PRESS RELEASE

Sanifit announces the creation of a Steering Committee for its Phase 2b ESRD Clinical Program with SNF472

Palma de Mallorca, Spain, December 21, 2015 - Laboratoris Sanifit S.L., a clinical-stage biopharmaceutical company, announced today the creation of a Steering Committee for its phase 2b clinical trial in End-Stage Renal Disease with SNF472. SNF472 is being developed by Sanifit for the treatment of cardiovascular diseases linked to calcification in ESRD patients on dialysis. This patient population experiences significantly higher rates of cardiovascular morbidity and mortality as a consequence of accelerated progression of cardiovascular calcification. Half of the mortality in dialysis patients is from cardiovascular complications. There are approximately 2.5 million dialysis patients worldwide with no effective treatment for this medical condition. SNF472 has shown significant efficacy data in more than 20 preclinical studies. It has also shown excellent safety and tolerability in a phase I clinical trials in healthy volunteers and hemodialysis patients up to 1 month of exposure.

The newly created Steering Committee includes 4 well known scientists and clinicians who will provide the overall supervision of the phase 2b study with SNF472.

Dr. Jessica Mann, Chief Medical Officer of Sanifit, comments: "we are delighted to have such an outstanding expert panel supporting this important study for Sanifit. It will enhance the quality of the trial and allow us to have a study led by the top experts in the field"

The Steering Committee meetings will include:

- **Prof. Markus Ketteler**

After completing nephrology training and a post-doctoral fellowship in Berlin, Germany, and Salt Lake City, USA, Markus Ketteler moved to the Department of Nephrology and Clinical Immunology at the University Hospital Aachen in 2000. His research focus was aimed at the understanding of pathomechanisms involved in extraosseous calcifications (e.g., fetuin-A, MGP) and at the pathophysiology of phosphate and vitamin D metabolism in chronic kidney disease (CKD). In 2007, he was appointed Professor of Medicine and Division Chief of Nephrology at the Klinikum Coburg in Coburg, Germany. Markus Ketteler is currently author on > 170 peer-reviewed publications (including The Lancet, JASN, J Clin Invest, Kidney Int, Circulation etc.). He is on the editorial boards of nephrology journals such as JASN and NDT (theme editor), acted as a KDIGO workgroup member on CKD-MBD guidelines, and co-leads the German Calciphylaxis Registry. He is currently Council member and "Chairman of the Office" of the ERA EDTA, served as Chairman of the Paper Selection Committee of the ERA EDTA Congresses for 3 consecutive years until May 2013 and for the ISN World Congress of Nephrology in 2015. Most recently, he acted as co-chair of the KDIGO Controversies Conference on CKD-MBD which took place in Madrid in October 2013 and was appointed to co-chair the upcoming update of the KDIGO CKD-MBD guidelines in 2015.

- **Prof. Geoffrey Block**

Dr. Block joined Denver Nephrology in 1997 after completing his fellowship at the University of Michigan at Ann Arbor. Dr. Block is the Director of Clinical Research at Denver

Nephrology, a department he created to further enhance the care and treatment of patients suffering from Chronic Kidney Disease (CKD) and its effects.
Dr. Block is the Principal Investigator or Investigator for several international and national clinical studies. He also served as Global Steering Committee member for several clinical programs, including the Sevelamer (Genzyme) and Cinacalcet (Amgen) Development Programs. He has served on the Scientific Advisory Board of Cytochroma, REN Pharmaceuticals, Ardelyx and Celgene.
Dr. Block frequently is asked to present or lecture at national and international meetings such as the Scandinavian Society of Nephrology Annual Meeting, the Australian Society of Nephrology Annual Meeting, the British Renal Society Annual Congress, the National Kidney Foundation, and the American Society of Nephrology annual meeting. He serves as an advisor and consultant for several pharmaceutical and biotechnology companies interested in developing medicine to help patients with kidney disease.
Presently, Dr. Block serves as an associate clinical professor in medicine at the University of Colorado Health Sciences Center, and as an attending physician at St. Josephs Hospital. He also is the medical director of the DaVita-Lowry Hemodialysis Unit. In addition to his research activities, Dr. Block serves as a manuscript reviewer for several national and international nephrology publications including American Journal of Kidney Disease, the Journal of the American Society of Nephrology, Circulation, Journal of Renal Nutrition and Kidney International.

