Sanifit to start new clinical development program of SNF472 in End Stage Kidney Disease patients with Peripheral Artery Disease

- *FDA has agreed to key aspects of the clinical program, including the primary endpoint for the single pivotal phase 3 study*
- *There are approximately 175,000 and 150,000 ESKD patients with PAD in the USA and Europe respectively with no approved treatments*

Palma, Spain and San Diego, USA, 20 July 2020 – Sanifit, a clinical-stage biopharmaceutical company developing treatments for calcification disorders, announces today that it will start a new clinical development program to investigate the effect of SNF472 in End Stage Kidney Disease (ESKD) patients with Peripheral Artery Disease (PAD), a cardiovascular disease affecting peripheral arteries by reducing blood flow to the limbs.

PAD leads to reduced mobility, pain in lower extremities, and can lead to limb-threatening ischemia and amputation. One distinguishing feature of PAD in ESKD is a profound degree of arterial calcification, with PAD prevalence in patients on chronic hemodialysis reported to be as high as 37%.

The clinical program will consist of a cross-sectional study, planned to commence in Q3 2020, in a target population of ESKD patients with PAD. This will be followed by a single pivotal Phase 3 study planned for 2021.

The clinical program was discussed with the FDA at a recent Type C meeting. The agency acknowledged that PAD in ESKD represents a significant unmet medical need and agreed with the key aspects of the program, including the primary endpoint for the pivotal study and supportive analyses. The design and protocol of the Phase 3 study will be finalized after completion of the cross-sectional study.

Results of a Phase 2b randomized placebo-controlled study (CaLIPSO) presented at the American Heart Association (AHA) in 2019 and published in the AHA journal *Circulation* demonstrated that SNF472 reduced progression of coronary artery calcium compared with placebo (Raggi, 2020), and thus may lead to clinical benefit in cardiovascular diseases such as PAD. SNF472 has also been shown to be associated with improved wound healing and pain in a Phase 2 study in patients with calciphylaxis and is currently in Phase 3 study (CALCIPHYX).

Joan Perelló, Chief Executive Officer of Sanifit, said: "We are excited to investigate SNF472 in this severe condition for which there are currently no

Sanifit Therapeutics S.A.
Phone: +34 971 439 925
PARC BIT. Europa Building. 2nd floor | 07121 Palma. Spain

Sanifit Inc.
Phone: +1 858 535 48 44
3655 Nobel Drive Suite #540 | CA 92122 San Diego, USA

info@sanifit.com www.sanifit.com

treatment options. Given the prominent role of calcification in this disease, the clinical and preclinical data, we believe SNF472 has potential for clinical benefit."

Dr. William Hiatt, Professor of Medicine (Cardiology) at University of Colorado and CPC Clinical Research (a University-affiliated academic research organization) commented: "PAD is a very serious condition leading to significant complications in ESKD patients on dialysis with increased morbidity and mortality. PAD causes deterioration in walking ability, quality of life, and ultimately increases the overall risk of amputation and death. There is currently no effective treatment for ESKD patients suffering from PAD, and prior clinical trials have excluded these patients. This clinical program therefore represents a great opportunity to build on the promising data showing the ability of SNF472 to inhibit vascular calcification, a major driver of disease in these patients and investigate its ability to improve function and quality of life in these patients."

-ENDS-

For further enquiries:

Sanifit
Joan Perelló, CEO
Antonio Jiménez, VP Operations

For media enquiries:

Consilium Strategic Communications
Amber Fennell, Chris Welsh, Sarah Wilson
Tel: +44 (0) 20 3709 5700
Email: sanifit@consilum-comms.com

About Sanifit

Sanifit is a clinical-stage biopharmaceutical company focused on treatments for vascular calcification disorders. The company is a spin-off from the University of the Balearic Islands and has offices in Spain and the U.S.. The company's lead asset, SNF472, has successfully completed a Phase 2 proof of concept study in calciphylaxis, and showed a significant reduction in progression of coronary calcification in a Phase 2b study among hemodialysis patients. A Phase 3 pivotal study in calciphylaxis is currently underway and a Phase 3 trial in Peripheral Arterial Disease in End Stage Kidney Disease patients will launch in 2021. Sanifit has raised approximately $130M, including a 2019 Series D round of $61.8M (€55.2M) in mid-2019. For more information please visit www.sanifit.com.

About SNF472

SNF472 is an intravenous formulation of myo-inositol hexaphosphate with a novel mechanism of action for the treatment of cardiovascular diseases linked to calcification. SNF472 is in phase 3 development for calciphylaxis, a devastating rare disease which leads to the death of approximately 55% of patients within the first year of diagnosis. SNF472 has been granted orphan drug status for the treatment of calciphylaxis by both the EMA and FDA. Sanifit will also launch a phase 3 trial in Peripheral Arterial Disease in 2021 with SNF472, with additional indications related to progressive vascular calcification under consideration. SNF472 selectively blocks the progression of pathological cardiovascular calcification and poses an innovative solution for this unmet medical need.

Sanifit Therapeutics S.A.
Phone: +34 971 439 925
PARC BIT. Europa Building. 2nd floor | 07121 Palma. Spain

Sanifit Inc.
Phone: +1 858 535 48 44
3655 Nobel Drive Suite #540 | CA 92122 San Diego, USA

info@sanifit.com www.sanifit.com