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A Roundtable Discussion With Invatec


Andrea Venturelli


Stefan Widensholer


Jack Springer

Last month, Invatec, a comprehensive innovator of vascular interventional products with its global headquarters based in Italy, announced that it has launched its operations in the US. The company currently has a full percutaneous transluminal angioplasty balloon product line and a thrombus-management catheter available for sale in the US and a clinical trial underway to assess the safety and efficacy of a proximal protection device for use in carotid stenting. Invatec is also planning to launch numerous additional clinical trials intended to bring new products and products currently available in Europe to the US.

We spoke with Andrea Venturelli, CEO, CTO, and cofounder; Stefan Widensholer, cofounder and member of the Executive Board; and Jack Springer, President, US, to learn more about Invatec's vision and future plans.

What has been your vision in your years at Invatec?

Mr. Venturelli: It is our belief that growing markets stimulate physicians' ideas for better medical products that improve patients' health. Since its inception, Invatec's vision has been to serve as our physicians' preferred partner and bring to market innovative products that they deem essential and necessary to practice better medicine. Our goal is to be the physician's first choice when it comes to partnering to develop innovative concepts for the treatment of peripheral vascular disease.

Mr. Widensholer: In keeping with our vision to be a leading innovator in partnership with our physicians, we have focused on a few key priorities as we've developed our business, offering 35 product families in 70 countries. We have been successful with this approach for the past 12 years.

First, we maintain a solid in-house technology base to provide flexibility and independence from outside sources. Second, we continually work to build strong partnerships and working alliances with innovative physicians around the world to focus on emerging market opportunities. Finally, our team is committed to taking these physician ideas and quickly translating those ideas into products.

Mr. Venturelli: We are proud that our growing portfolio of innovative products has been the result of focused physician partnership alliances such as a below-the-knee treatment concept, lesion-specific stenting approach, thrombus aspiration technology, carotid proximal protection devices, and hybrid carotid stenting.

What prompted the decision to launch in the US?

Mr. Springer: Our launch in the US represents a tremendous opportunity to expand our strong base and continue to develop innovative new products. When it comes to developing new ideas, having a connection in the US and the ability to integrate into the US market is a must for any global medical device company. Introducing our products and launching clinical trials is only the beginning; we've talked about having an R&D arm in the US to increase our connections to US physicians and continue to expand our presence over time.

Mr. Widensholer: We always planned to bring our product concepts to the US market. Many US physicians, especially those who had access to our products via their international teaching assignments, encouraged us to start US operations.

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We are very proud to participate in the most prestigious and rewarding market of the world. Our highly experienced team here in the US, as well as our support team in Europe, which includes R&D and production facilities, has every confidence that we will generate positive customer feedback on our many treatment concepts.

What new developments at Invatec have you the most excited?

Mr. Venturelli: Physicians in the US will see a huge amount of products coming their way, especially our lesion-specific stent line and our coronary balloon line. This includes the smallest balloon in the world—the 1-mm Falcon CTO balloon.

Given our solid technology base in polymer, metal, and "surface treatment" with bioactive coatings, physicians should also watch for many new treatment concepts that are currently under development by Invatec in the interventional vascular space.

Mr. Springer: As a newcomer to Invatec but a veteran in the field of vascular technologies, I am most excited by the company's focus on collaboration with physicians for R&D efforts.

Also remarkable is the timeline for products in the US. Invatec has four products that are available right now: Diver CE, Amphirion Deep, Submarine Plus, and Admiral Xtreme. However, we have developed dozens of products that have a potential place in the US market. In addition, we have clinical trials currently underway and another five studies lined up that are to begin in the near future. Between now and 2012, there will be a number of endovascular products coming into the market.

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One particularly exciting area of innovation is the work Invatec is conducting to develop devices appropriate for below-the-knee procedures. Blockages below the knee can be a severe problem that can lead to amputation if not addressed properly—more than 100,000 amputations take place each year. There is also the issue of keeping blood flowing to address chronic ischemia and leg pain. Invatec has developed some low-profile balloons that offer easy access and can get deep into the foot to open up arteries. The company is also examining whether stents would be of value below the knee and to better understand whether other therapies such as drug-eluting balloons might encourage healing.

