

# Sanifit announces that the Phase 2b CaLIPSO trial of SNF472 met its primary endpoint in slowing the progression of cardiovascular calcification in patients on hemodialysis

Top line data to be presented at 2019 Scientific Sessions of American

Heart Association

Webcast to be held on Monday 18 November at 11.00 ET

Palma, Spain and San Diego, USA, 30 October 2019 – Sanifit, a clinical-stage biopharmaceutical company focused on treatments for progressive vascular calcification disorders, today announced that the international Phase 2b CaLIPSO study of SNF472 in patients with end stage kidney disease (ESKD) on hemodialysis has met its primary endpoint. The study demonstrated a reduction in coronary artery calcium (CAC) volume in patients treated with SNF472 as compared to patients receiving placebo over a 52-week period.

The CaLIPSO Study is a 52-week, double-blind, randomized, placebo-controlled trial evaluating the effects of 300mg and 600mg of SNF472 on the progression of cardiovascular calcification (CVC) assessed by the CAC score and other

assessments by computed tomography (CT). The study was conducted at 65 investigational sites in the US, Spain and the UK.

The top line 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 at Room 103A.

Joan Perelló, Chief Executive Officer of Sanifit, commented: "These are the first results showing promise in directly targeting the final common pathway in cardiovascular calcification and could lead to improvement in the cardiovascular sequelae of end-stage kidney disease. We look forward to presenting the topline data at AHA and continuing our efforts in the development of SNF472 as a novel treatment for disorders related to cardiovascular calcification in ESKD patients on

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, on a conference call to discuss the data 11am ET on Monday 18 November. Slides will be available on the Sanifit website shortly before the webcast. Dial-in details are as follows:

US Freephone: 1 866 966 1396 UK Freephone: 0800 376 7922 Spain Freephone: 800 098 826

Standard International No: +44 (0) 2071 928 000

Conference ID: 6309838

### For further enquiries:

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## About SNF472 About Sanifit

SNF472 is an intravenous formulation of myoinositol hexaphosphate with a novel mechanism of action for the treatment of haemodialysis patients with cardiovascular diseases linked 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.

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