Sanifit Granted Orphan Drug Designation by the FDA for SNF472 for the Treatment of Peripheral Arterial Disease in Patients with End-stage Kidney Disease

Palma, Spain and San Diego, USA, February 10, 2021 – Sanifit, a clinical-stage biopharmaceutical company focused on developing treatments for calcification disorders, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to its lead compound SNF472 for the treatment of peripheral arterial disease (PAD) in patients with end-stage kidney disease (ESKD).

The FDA Office of Orphan Products Development grants orphan status to support the development of drugs for the safe and effective treatment of rare disorders which affect fewer than 200,000 people in the U.S. Receiving Orphan Drug Designation may qualify Sanifit for a seven-year period of U.S. marketing exclusivity upon approval of SNF472, and a waiver of the Prescription Drug User Fee Act filing fees, subject to certain conditions.

Joan Perelló, Ph.D., Chief Executive Officer, of Sanifit, commented: "Orphan drug designation from the FDA for PAD in ESKD is an important recognition for patients suffering from this condition and it further validates the potential of SNF472 in this indication. There are approximately 175,000 and 150,000 patients with PAD-ESKD in the U.S. and Europe respectively, with no effective treatments and prior clinical trials have excluded these patients. We plan to advance clinical development of SNF472 to phase 3 in patients affected by this severe disease."

SNF472 is a first-in-class inhibitor of vascular calcification and the only drug candidate in clinical trials, which directly targets the deposition of solid calcium (hydroxyapatite) in the cardiovascular system. PAD is a cardiovascular disease affecting peripheral arteries by reducing blood flow to the limbs. PAD in ESKD has a profound degree of arterial calcification making this a challenging condition with no currently available therapies. PAD prevalence in patients with ESKD on chronic hemodialysis is reported to be up to 38% in the U.S., with similar prevalence in other countries.

SNF472 is also being evaluated in an ongoing Phase 3 study for the treatment of calciphylaxis or calcific uremic arteriolopathy (CUA) in ESKD patients, which has also received orphan designation from the FDA and European Medicines Agency.

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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. Sanifit'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 in hemodialysis patients. A Phase 3 pivotal study in calciphylaxis is currently underway and the Company is also pursuing peripheral arterial disease (PAD) in patients with end-stage kidney disease as a second indication for SNF472.

For more information, please visit www.sanifit.com.

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