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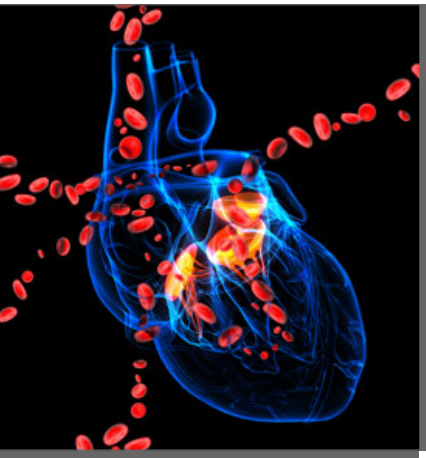

Livanova says Caisson TMVR device ready for EU, U.S. pivotal trials

By Mark McCarty, Regulatory Editor

Livanova plc of London has concluded the PRELUDE study, a 20-patient feasibility study of the Caisson transcatheter mitral valve replacement (TMVR) device the company acquired in 2017. The company said pivotal studies for both the EU and the U.S. markets are either enrolling or will soon will be, but other companies are already into pivotal trials for their TMVR devices. Nonetheless, Paul Buckman, Livanova's general manager for mitral valve devices, said the company expects to compete successfully

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Inside

Evidation raises $30M series C round, launches behavioral health data platform

By Stacy Lawrence, Staff Writer

Evidation Health Inc. has raised a $30 million series C financing to back its analytics based on the integration of electronic health record, wearable and medical device data. The San Mateo, Calif.-based company works mostly on postmarketing programs for pharmaceutical and medical device partners to enable patient-oriented and value-based analyses.

The new round was led by new investor SV Health Investors and existing investor B Capital Group. It included participation from existing strategic

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Dark arts to digital

Medicinal chemistry goes digital, at long last

By Nuala Moran, Staff Writer

Medicinal chemistry is lagging behind in the digital world, but now scientists at Glasgow University, U.K., have reported the development of an automatic synthesis robot that can apply machine learning to search for new reactivity in real time.

The robot can perform chemical reactions and analyses faster than they can be performed manually and is able to predict the reactivity of possible reagent combinations after automatically conducting a small number of experiments.

After exploring 100, or 10 percent of possible

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New generation of orthopedic implants

I.Ceram launches first bioceramic sternal implant onto European market

By Bernard Banga, Staff Writer

PARIS – I.Ceram SA has achieved CE mark certification for its first new-generation implant: the Ceramil porous alumina sternal implant.

André Kérisit, CEO of Limoges, France-based I.Ceram, told *Bioworld MedTech,* "This European certification confirms the implant's biocompatibility, osteointegration and radiolucency properties, making it the reference device for sternal reconstruction surgery."

This technology is intended for patients who

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Korea's Samyang Biopharma to establish U.S. office for biologics development

By Chermaine Lee, Staff Writer

HONG KONG – South Korea's Samyang Biopharmaceutical Corp. is set to expand to the U.S. with a new office in Boston, scheduled to open this month. The new location will focus on biologics product development as well as

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BioWorld MedTech's Cardiology Extra

Staff Writer Liz Hollis on one of med-tech's key sectors

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I.Ceram

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have developed cancer of the sternum through metastasis or from radiotherapy used to treat breast cancer, as well as for those born with a complete sternal cleft. This translates into a population across Europe of 2,500 patients a year, and the same in the U.S. Until now, thoracic surgeons had just two prosthetic options available to them. The first involves replacing the sternum with a titanium prosthetic, while the second relies on construction during surgery of a bespoke part using bone cement (polymethyl methacrylate or PMMA) and metal fixings. Both these conventional options increase patient infection risk. Furthermore, they do not maintain elasticity of the rib cage needed for unimpaired respiratory function.

"Our Ceramil technology is the only one allowing osteointegration, where the bone is still alive and grows in and around our material," said Kérisit.

The company developed a bioceramic part from alumina (Al_2O_3). This strongly resembles cancellous bone: high mechanical strength, cellular porosity with open cells between 400µ and 900µ coupled with interconnections varying between 100µ and 500µ. These features help with stability and biocompatibility for this new material, as well as osteoconduction and bone recolonization.

Patented Ceramil technology came out of research at the Ecole Nationale Supérieure de Céramiques Industrielle (ENSCI) based in Limoges. The innovation was featured in the world's first sternal implant using porous alumina, in 2015. This was on a 55-year-old patient who had developed radiation-induced cancer of the sternum, following radiation therapy for breast cancer.

François Bertin, thoracic surgeon at the Limoges University Hospital, took part in developing the medical device and performed this initial sternal implant. He told *BioWorld MedTech,* "The implant became an integral part of the bone in under two months." Since then, approximately 10 more sternal implants have been performed on patients in France. The most recent I-Ceram ceramic sternal implant was performed at the start of the year at the Timone Hospital in Marseille, on a 9-year-old girl born with a complete sternal cleft due to agenesis (incomplete development during the fetal period).

"Ceramil technology truly benefitted from significant clinical experience, as it has been in use since 2006 for high tibial osteotomy in realignment of the lower limbs, for cervical cages and also to close gaps in the skull," said Kérisit. More than 6,000 of this type of implant have been performed to date in France and abroad, without any vigilance system incidents.

The company has invested $3.5 million in a manufacturing base, combining not just design with a ceramics laboratory, but also production, with an ultra-modern machining operation. I-Ceram eventually sees a worldwide market available worth $100 million, based on 7,000 implants costing just over $14,000 each.

"Our marketing strategy relies on distribution partnerships with companies specialized in medical device sales for thoracic surgery," said Kérisit. I-Ceram has already signed exclusive national distribution contracts in 15 European countries. Notably, in partnership with Europrisme Medical RD, Bio

Ceramic sternal implant; I.Ceram SA

Distribution Sàrl and ACV External SLU for the distribution of sternal implants in France, Belgium, the Netherlands, Luxembourg, Switzerland, Italy, Spain, Greece and Morocco.

"Alongside these initial countries, the sternal implant will also be distributed in Portugal and South Africa through our subsidiary companies, I.Ceram Pt. and I.Ceram South Africa," added Kérisit. He also mentioned talks at an advanced stage in other substantial markets.

The company is working on development of an active Ceramil bone implant, which delivers antibiotics straight to an infected bone. Just last year, two implants using the biomaterial Ceramil incorporating gentamycin were performed successfully on French patients. These involved a patient with an infected sternum, and one presenting with chronic MRSA osteitis.

"Our ambition is to launch an active bone implant onto the market by 2020. We are going to continue our efforts to offer a sternum which incorporates substances indicated in bone infections," said Kérisit.

The market for bone infection is significant. Indeed, infection risk is a serious complication that often needs reintervention and in the most extreme cases, can lead to amputation. With 2 percent to 4 percent of prosthetics becoming infected each year worldwide, I.Ceram should be able to tap into a substantial market.

Meanwhile, the company is starting a campaign in the U.S. this year with the goal of launching the sternal implant onto the market in 2020. The company, which has already raised $16 million since formation, is now about to proceed with increased share capital of another $10 million to continue developing Ceramil technology for other international markets. ♦