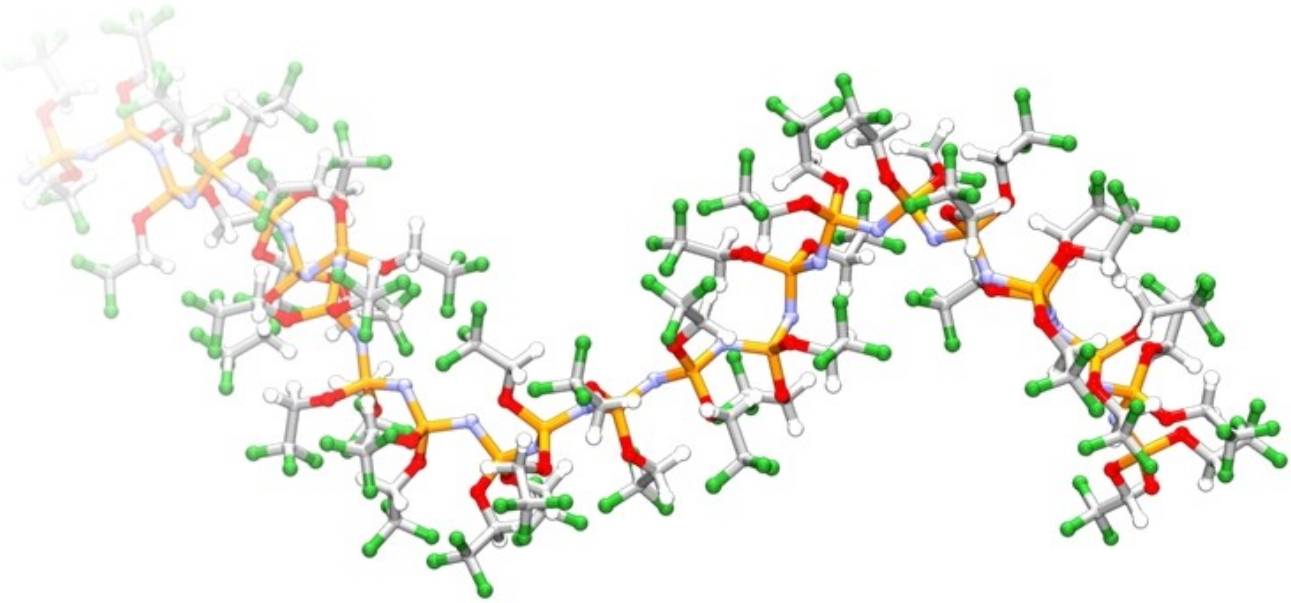
Healthcare industry BW

CeloNova is taking off

CeloNova BioSciences is a global medical device company whose core technology is currently mainly used for interventional cardiology (stents) and tumour embolisation (selective occlusion of tumour arteries) products. The company has been expanding since 2010. CeloNova products are currently available in 52 countries and there are plans to place them on the Asian market in 2014 and further increase company turnover.



CeloNova's core technology: the high-tech polymer poly[bis(trifluoroethoxy)phosphazene] is marketed as Polyzene®-F.

The company's relocation from the centre of the city of Ulm into a large independent building in the

Ulm-Donautal industrial estate in late 2013 is part of the expansion that the company has been undergoing since 2010. In the new location, Dr. Roman Denk, supported by 27 employees, is setting up a production and logistics centre.

This move brings full circle to the eventful American-German company history which started in 2000 when Dr. Roman Denk, a chemist from Ulm, and Prof. Dr. Michael Grunze, professor of applied physical chemistry from Heidelberg, jointly founded the company Polyzenix. Polyzenix was sold to an US investor group in 2004 and has been operating under the name CeloNova BioSciences since 2006.

Company headquarters, marketing and sales for the US market as well as some production facilities are located in Texas and California. Marketing and sales for Europe and the rest of the world are with the company's subsidiary in the Netherlands. Production and R&D are carried out in Baden-Württemberg.

The company site in Ulm is in charge of production, global distribution and customer support; research and development is carried out by seven people in Heidelberg in close vicinity to important institutions of Heidelberg University, and one member of staff coordinates clinical research projects in Karlsruhe.

