



Press
Release

Vifor Pharma to acquire Sanifit to further strengthen late-stage pipeline in nephrology

- Vifor Pharma to acquire Sanifit, a clinical-stage cardio-renal biopharmaceutical company focused on treatments for progressive vascular calcification disorders, complementing and strengthening the Group's growing nephrology portfolio
- Sanifit's lead compound, SNF472 is a novel, first-in-class inhibitor of vascular calcification in phase 3, developed for the treatment of calcific uremic arteriolopathy (CUA) and peripheral artery disease (PAD) in patients with end-stage kidney disease
- Purchase price includes an upfront payment of EUR 205 million, precommercial milestones for up to EUR 170 million and progressive commercial milestones

St. Gallen, Switzerland, and Palma, Spain, 22 November 2021 – Vifor Pharma and Sanifit Therapeutics, a clinical-stage cardio-renal biopharmaceutical company focused on treatments for progressive vascular calcification disorders, today announced the companies have entered into a definitive agreement. Vifor Pharma will acquire Sanifit, for the continued development and commercialization of SNF472, a novel, first-in-class inhibitor of vascular calcification for the treatment of CUA and PAD in patients with end-stage kidney disease. There are currently no approved medicines indicated for CUA or for PAD specifically in this population. SNF472 has already been granted orphan drug designation for the treatment of CUA and PAD by the US Food and Drug Administration and for CUA by the European Medicines Agency.

Under the terms of the acquisition agreement, Vifor Pharma will acquire 100% of the outstanding shares in Sanifit Therapeutics, receiving full global rights for SNF472, further enhancing the company's portfolio of innovative assets. Shareholders of Sanifit will receive an upfront payment of EUR 205 million, clinical, regulatory and market access milestones for up to EUR 170 million and tiered sales-based milestones that could reach mid to high triple digit EUR millions at peak sales.

"Today's exciting announcement helps us to build on our strong nephrology pipeline to help end-stage kidney disease patients globally", commented Abbas Hussain, Chief Executive Officer of Vifor Pharma Group. "Through the acquisition of Sanifit and its lead compound SNF472, we will further expand our growing nephrology pipeline into vascular calcification, a major cause of morbidity and mortality in patients with end-stage kidney disease. SNF472 is the only novel asset addressing a great unmet medical need for end-stage kidney disease patients with calcific uremic arteriolopathy and peripheral artery disease. We look forward to bringing this highly promising, innovative treatment option to over 330,000 patients in the US and Europe, living with CUA or PAD, as soon as possible."

Joan Perelló, Ph.D., Chief Executive Officer of Sanifit, said; "From the very beginning, Sanifit has been a pioneer of new approaches to treat calcification disorders, a huge area of unmet need. This agreement is a testament to the enduring commitment of our dedicated team and investors, as well as our unique approach to combat vascular calcification, which originated from the University of the Balearic Islands. We are excited to join forces with Vifor Pharma, which has a world-renowned commitment to patient focused cardio-renal therapies. Vifor Pharma is the ideal partner to take the development of Sanifit's calcification franchise forward and bring these novel treatments to patients as quickly as possible."

Sanifit conducted a phase-IIb trial (CaLIPSO) to assess the effect of SNF472 on slowing arterial calcification, a major risk factor for cardiovascular disease in dialysis patients. The trial met its primary endpoint in reducing coronary artery calcium progression in patients treated with SNF472, compared to patients receiving placebo over a 52-week period. SNF472 is currently in phase-III trials in CUA in patients on dialysis, to measure primary endpoints for wound healing and pain. A phase-III trial in PAD in patients on dialysis, is planned to commence in 2022.

Closing of the transaction is contingent on customary closing conditions, including the FDI procedure in Spain and merger filings in certain countries, and is expected to take place in Q1 2022.

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About Vifor Pharma Group

Vifor Pharma Group is a global pharmaceuticals company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is a partner of choice for pharmaceuticals and innovative patient-focused solutions. Vifor Pharma Group strives to help patients around the world with severe and chronic diseases lead better, healthier lives. The company develops, manufactures and markets pharmaceutical products for precision patient care. Vifor Pharma Group holds a leading position in all its core business activities and consists of the following companies: Vifor Pharma and Vifor Fresenius Medical Care Renal Pharma (a joint company with Fresenius Medical Care). Vifor Pharma Group is headquartered in Switzerland, and listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348). For more information, please visit viforpharma.com.

About Sanifit Therapeutics

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, 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. In 2015 and 2019, Sanifit announced the largest private biotech fundraises in Spain and has been supported by a variety of healthcare focused investors including: Caixa Capital Risc, Ysios Capital, Lundbeckfonden Ventures, Forbion Capital Partners, Gilde Healthcare, Andera Partners, Columbus Venture Partners, Alta Life Sciences, Baxter Ventures, HealthEquity and INNVIERTE ECONOMÍA SOSTENIBLE, a venture capital fund managed by the Centre for the Development of Industrial Technology ("CDTI") of the Spanish Government. Sanifit is headquartered in Palma, Spain.

About SNF472

SNF472 is an intravenously administered selective calcification inhibitor, developed by Sanifit as a potential treatment for peripheral artery disease (PAD) and calcific uremic arteriolopathy (CUA) in hemodialysis, both rare diseases related to progressive cardiovascular calcification (CVC).

About CUA

Calcific uremic arteriolopathy also known as Calciphylaxis (CUA), is a rare but potentially devastating condition most often observed in patients with end-stage renal disease (ESRD), although it does occasionally develop in patients without renal failure. Calciphylaxis is a severe form of CVC in which the calcium deposits block small blood vessels in skin and fat tissue. These blockages cause the development of intensely painful and debilitating chronic skin lesions. Calciphylaxis is a devastating rare disease that affects 1-4% of dialysis patients and has a 1-year mortality rate of 55%.

About PAD

Peripheral artery disease (PAD) in end-stage kidney disease (ESKD) affects patients who depend on ongoing renal replacement therapy, most commonly hemodialysis. PAD causes patients to reduce their mobility, have pain in lower extremities, and can lead to chronic limb threatening ischemia and amputation. PAD is a marker for vascular calcification - a major contributing cause of death among patients in dialysis.