Novel inhibitor of vascular calcification tested in trial of haemodialysis patients

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Cardiovascular calcification is a major health concern in patients with kidney failure undergoing haemodialysis. A first-time-in-human clinical trial of an investigational calcification inhibitor has generated promising results in terms of safety, tolerability, and pharmacokinetics. The findings are published in the *British Journal of Clinical Pharmacology*.

The drug, called SNF472, is being studied in additional clinical trials, using various doses and dosing schedules. A phase 1b study was completed in 2016, evaluating the safety, tolerability, and pharmacokinetic and pharmacodynamic activity of SNF472 at repeated dosing in haemodialysis patients. A phase 2 proof of concept study in calciphylaxis patients undergoing haemodialysis was successfully finalized in early 2018, suggesting a positive effect of SNF472 on wound healing and pain in this very ill patient population. A 270-patient, phase 2b, randomized, placebo-controlled study is evaluating the effect of SNF472 in attenuating cardiovascular calcification over 1 year in haemodialysis patients.

"We are very proud of this first-in-human trial, which reveals a linear and predictable pharmacokinetic behavior and strengthens the excellent safety profile of SNF472", said senior author Dr. Carolina Salcedo, of Laboratoris Sanifit, in Spain.

"This study is just the first step of an ambitious clinical development program with SNF472 to address severe unmet medical needs in patients who suffer from the devastating consequences of accelerated

cardiovascular calcification. We are hopeful that in the near future this experimental drug will be available to calciphylaxis and haemodialysis patients", added senior author Dr. Joan Perelló, also of Laboratoris Sanifit.

More information: J. Perelló et al, First-Time-In-Human Randomized Clinical Trial in Healthy Volunteers and Haemodialysis Patients with SNF472, a Novel Inhibitor of Vascular Calcification, *British Journal of Clinical Pharmacology* (2018). DOI: 10.1111/bcp.13752