A high-chem polymer

A lot of know-how has gone into the development of a macromolecule known as poly[bis(trifluoroethoxy)phosphazene], which combines excellent biocompatible as well as haemocompatible properties. It is therefore predestined for application in the human body. The material works so well because of its outstanding affinity to albumin and its biological stability, which ensures permanent biocompatibility and, as Dr. Denk explains, prevents implant complications due to surface effects.

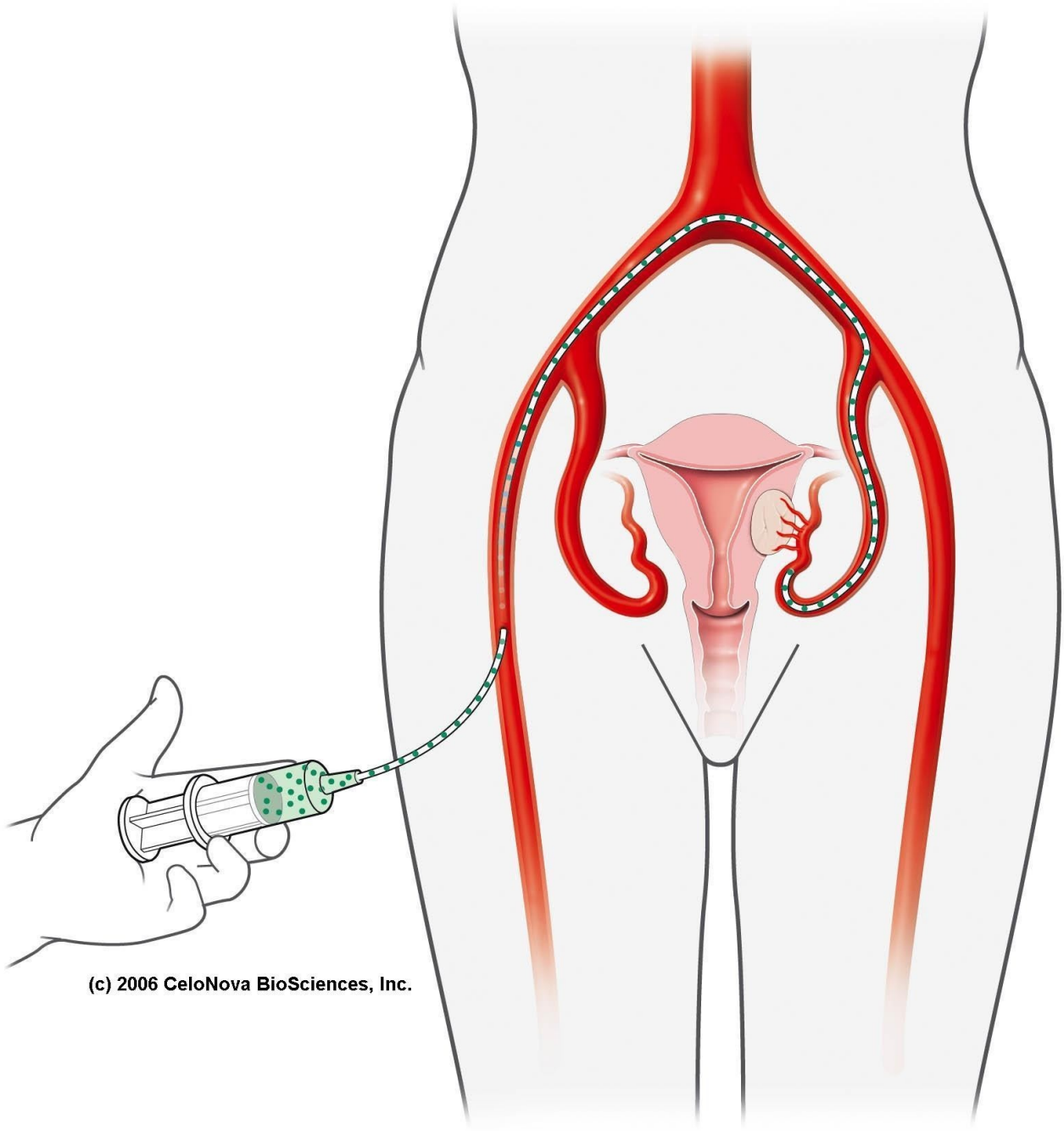
The thread-like polymer consists of around 250,000 individual building blocks and is synthesised using a very time-consuming and complex process. However, it is not just the production of the polymer that is challenging, the same also applies to its application and processing. CeloNova's embolisation material consists of a hydrogel core that is coated with a Teflon-like material. "This technique enables us to attach a polymer, which per se is extremely hydrophobic, to an aqueous surface."

