MedTech Radar

Innovations in medical technology

A media service about innovations in medical technology
provided by the Bundesverband Medizintechnologie,
Earlybird Venture Capital and High-Tech Gründerfonds

Issue 1 - December 2011

Focus: Innovations in the battle against the heart attack

Executive Summary

Illustrated with examples from the industry, **MedTech Radar** will give an insight into the world of innovation in the MedTech sector. As a media service, it will analyse strengths and weaknesses and provide background information.

The focus of the first issue is innovation in the battle against heart attacks. Most people do not realise that only 15 percent of cases are due to the gradual narrowing of the arteries caused by vascular disease. 85 percent of all heart attacks are caused when an inflamed fat deposit suddenly ruptures.

The case study by Cryotherapeutics GmbH shows how the targeted application of cold temperatures can be used for therapeutic purposes. The Potsdam-based company is working on the development of a -10 to -20°C catheter that will ease inflammation in the artery and prevent rupturing. "The environment in Germany in the medical technology sector is very supportive for entrepreneurs", says the English company founder Dr. John Yianni.

Editorial

*The aim of **MedTech Radar** is to provide those who are interested with a regular insight into new developments in the world of innovation in medical technology. Using examples from the industry, it will show the complex journey a medical product makes from initial research through to use by patients, and in so doing will illustrate the important role innovation funding plays to the benefit of patients.*

Germany is well-established as a first class location for developments in medical technology. As well as industry carrying out its own research and launching products, university research also supplies innovations that play an important role in medical care. But the journey for an innovation from invention to the market is a long one and not always easy.

High-Tech Gründerfonds, Earlybird Venture Capital and the Bundesverband Medizintechnologie (BVMed) – who are also the publishers of MedTech Radar – accompany products on this journey from idea to patient.

High-Tech Gründerfonds (an initiative of the Bundesministerium für Wirtschaft und Technologie (BMWi), KfW and twelve industrial groups) supports young inventors by providing initial financing and operational assistance so that technologies reach at least the prototype stage or the point of market launch. Following this "seed phase", a venture capitalist such as the company Earlybird Venture Capital helps to grow the business beyond market readiness and to scale it to the international market.

The Bundesverband Medizintechnologie (BVMed) is an industry association that represents over 230 industrial and commercial companies in the medical technology sector. Among its members are 20 of the largest medical device manufacturers worldwide in the field of consumer goods.

Focus
Coronary heart disease

The heart

The heart is a living pump – a hollow muscle approximately the size of a fist – that keeps our circulation going by pumping blood through blood vessels and thereby supplying the organism with oxygen and nutrients. Driven by the heart's power, the blood flows along more than 100,000 kilometres of blood vessels – over twice the circumference of the Earth.

Anatomically, the heart is divided into two halves, each of which consists of a ventricle and an atrium. The ventricles and atria are separated by heart valves which allow the

blood to flow through in one direction only: the arteries transport oxygenated blood from the heart to the organs and the veins carry de-oxygenated blood from the organs to the heart. The blood circulates in this cycle through the body over 1,400 times a day, ideally over a whole lifetime – a powerful performance that no machine to date can achieve in the same way.

The heart is one of the most resilient organs in the human body. But if this living pump stops functioning properly, the consequences for the person can very quickly become life-threatening. In 2008 cardiovascular diseases were the cause of more than 40 percent of all deaths in Germany. But there is hope for affected patients, thanks to modern medical technology. In recent years and decades, medical research has yielded ground-breaking innovations that save the lives of hundreds of thousands of people annually.

Clinical features of coronary heart disease

To be able to keep us alive, the heart muscles must be supplied with sufficient oxygen and nutrients by the heart's blood vessels (in medical terms: coronary arteries). They cover the heart in a network of smaller and larger blood vessels

If there is a blockage in the system of coronary arteries and therefore a restriction in the supply of oxygen to the heart, this is called coronary heart disease, which frequently has serious consequences such as chest pain (angina pectoris), heart failure or heart attack. In Germany alone 340,000 people die every year of this disease. Coronary heart disease is civilisation's number one disease, a long way ahead of cancer. A heart attack is the term used to describe the death of part of the heart muscle due to a circulatory disorder: if the blood supply is completely cut off, parts of the heart muscle start to die after 15 to 20 minutes.

New prospects: heart attack

Arteriosclerosis is the name of disease of the blood vessel wall in which the artery becomes narrower due to an accumulation of deposits. Up until a few years ago, doctors assumed that a heart attack occurs when a long period of illness leads to the complete closure of the arteries.

However, research in the last 20 years has shown that only around 15 percent of heart attacks are caused by the gradual narrowing of the arteries. According to recent studies, the nature of the deposits is the bigger problem: the composition of white blood cells and lipids (fat cells) is inflammatory and can rupture suddenly. The body's normal defence is to clot the blood in order to close the wound – and it is this clotting that blocks the arteries and, if it is big enough, stops the blood supply to the heart. 85 percent of all heart attacks are now put down to the sudden rupture of fat deposits.

Arteriosclerosis vs inflamed fat deposits

While arteriosclerosis is deemed to be a disease that affects old people and high risk groups, the group that is vulnerable to the sudden rupture of inflamed fat deposits is significantly more difficult to identify. This vascular disease can have genetic causes and is aided by an unhealthy diet and lack of exercise, but it often also affects people who were previously considered healthy.

