides will be available on the Sanifit website shortly before the webcast.

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About SNF472

SNF472 is an intravenous formulation of myo-inositol hexaphosphate with a novel mechanism of action for the treatment of hemodialysis patients with cardiovascular diseases linked to calcification. SNF472 is being developed for two indications: calciphylaxis and cardiovascular disease in end stage renal disease (CV-ESRD) patients undergoing dialysis. SNF472 has orphan drug status for the treatment of calciphylaxis from both the EMA and FDA. SNF472 selectively blocks the progression of pathological cardiovascular calcification, and poses an innovative solution for these unmet medical needs.

About Cardiovascular Disease (CVD)

Accelerated CVC in the coronary arteries, heart valves, and aorta leads to a number of complications including the development of cardiac dysfunction and failure, with an increased likelihood of arrhythmia and sudden cardiac death. The annual cardiovascular event rate in ESRD patients on dialysis is around 20%. Approximately 80% of the 3+ million dialysis patients worldwide are affected by CVD. In addition, the annual mortality rate of dialysis patients is approximately 17%, with approximately 40% of those deaths caused by cardiovascular events. There are no approved treatments for CVD in dialysis. There is therefore a significant unmet need for a novel therapy to reduce the progression of CVC and lower the burden of morbidity and mortality in these patients.

About Sanifit

Sanifit is a biopharmaceutical company focused on calcification disorders. The company launched in 2007 as a spin-off from 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. The company's lead asset, SNF472, has successfully completed a Phase 2 proof of concept study in calciphylaxis, with a Phase 3 pivotal study in preparation. Sanifit has raised around $130M, including a Series D funding of $61.8M (€55.2M) in mid-2019. For more information please visit www.sanifit.com

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