Products for embolisation and stents

CeloNova BioSciences has two major product lines – microspheres for use in embolisation therapy and stents.

The company has established itself on the European market with precisely calibrated microspheres for application in embolisation therapy. CeloNova has been pursuing this approach since 2004 and has worked closely with medical doctors, particularly in the application of the microspheres in the field of interventional radiology. The microspheres generate no adverse body reactions and are thus perfect for closing tumour arteries.

Embolisation therapy is a minimally invasive procedure that has become a popular alternative to standard therapeutic interventions, in particular in the fields of gynaecology, urology and oncology. For instance, interventional radiologists use microspheres 500 to 900 micrometers in size for the treatment of uterine myomas, benign tumours that grow within the muscle tissue of the uterus. Using this type of treatment enables doctors to preserve the uterus and the length of hospital stays



Schematic showing how uterus embolisation therapy works.
© CeloNova Biosciences

can be drastically reduced. Although this minimally invasive procedure is already available in Germany, as many as 75,000 women still undergo hysterectomies due to uterine myomas.

This therapeutic approach has also been successfully applied to the treatment of benign prostate growth (prostate hyperplasia) since 2012. In this case, microspheres of between 250 and 400 micrometres are used. Prostate embolisation is virtually pain-free and helps maintain organ function.

CeloNova offers microspheres in ten different sizes, ranging from 40 to 1,300 micrometres. The different microspheres can therefore also be used for applications other than gynaecology, urology and oncology, such as in the field of neuroradiology.

Massive attack on liver tumours using drug-loaded microspheres

The company has great expectations for the further development of its microspheres, and has found a way to load them with drugs. Such drug-loaded microspheres have been available in the EU since May 2012. The polymer spheres and their pharmaceutical cargo are used as a kind of "overkill" measure for the treatment of tumours, mainly solid liver tumours.

Solid liver tumours are very difficult to remove surgically, which is why radiologists prefer to use a minimally invasive technique for destroying the tumour from inside. "We not only close the tumour arteries, but also provide a transport medium which, when loaded with a drug, is able to release a dose 2,000 times higher than the systemically possible dose directly at the site of the tumour in the body," says Roman Denk, explaining the principle of the microsphere-based treatment. CeloNova produces the 'naked' microsphere, pharmacists load the spheres with drugs and doctors apply the drug-loaded spheres directly into the arterial system of the tumour.

The company established its second product line in 2011 when it acquired a stent manufacturer. In 2013, CeloNova placed on the market a coated cardiovascular stent, whose surface properties and mechanics set new standards. The stent is characterised by excellent haemocompatibility and is made of stent struts that are half the thickness of the best cobalt chrome stents currently on the market.

Further growth

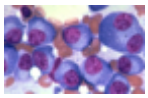
CeloNova has plans to further expand its product portfolio around the world. The company is particularly targeting large medical centres that offer alternative minimally invasive therapies in addition to standard invasive interventions. The company envisages that around 25,000 patients will be treated with CeloNova products in 2014. "We also aim to expand our product portfolio with microspheres that can be loaded with other drugs. We also hope to develop products for the specific treatment of liver metastases," says Denk, well aware of the fact that it takes quite some time for new therapeutic approaches to be accepted, if they are at all. This also applies to the treatment of tumours. "At present, we have an excellent basic structure which we can equip with different drugs," says Denk pointing out that the company will now focus on tapping as many as markets as possible and expanding the company site in Ulm.

CeloNova BioSciences started as an American company with German roots and has since become a globally acting and globally recognised medical device manufacturer with high growth potential in Ulm.

Article

26-Mar-2014
wp
BioRegionUlm

The article is part of the following dossiers



Cancer therapy and cancer diagnostics

CELO NOVA®