There are also differences in the methods of treatment. Arteriosclerosis is treated by established procedures; mostly by a "balloon dilation" in which a small balloon is used to re-expand the constricted blood vessels. The procedure is called Percutaneous Transluminal Coronary Angioplasty (PTCA) and is carried out in Germany approximately 270,000 times a year. The disadvantage of this procedure, however, is that 30 to 50 percent of the vessels treated in this way become constricted again after no longer than six months. That is why it has now become common, in addition, to implant in the blood vessel a stent (a small vessel support made of wire mesh, often coated with a drug) in order to prevent the renewed formation of constrictions (restenosis). The procedure is called Percutaneous Coronary Intervention (PCI).

Inflamed fat deposits are more difficult to treat in two respects. First of all, there are very few methods of identifying those affected – presently the patient usually only becomes noticeable as a result of a heart attack and only then can they be treated. In addition, with the exception of medications which can only achieve results in the long run, there are no methods of treatment. Medical research is currently in search of ad hoc solutions that bridge the time gap from when a heart attack first occurs to when the drugs take effect.

Case study: Cryotherapeutics GmbH

One approach to treating the inner lining of arteries (in medical terms: endothelium) is cryotherapy – the targeted use of cold temperatures for therapeutic purposes. One of the pioneers in this area is Cryotherapeutics GmbH in Potsdam.

The company is working on the development of a -10°C to -20°C catheter that reduces the inflammation in the artery and prevents rupturing. It is similar to the way we cool a bruise to prevent swelling. The endothelium is strengthened by the moderate cooling, but the muscle in the vessel is not damaged. The treatment goes like this: the catheter is inserted into the affected artery at the inflamed endothelium. Using a cooling agent, a temperature of between -10°C and -20°C is produced at the tip of the catheter. The supply of the cooling agent is controlled by software.

The Englishman Dr. John Yianni, founder of Cryotherapeutics GmbH, has good reasons for bringing his business model to Germany: "The environment in Germany in the medical technology sector is very supportive for entrepreneurs. Apart from the positive financing environment for young innovative businesses, Germany also has an excellent infrastructure for clinical studies, very good technical expertise and a talented workforce. The conditions are ideal for developing technologies to the highest level."

Cryotherapeutics is supported by High-Tech Gründerfonds, US investors and Investitionsbank Brandenburg. With the €1.2 million in financing that it has so far received, the company has been able to develop the cryotherapy catheter and test it successfully in preclinical models. Further clinical trials are necessary and a further €3 million in financing before the system can be used in testing on heart attack patients. Once the test phase is completed, the product will be registered and commercialised across Europe.

"Approval of this product will significantly improve the acute care of heart attack patients. But there will be a far bigger breakthrough when the therapy can be used in a prophylactic way to prevent heart attacks.", says John Yianni. "However, in order for this to happen there need to be further innovations in the area of disease detection." So, on with the research. If it works out, then the first patients will be able to benefit from this innovative therapy in three years time.

Background and service

Experts for the case study

Prof. Dr. med. Norbert Frey, Chair of the Clinic for Cardiology & Angiology at Christian Albrecht University, Kiel. Tel. +49 - 431-597 1440, norbert.frey@uk-sh.de

Prof. Dr. Klaus Paulat, Faculty of Mechatronics and Medical Technology, Ulm University of Applied Sciences. Tel. +49 - 731-50 28606, paulat@hs-ulm.de

Links to further Information

Article in Scientific American Magazine, May 2002

"Atherosclerosis: The New View"
A long-held idea about how atherosclerosis develops has been overturned, offering clues to fighting this deadly disease (by Peter Libby, 4 May 2002):
http://www.bvmed.de/download.php?57650

Information about innovative MedTech procedures in heart disease, from the BVMed Initiative "Maßstab Mensch":
http://www.massstab-mensch.de/Medizintechnologien/Herz/article/Kunstherz.html

MedTech industry report: http://www.bvmed.de/branchenbericht

Germany:
Excellent care and perfect infrastructure, but weaknesses in MedTech reimbursement

Additional information from the MedTech autumn survey, in which 117 BVMed member companies took part in October 2011:

Germany is given good marks overall by medical technology companies. 60 percent of the participants consider the level of patient care to be high. Its big strengths are listed as: good infrastructure (58 percent), fast regulatory approval (47 percent), well trained doctors (44 percent) and a high standard of clinical research (42 percent).

The companies see weaknesses in the area of reimbursement. 59 percent are unhappy about the increasing pressure on prices caused by purchasing groups; 52 percent consider the level of reimbursement in Germany to be too low in general. Just under 50 percent of the companies are critical of the health insurance companies' policies, which they see as unsupportive for innovation. The growing skills shortage is an aspect which is becoming more and more important.

For more information about the survey:
http://www.bvmed.de/stepone/data/downloads/8b/e0/00/4_schmitt.pdf

Contact details for the three editorial partners

BVMed
Manfred Beeres, Head of Communication/Press
Tel. +49 - 30 246 255-20, beeres@bvmed.de, www.bvmed.de

Earlybird
Christine Höfer
Tel. +49 - 40 432941 0, hoefer@earlybird.com, www.earlybird.com

High-Tech Gründerfonds
Stefanie Zillikens
Tel. +49 - 228 82300107, s.zillikens@htgf.de , www.htgf.de

Imprint

Responsible for content under German Press Law:
BVMed - Bundesverband Medizintechnologie, Reinhardtstr. 29 b, 10117 Berlin
Earlybird Venture Capital GmbH &Co KG, Van-der-Smissen-Str.3, 22767 Hamburg
High-Tech Gründerfonds Management GmbH, Ludwig-Erhard-Allee 2, 53175 Bonn