First patient dosed in pivotal phase 3 trial of SNF472 in calciphylaxis

First patient dosed in phase 3 trial of SNF472 for the treatment of calcific uremic arteriolopathy (CUA) or calciphylaxis

Palma, Spain and San Diego, USA, 13 February 2020 – Sanifit, a clinical-stage biopharmaceutical company focused on developing treatments for calcification disorders, today announced that the first patient has successfully been dosed in its pivotal phase 3 trial of the Company's lead asset SNF472, for the treatment of the orphan disease calciphylaxis or calcific uremic arteriolopathy ("CUA").

The phase 3 study, known as CALCIPHYX, is designed to assess the effect of SNF472 when added to background care for the treatment of calciphylaxis patients with end stage kidney disease ("ESKD") being treated with hemodialysis. The endpoints of the trial will be: improvement in wound healing, assessed by the Bates-Jensen Wound Assessment Tool (BWAT) score; and pain, assessed by a Visual Analog Scale (VAS). The study consists of a double-blind, randomized, placebo-controlled period of 12 weeks followed by an open-label active treatment period of 12 weeks. The multi-centre study will be conducted in the US and Europe.

Calciphylaxis is a devastating rare disease which leads to the death of approximately 55% of patients within the first year of diagnosis. The underlying cause of the disease is severe calcification affecting arterioles of the skin. In a phase 2 study, SNF472 was associated with improved wound healing and pain in calciphylaxis patients and has been granted Orphan Drug Designation by the FDA and EMA. A recent randomized controlled trial showed SNF472 also reduced progression of coronary calcification in patients with ESKD receiving hemodialysis.

Dr. Alex Gold, Chief Medical Officer of Sanifit, said: *"SNF472 has shown promise in reducing cardiovascular calcification progression and we are pleased to commence this phase 3 pivotal trial in calciphylaxis, bringing SNF472 one step further in its development as a potential treatment for this devastating disease with no approved therapies. We are delighted to be working with leading experts in this field, both US and European clinical investigators, to evaluate this promising drug candidate."*

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About Sanifit

Sanifit is a clinical-stage biopharmaceutical company focused on developing treatments for calcification disorders. The company launched in 2007 as a spin-off from the University of the Balearic Islands and expanded its activities to the USA in 2016 with the incorporation of a subsidiary with offices in San Diego, CA. 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. 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 hemodialysis patients with 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, with additional indications related to progressive vascular calcification under consideration. SNF472 has been granted orphan drug status for the treatment of calciphylaxis by both the EMA and FDA. SNF472 selectively blocks the progression of pathological cardiovascular calcification, and poses an innovative solution for this unmet medical need.