Data from SNF472 Phase 1b Clinical Trial published in British Journal of Clinical Pharmacology

Data show SNF472 inhibits induction of HAP crystallization

Results provide support for further development of SNF472 as a novel treatment for CUA

Palma, Spain and San Diego, USA, 4 March, 2019 – Sanifit, a clinical-stage biopharmaceutical company focused on the treatment of conditions related to progressive vascular calcification, today announces the publication in the British Journal of Clinical Pharmacology of further data assessing the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of its lead drug candidate SNF472 in haemodialysis (HD) patients.

The double blind, randomized, placebo-controlled Phase 1b study investigated the safety, tolerability, PK and PD of SNF472 in HD patients after repeated administrations for up to 28 days. A PD assessment was performed to evaluate the potential for SNF472 to inhibit hydroxyapatite (HAP) formation, which is the form of solid calcium that deposits in the heart, arteries and arterioles. Evidence suggests that HAP deposition is the final common pathway of vascular calcification progression.

SNF472 was shown to be safe and well tolerated in HD patients following multiple ascending doses for one week and repeated dosing of 10 mg/kg for 4 weeks. Under both conditions SNF472 inhibits the induction of HAP crystallization. These results support further investigation of SNF472 in conditions related to progressive vascular calcification.

Dr. Carol Salcedo, Chief Scientific Officer of Sanifit commented: *"This study shows that SNF472 inhibits HAP formation in patients and is well tolerated. This provides us with further validation as we continue our progress through the clinic and shows SNF472's potential as a novel treatment for disorders related to cardiovascular calcification in dialysis patients, a key driver of mortality and morbidity for these patients with no currently approved treatment."*

The full article, 'A Phase 1b Randomized, Placebo-Controlled Clinical Trial with SNF472 in Haemodialysis Patients', published in the British Journal of Clinical Pharmacology, can be accessed here.

SNF472 is currently being assessed in CaLIPSO, a Phase 2b proof of concept study in haemodialysis patients assessing the effect of SNF472 in reducing progression of cardiovascular calcification. CaLIPSO completed enrolment in August 2018.

SNF472 is in development for treatment of CUA, also known as calciphylaxis, a devastating rare disease with 55% 1-year mortality rate, where severe cardiovascular calcification blocks small blood vessels in skin and fat tissue. These blockages cause the development of intensely painful and debilitating chronic skin lesions. Sanifit is currently in preparations for a pivotal phase 3 CUA study, after having met the primary and secondary endpoints in the phase 2 study in this indication.

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About SNF472

SNF472, the hexasodium salt of myo-inositol hexaphosphate, is a calcification inhibitor. with a novel mechanism of action for the treatment of haemodialysis patients with cardiovascular diseases linked to calcification. SNF472 inhibits the development and progression of ectopic calcifications by binding to the growth sites of the hydroxyapatite crystal, the main component of cardiovascular calcification deposits. SNF472 is being developed for calciphylaxis in patients undergoing dialysis, for which it has orphan drug status 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 Sanifit

Sanifit is a biopharmaceutical company focused on calcification disorders. The company started activities in 2007 as a spin-off of 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. The company is also investigating SNF472 in a Phase 2b proof of concept study to assess its effect on the reduction of cardiovascular calcification progression, with results expected in Q4 2019. Sanifit has raised around $70M, including a series C funding of $41.3M (€36.6M) in mid-2015. For more information please visit www.sanifit.com