

Spain's Sanifit preps for phase III calciphylaxis trial with \$80.9M private round

By Nuala Moran, Staff Writer

Laboratoris Sanifit SL has closed Spain's largest ever private biotech round, raising €72.2 million (US\$80.9 million) to fund phase III development of SNF-472 in the treatment of calciphylaxis, an orphan disease that occurs in end-stage renal disease patients on dialysis.

The new money is made up of a €55.2 million series D and the capitalization of €17 million of convertible bonds. The fundraising was led by existing investor Caixa Capital Risk, a Spanish venture capital firm, and attracted Columbus Venture Partners and Alta Life Sciences as new investors.



Joan Perello,
co-founder and CEO,
Laboratoris Sanifit

Existing shareholders who put \$41 million in the September 2015 series C, including Lundbeckfonden Ventures, Ysios Capital, Forbion Capital Partners, Gilde Partners and Andera Partners, followed on.

In addition to a phase III U.S./European trial in 65 to 70 patients with calciphylaxis, the new money will fund work on manufacturing scale-up of SNF-472 (hexasodium phytate) and the completion of a phase IIb study in the broader indication of cardiovascular calcification in hemodialysis patients.

Before raising the series C, Palma, Majorca-based Sanifit had raised only €6 million from local funds, grants and private individuals, since it was formed in 2007.

Assuming positive clinical results in the phase III calciphylaxis study, Sanifit now has enough money to see it through to FDA and EMA marketing submissions.

"It's an amazing story," said Joan Perello, co-founder and CEO. "We succeeded last time with phase I data. Now we've got two parallel phase IIs on [the basis of] the last raise, and funding for the phase III," he told *BioWorld*. SNF-472 is the only molecule based on university research carried out in Spain to have made it through to phase III development, Perello said.

Calciphylaxis is a severe and usually fatal disorder in which calcium is deposited in the small peripheral blood vessels of the limbs and abdomen. That leads onto the formation of

painful skin ulcers and the necrosis of surrounding tissues. Calcification progresses rapidly and there is a one-year mortality rate of 55%.

The phase II open-label study, which reported last year, assessed the effect on wound healing in 14 patients. They were treated with an intravenous formulation of SNF-472 during hemodialysis, three times a week, for up to 12 weeks. There were clinically and statistically significant improvements in wound healing and pain, and SNF-472 was generally well-tolerated.

The phase III trial will open in Spain and the U.K. by the end of the year. Centers are being evaluated elsewhere in Europe, and in the U.S., big hemodialysis centers will be an important source of patients, Perello said.

As recruitment gets underway in the phase III trial in calciphylaxis, Sanifit is expecting the read-out from the phase IIb trial of SNF-472 in the treatment of cardiovascular calcification in end-stage renal disease patients.

Most patients at the end stage of renal disease have accelerated calcification in the coronary artery. That correlates with higher cardiovascular risk, and cardiovascular disease is the most common cause of death. There are no approved therapies and it is estimated there are 2.5 million patients worldwide.

The 350-patient double-blind, placebo-controlled 52-week phase IIb completed last August.

SNF-472 works by preventing the formation of microcrystals of calcium hydroxyapatite, the penultimate step in the pathway leading to vascular calcification. In the phase IIb, the endpoint is the drug's effect on cardiovascular calcification, as assessed by coronary artery calcification score.

"In preclinical models, if calcification is blocked, or slowed down, [cardiovascular] disease can be reversed. But it's not the drug doing it, from a mechanistic point of view," said Perello.

The phase IIb data will be an important inflection point for Sanifit. "At the year end, with data in hand, we will look for [commercialization] partners," Perello said. The next step beyond that will be to conduct a phase III to see if SNF-472 reduces cardiovascular events in end stage renal disease. ♦