Press Release

Vifor Pharma to spearhead development of vascular calcification field, through acquisition of Sanifit Therapeutics and Inositec AG

- **Sanifit Therapeutics and Inositec AG, both clinical stage biopharmaceutical companies, are developing first-in-class treatments for progressive vascular calcification and soft tissue disorders**
- **Sanifit's SNF472 is a novel, first-in-class inhibitor of vascular calcification in phase-III, developed for the treatment of calcific uremic arteriolopathy (CUA) and Peripheral Artery Disease (PAD) in patients with end-stage kidney disease**
- **Inositec's INS-3001 is being developed in non-dialysis vascular and cardiovascular calcification disorders, such as CKD-associated PAD and Aortic Valve Stenosis (AVS)**
- **With INS-3001 and SNF472, Vifor Pharma will further strengthen its nephrology portfolio helping patients suffering from accelerated vascular calcification disorders at all stages of chronic kidney disease (CKD)**
- **Sanifit purchase price includes an upfront payment of EUR 205 million, precommercial milestones for up to EUR 170 million and progressive commercial milestones. Inositec purchase price includes an upfront payment of CHF 20 million and success based clinical earn-out payments**

– Vifor Pharma will host a conference call and webcast today at 3:30 pm CET –

St. Gallen, Switzerland, Palma, Spain and Zurich Switzerland, 22 November 2021 – Vifor Pharma has announced the acquisition of Sanifit Therapeutics, a Spanish clinical-stage cardio-renal biopharmaceutical company focused on treatments for end-stage kidney disease patients with progressive vascular calcification disorders, and Inositec AG, a Swiss company, developing first-in-class non-dialysis treatments for soft tissue and vascular calcification disorders. Through these acquisitions, Vifor Pharma will be able to serve a continuum of vascular calcification disorders at all stages of CKD.

Acquisition of Sanifit is for the continued clinical development and commercialization of SNF472, a novel, first-in-class intravenously administered 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.

Inositec's novel asset INS-3001, is a once-daily subcutaneous treatment for patients with vascular calcification disorders PAD and AVS, which are both major contributors to cardiovascular morbidity and mortality in affected patient populations. With INS-3001 daily subcutaneous dosing, patients with earlier stages of vascular calcification can be optimally treated, while end-stage kidney disease patients will benefit from the three times per week dosing regimen of SNF472.

"We are gaining momentum with our ambitious strategic growth plans as we today add Sanifit, Inositec and their promising assets to our strong nephrology portfolio", commented Abbas Hussain, Chief Executive Officer of Vifor Pharma. "These acquisitions are a perfect fit for our expanding nephrology pipeline, which now includes vascular calcification inhibition treatments across various stages of non-dialysis CKD and even non-CKD patient populations. Vifor Pharma will be spearheading the vascular calcification field, emphasizing our strategic focus to bring innovative assets to patients with high unmet medical need as we strive to improve lives of people suffering from serious diseases around the world."

Vifor Pharma Group
Flughofstrasse 61
8152 Glattbrugg
Switzerland

Phone +41 58 851 8000
E-mail info@viforpharma.com
Web viforpharma.com

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. Vifor Pharma will acquire 100% of the shares in Inositec AG, receiving full global rights for the lead asset INS-3001. Inositec will receive an upfront payment of CHF 20 million and be eligible for success based clinical earn-out payments in the low triple digit million range.

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."

"This acquisition builds on years of hard work from the entire Inositec team and provides a strong foundation for improving outcomes for patients suffering from cardiovascular and vascular calcification disorders," said Mattias Ivarsson, Founder and Chief Executive Officer of Inositec, adding "Inositec's transition to a clinical-stage company represents an ideal time to partner with Vifor Pharma to accelerate the clinical development of INS-3001."

Sanifit conducted a phase-IIb trial (CaLIPSO) in 274 patients 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.

Inositec's lead vascular calcification inhibitor, INS-3001, is being developed to treat indications of high unmet medical need and has obtained approval for its phase-I trial, with the first healthy volunteer to be dosed on November 30, 2021. If successful, the plan is to initiate two phase-II programs in 2023, one in non-dialysis CKD patients suffering from PAD, and a separate trial in patients suffering from AVS, a serious condition whereby the aortic valves calcify to the extent that surgical intervention is the only available option.

The expected addressable patient population in the U.S. and EU suffering from calcifying non-dialysis and dialysis-associated PAD is estimated to be over 600,000. CUA is an ultra-orphan disease with approximately 10,000 patients across the US and EU. For AVS we are estimating approximately 1.1 million patients in the two geographies eligible to receive treatment.

Closing of both transactions is contingent on customary closing conditions, including for the Sanifit transaction a potential Foreign Direct Investments (FDI) procedure in Spain and a merger filing in the United States. Closing of the Sanifit transaction is expected to take place in Q1 2022 whereas closing of the Inositec transaction is expected to occur still in Q4 2021.

Live conference call and webcast

A live webcast and conference call will be held on 22 November 2021 at 3:30 pm CET.

Access to live webcast → link

Pin code and phone numbers for the live conference call:

Pin code: 3537174

Vifor Pharma Group
Flughofstrasse 61
8152 Glattbrugg
Switzerland

Phone +41 58 851 8000
E-mail info@viforpharma.com
Web viforpharma.com

Country	Phone number
Switzerland	+41 31 580 0059
France	+33 17 670 0794
Germany	+49 692 443 7351
United Kingdom	+44 207 192 8000
United States of America	+1 631 510 7495
Other countries	+44 207 192 8000

Replay
A webcast replay (link) will be available shortly after the end of the live conference.

Contact and further information:

Media Relations
Nathalie Ponnier
Global Head Corporate Communications
+41 79 957 96 73
media@viforpharma.com

Investor Relations
Julien Vignot
Head of Investor Relations
+41 58 851 66 90
investors@viforpharma.com

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 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 INS-3001
INS-3001 is a subcutaneously applied calcification inhibitor based on the natural compound inositol hexaphosphate (IP6). In preclinical studies, INS-3001 was found to display superior efficacy, and more favorable pharmacokinetic and tolerability profiles than IP6 itself. The scientific foundations supporting the role of INS-3001 in several potential therapeutic indications has been rigorously validated in a variety of preclinical calcification models and safety studies. INS-3001 is entering Phase-I testing.

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) is a progressive vascular calcific disorder particularly common in chronic kidney disease patients and characterized by stenosis of arteries in the lower extremities causing reduced blood flow to the legs. Patients present with recurrent fatigue or pain that is known as intermittent claudication, which causes a poor quality of life. Progressive PAD requires vascular surgery to reduce the risk for limb amputation.

About AVS
Aortic Valve Stenosis (AVS) is a progressive deterioration of the aortic valve, which can only be treated by implantation of a new valve. AVS occurs when the orifice of the aortic valve is significantly reduced due to calcification. This causes an effective increase in afterload, left ventricular hypertrophy and, eventually, symptoms of congestive heart failure.