Invatec is also starting the largest registry of below-the-knee patients in the world to understand the effectiveness of treatment in this area.

What do you see as the biggest challenges in the field of peripheral arterial medicine today?

Mr. Widensholer: The potential market for endovascular treatment is huge and still in its infancy. The number of patients affected by the underlying disease of diabetes continues to grow. We know that at a certain stage, diabetes causes patients to experience severe vascular disorders and pain.

With our interventional endovascular treatment concepts, we can help cure a patient's pain immediately. Our biggest challenge is to enhance awareness of this underutilized treatment option for patients. Invatec is fully committed to help build this awareness by spreading the news about successfully treated patients, sup-

porting educational meetings, and starting new clinical trials to prove the benefits of endovascular treatment options.

Mr. Springer: I agree that there is still an issue of awareness when it comes to peripheral medicine. Peripheral vascular disease is an underdiagnosed area—many people are still not being diagnosed or treated.

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Related, there exists a lack of clinical data, especially compared to what is available for coronary procedures. More work needs to be done to understand these devices and their effects. Invatec is dedicated to helping address this issue, with plans underway to launch more than five US clinical trials over the next 3 years.

What can you tell us about the ARMOUR trial?

Mr. Venturelli: The Mo.Ma system is very different from other devices that are currently available because it offers proximal protection as opposed to distal protection—it does not cross the lesion prior to deploying the product, and, therefore, the risk of emboli is less. The device allows the physician to establish embolic protection during carotid stenting before lesion crossing with the principle of blood flow cessation by "endovascular clamping" via common carotid and external carotid artery balloon occlusion.

This proximal protection approach is what physicians have wanted, but early on, the technology wasn't available. With Mo.Ma, we are finally looking at technology that is able to treat patients with less risk of emboli. Using distal protection, if you can't get the device past the lesion, you can't perform the procedure. With proximal protection, physicians will be able to treat another subset of patients who could not be treated with stents previously.

Recruitment in the ARMOUR study is progressing quickly within 25 investigational sites in the US and Europe under the guidance and supervision of Principal Investigators Gary Ansel, MD (Riverside Methodist Hospital, Columbus, Ohio) and L. Nelson Hopkins, MD (University of Buffalo, Buffalo, New York).

Since its introduction to the European market in 2001, safety and efficacy of the Mo.Ma system have been reported in multiple clinical studies, which also showed broad applicability in standard-to-complex cases with an unmatched high level of technical success. The ARMOUR study now aims to confirm safety and efficacy of Mo.Ma in patients at high surgical risk undergoing carotid stenting with any FDA-approved carotid stent.

What technologies and advancements are in the pipeline at Invatec?

Mr. Venturelli: Invatec has been able to build a solid, vendor-independent technology platform consisting of advanced polymer technology, multilevel metal technology, and surface modification ranging from bioactive surfaces to local delivery. This is supported by our in-house surface treatment nanotechnology, which ranges from cell culture technology to proteomics and gene expression.

Mr. Widensholer: We believe that next-generation devices will most likely include some kind of bioactive substances. As a result, Invatec will continue to enhance its product offerings on the basis of these in-house technologies, which provide a huge opportunity for clinical studies before bringing next-generation "combo-devices" to the US market.

How has this field changed over your years in the field of endovascular medicine?

Mr. Venturelli: The interventional field has clearly been changed by the many new product concepts that have been developed in recent years. However, the basis of that innovation has remained the same: it is still the physicians and their innovative ideas that drive emerging markets. This strikes us as appropriate; we commit our teams and our resources to participating in the development of these innovations in order to make ideas come alive and to make them applicable for treatment the fastest way possible.

Mr. Springer: When I became involved in this field in the 1990s, there was a tremendous lack of awareness and understanding of peripheral vascular disease. Back then, there were a lot of surgeries or no treatment plan at all—vascular disease was simply chalked up as a consequence of growing old. Now, with new technology and better understanding of vascular disease, there is a realization that we can open up these arteries just like we open up the heart and really make a difference for patients. However, there's more that can be done, and this area represents a great opportunity to make a difference for patients. ■