Interview with Wolfgang RÃ¼dinger, CEO, Cytonet

21.09.2009

Tags:

Cytonet

Cytonet is today Germanyâ??s largest cell therapy enterprise. However, it went through many transformations since its spin-off from Roche Diagnostics in 2000. Could you briefly introduce the company to our readers and highlight its main milestones?

We identified the field of cellular based biotechnology as an interesting area well ahead of time, more then 15 years ago. By then, Cytonet was part of Boehringer Mannheim (now Roche) and we recognized that cellular based medicine could have a huge impact on traditional drugs and diagnostic development, and it proved true.

Within Boehringer Mannheim we started to build up three cleanroom cell based production facilities; one in San Diego together with the University of California San Diego (UCSD); another in Milan with Claudio Bolignion and the Hospital San Rafael; and the third one here in Germany together with Hanover Medical School (HMS), which for more then 15 years has had a strong focus on regenerative medicine.
Before 2000 Cytonet belonged completely to Roche; but nowadays it has two major shareholders â?? the family of Dietmar Hopp, co-founder of SAP systems, with the majority of shares, and Roche as a minority holder.

And what were the main challenges Cytonet faced when it gained independence from one specific group and started to work as a company on its own?

The biggest challenge Cytoned faced was the constant repositioning it had to go through from research and production to clinical development. The knowledge and skills necessary to do clinical trials are totally different from those needed in research and production. Cytonet lacked know-how in regulatory affairs and clinical trials; thus, it had to strengthen its capacities in these important fields.

Traditionally, biotech companies start with research and struggle to take the following steps towards real production, especially because they lack the skills and experience to do so. The â??skill shiftâ?? is the greatest challenge biotech companies have to face and thatâ??s where they should focus their efforts early in time. After 15 years of history and thanks to being part of big organizations such as Roche, Cytonet did not waste its time, money and motivation in projects that were not well planned before hand and we managed to overcome this initial challenge quite successfully.

When Cytonet was founded it was a pioneer in its niche. Looking at how the company developed, does it meet with your initial expectations? How is the company growing nowadays?

When Cytonet was created it expected to take only five to six years to take a product from research to the end of clinical trials. However, in 2005 the company was confronted with the situation where cellular based drugs were moved from the transplantation laws to the drug laws umbrella.

Overall, this was actually a positive change because a product regulated by the drug act is much safer and people identify it as such facing the safety gaps imposed by the transplantation laws. From the beginning Cytonet planned to grow in the orphan drug field and that is where we put our efforts in. Orphan drugs offer attractive advantages e.g: a market protection of 12 years after market approval for a new type of pediatric drug in rare diseases. This advantage would not exist for cellular based products regulated under the transplantation law.

Regarding growth, our vision at the beginning was to double sales on a year to year base. This was an ambitious aim and it wasnâ??t easy to achieve at the beginning. But we still believe that Cytonet will be able to fulfill it once our liver cell based product enters the market.
Cytonetâ??s first sales started with the production of blood stem cell and bone marrow preparations for treating leukemia and other tumor diseases. In this field it has a leading position in Germany with sales of around four million euro. However, this is a flat commodity market. Cytonetâ??s real product is its liver cell based product that is used in the treatment of severe liver diseases as well as metabolic liver defects in newborns and infants. This is the area where Cytonet stands alone and expects to benefit greatly from such a promising and unexplored niche.

With Cytonetâ??s great emphasis in the research and development of new products, how do you expect your product portfolio to evolve and what are the most promising therapeutical areas for Cytonet?

Cytonetâ??s product portfolio will definitely add more options to stem cell products and liver cell based drugs, developing new indications in these areas step by step. Based on the liver cell research we have identified acute liver failure and as first indication enzyme defects of the urea cycle in newborns. The aim is to cure these severe, life-threatening diseases and to validate therapeutic options in further genetic defects of liver metabolism. One in 8000 kids in Germany suffers from urea cycle disorders through the accumulation of ammonia with inevitably destruction of the brain.

The clinical results with liver cells are very promising. What Cytonet does is to infuse healthy liver cells that are able to convert ammonia into urea. So far weâ??ve learned that only 3 to 5 percent of healthy liver cells in the diseased liver are sufficient to compensate the organâ??s malfunction.

So far all 4 children which could be treated in individual therapeutic attempts resulted in a normalization of ammonia. This promises a great chance for all concerned children to have a normal life â?? and I must say that this is a special value in addition to the commercial advantage of our product.

When we had the opportunity to meet with Mr. Otmar D. Wiestler from the German Cancer Research Center (DKFZ) he told us about the gap between the German industry and its academy and research institutes. Having so many important partnerships with local and international universities and research institutes, whatâ??s your assessment over this issue?

I actually see the situation the other way around; I think there is a certain reluctance at the local academy and research institutes to collaborate with the German industry. Cytonet has a strong focus and important partnerships in the USA and there we see how much easier and natural it is to collaborate with local research institutes and universities.