- **Prof. Paolo Raggi**

Paolo Raggi, MD, is a Professor of Medicine at the University of Alberta in Edmonton, AB and he is the current Director of the Mazankowski Alberta Heart Institute and Chair of Cardiac Research at the University of Alberta, in Edmonton AB, Canada. Dr. Raggi received his MD degree Summa Cum Laude from the University of Bologna, in Bologna, Italy. He served a residency in internal medicine in New York City and completed a cardiovascular fellowship at the Long Island College Hospital-State University of New York in Brooklyn, NY.
Dr. Raggi has been involved in research on mechanisms of cardiovascular disease in the following fields: atherosclerosis, vascular calcification, lipid metabolism, cardiovascular disease associated with chronic kidney disease, rheumatological disorders, HIV infection, diabetes mellitus and the metabolic syndrome. He regularly engages in the interpretation of echocardiography, computed tomography, magnetic resonance and nuclear cardiology imaging studies for the diagnosis of coronary artery disease, subclinical atherosclerosis and evaluation of left ventricular function and viability. He is a regular lecturer both nationally and internationally and is a research mentor for several trainees. The results of his work have been published in the *New England Journal of Medicine, The Lancet, Archives of Internal Medicine, Circulation, Journal of the American College of Cardiology, European Heart Journal, Kidney International, American Journal of Kidney Diseases, Radiology, Chest and several others.* He has contributed 290 publications to major peer-reviewed journals and 26 chapters for books on cardiovascular imaging and preventive cardiology. Dr. Raggi has received numerous awards as best teaching attending and best clinical investigator nationally and internationally. He serves as a consultant for 30 scientific medical publications and sits on the Editorial Board of 4 peer-reviewed medical journals. He is a fellow of the American College of Physicians, the American College of Cardiology, the American Heart Association, the Canadian Cardiovascular Society, the American Society of Nuclear Cardiology and the Society of Cardiac Computed Tomography of which he was a co-founder.

- **Prof. Luis Miguel Ruilope**

Luis M. Ruilope is Professor at the Public Health and Preventive Medicine department of the Autonoma University and Head of Cardiovascular and Renal Risk at Instituto de Investigación 12 de Octubre, both in Madrid, Spain.

His main interested fields are Hypertension and Cardiovascular Risk.
Dr. Ruilope is an international fellow of the Council for High Blood Pressure Research and the Council of the Kidney in Cardiovascular diseases of the American Heart Association. Scientific Committee Member of the ISH (International Society of Hypertension) and he was president of the Spanish Hypertension Society and the Hypertension Spanish League.
He is or has been a member of the editorial board of several journals including Journal of Hypertension, Blood Pressure, Medicina Clínica, Hypertension, Journal of Human Hypertension, Journal of the American Society of Nephrology and Nephrology and Dialysis & Transplantation. He is also associated editor of the Current Hypertension Reports and Steering Committee member of the studies HOT, INSIGHT, SCOPE, CONVINCE, ROADMAP, ASCEND, and European coordinator of the IDNT study.

About ESRD
Renal disease leads to a progressive loss of kidney function. In its last phase, called End Stage Renal Disease (ESRD), kidney failure is permanent and irreversible. The patient requires renal replacement therapy through dialysis or a renal transplant. The etiology of ESRD is heterogeneous but the main causes of renal failure are diabetes and hypertension. There are more than 3 million ESRD patients worldwide; around 70% of them are treated with dialysis (2.5 million). ESRD patients suffer from accelerated cardiovascular calcification, which correlates with higher cardiovascular risk. The annual death rate in ESRD ranges from 20-30% and the annual cardiovascular event rate is around 20%. Half of the deaths in dialysis are due to cardiovascular causes. Currently, there are no drugs are approved for this condition; patients are treated with calcimimetics and phosphate binders to control related risk factors such as hypercalcaemia and hyperphosphataemia. A therapy to directly treat cardiovascular disease in ESRD and reduce the rate of cardiovascular events would be a first-in-class drug which would fulfil an unmet medical need with high market potential.

About SNF472
SNF472 is an intravenous formulation with a novel mechanism of action for haemodialysis patients with cardiovascular diseases linked to calcification. SNF472 is being developed for two indications: reduction of cardiovascular events in dialysis patients and for the treatment of calciphylaxis. SNF472 has orphan drug status for the treatment of calciphylaxis from both the EMA and the FDA. SNF472 selectively blocks the pathological cardiovascular calcification progression and poses an innovative solution for these unmet medical needs.

About Sanifit
Sanifit is a biopharmaceutical company focused on the development of SNF472. The company was founded in 2007 as a spin-off of the University of the Balearic Islands (Spain). SNF472 is an experimental drug for the treatment of cardiovascular diseases linked to calcification in the End Stage Renal Disease population undergoing haemodialysis. Sanifit has completed phase 1a studies with healthy volunteers in 2014. It is currently concluding a phase Ib/IIa study in haemodialysis patients. After a recent series C funding round of $41.3M (€36.6M), Sanifit will start in 2016 a phase IIb study in ESRD and extend the orphan program in calciphylaxis into phase II/III clinical trials. For more information please visit www.sanifit.com

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