However, Germany is experiencing a very positive tendency towards successful partnerships. Only ten years ago it was almost impossible to convince the academic world that patents, besides

scientific publicatons, were of great value, whereas in the USA everybody understood so and institutions financed research because they knew they could generate sufficient economic income with it. Nowadays, the same is starting to happen in Germany.

We are glad that the situation is changing in Germany and indeed Cytonet has very good and successful partnerships in Hanover and Heidelberg. We have a close partnership with Prof. Michael Manns who is the head of the department of gastroenterology and endocrinology at the MHH (Medical School Hanover) and also with Prof. Georg F. Hoffmann, head of the pediatric department of the University Childrenâ??s Hospital, Heidelberg.

Both belong to the most recognized specialists in their fields worldwide.

As you said, Cytonet has long been established in the USA, first with a partnership with the UCSD and more recently with the acquisition of Vesta therapeutics. Whatâ??s your strategy to penetrate the biggest biotech market worldwide?

Cytonet was aware of the magnitude and importance of establishing a subsidiary in the USA, especially when many biotech companies are failing in doing so since the American market is a much more competitive than any other. Nevertheless, things in America tend to work better because people have a very positive way of thinking; and Cytonet tries to integrate this characteristic into the whole company.

Cytonet acquired the facilities of Vesta approximately a year ago for many different reasons. To begin with, to isolate liver cells from donated organs benefiting from the bureaucratic procedure that is much more pragmatic in the USA. There are 58 organ procurement organizations; whereas in Germany there is a monopoly of the German Organ Procurement Organization. In the USA, these institutions are much more open to work with the industry and they understand that if an organ canâ??t be transplanted, then its liver cells should be used since the desire of the donor was to help saving lives through his donated organs.

Secondly, as I said, it is a pleasure to work with Americans because they are very positive. If you see a challenge it is good to have them working with you because they are actively looking for a solution instead of only trying to find out why the problem occurred.
Last but not least we see the size of the American market, which is very homogenous; whereas in Europe you have a comparable market in size but it is very fragmented and much more complex.

Besides the USA, Cytonet is also present in other international markets. What are the most promising international markets for Cytonet and whatâ??s your strategy to further penetrate them?

Recently Cytonet has been approached by important Japanese hospitals in order to export its expertise in the pediatric field. The Center for Childrenâ??s Health and Development in Tokyo, which has a very strong focus on genetic diseases, invited Cytonet to try to implement new technologies and possibilities in the Japanese market.

We plan the teratment of the first Japanese child before end of this year.

Another interesting possibility is the Middle East, especially the Gulf area. The University of Heidelberg has a close partnership with the Hamad Medical Centers in Doha since many years. Cytonet is working on an exclusive partnership aimed to implement our technique in order to save and improve kidsâ?? lifes there as well.

Turkey is another area of interest due to the high rate of sanguinity. â?? which happens when a marriage occurs between family members â?? the incidence of life-threatening genetic diseases is

higher there than in Western European countries. Therefore, there is a big demand for our technology. Besides the running Multicenter Study in Germany an the preparation of an US Multicenter Study we are in preparation of market approval studies together with selected medical centers in Turkey in a partnership with a private hospital chain. It is particularly important to have local partners in strategic areas to address the real needs of their population as effective as possible.

When do you expect to have Cytonetâ??s first drug in the market and where will the company go from there?

Cytonet expects to achieve market approval for its first product within the next years, but it is very hard to predict the timing and the decision making process of the responsible authorities. In the meantime, Cytonet will focus on other drugs for further clinical indications to broaden the therapeutic spectrum of our liver cell product.

There are hundreds of genetic defects and many of them are located in the liver. Our liver cell based drug is, in principal, able to effectively compensate all those diseases since the logic is the same: to substitute a missing enzyme or protein in the liver. We see a nearly endless list of other genetic diseases that could be treated. Therefore, Cytonet will identify disease after disease and develop those additive indications for our liver cell product.

In the technical field, Cytonet has successfully isolated not only mature liver cells but also stem cells in the liver that are responsible to repopulate the organ in case of a damage that needs strong regeneration. We isolate these cells with the aim to multiply them in order to have a sufficient amount and quality of cells to treat all effected children worldwide.

This will keep Cytonet busy for the next five to seven years; then we will focus on further areas of interest such as diabetes, or heart failure expanding our business perspectives.

As the head of Cytonet, what will be your final message to your prospective partners and readers of Pharmaceutical Executive in Germany and worldwide?

For small companies the message is very simple: you should identify an area where you can be the first one to develop a technology and be a pioneer â?? for instance, the still unexplored orphan drugs field where competition is weak combined with a definite medical need.

To big pharmaceutical players the message is that there are other fields beyond traditional drugs that should be looked at. Orphan drugs are attractive because they offer high price premiums, are still greatly unexplored and have a granted market protection. Cell based medicines are feasible in partnership with the global marketing and sales chains of big pharmaceutical players. They open interesting opportunities for partnerships between biotech companies and big pharmaceutical players. Therefore, you should be open to new technologies, possibilities and markets â?? and thatâ??s what Cytonet has to offer.

See more interviews