Diagnostics Breakout Q&A Session, London

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Heino von Prondzynski

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Participant

Now that you have FDA approval for the AmpliChip CYP450, what are your plans on marketing this new test?

Heino von Prondzynski

The FDA is quite interested in the ability to address both healthcare and drug safety. However, what also needs to be understood is the educational and informational process required at the physician level. Just knowing your metabolism status and coming with this information to a physician who is not in a position to know what to do - when the patient needs a lower dose, or a patient needs a higher dose - then that is a real issue that we need to address. With regards to reimbursement in the US, we are talking to HMOs, and to all interested groups. There has already been al lot of pre-discussions already, with a high interest being shown. My personal belief is that, in the US, the testing of people over 50 will be driven by the physicians' wish to cover all aspects of their drug selection. Because if there is an opportunity to avoid side effects and the patient finds out that they could have been avoided, it will be a difficult situation for the physician, also from a legal aspect. The legal part will partly drive it.

Participant

What is the deal with Innogenetics in regards to?

Heino von Prondzynski

The PCR Microbiology segment of Molecular Diagnostics business area will first launch a Sepsis test into the market in Europe, as we foresee at the moment, in Q3/ Q4 this year. It will be the first generation to be run on the LightCycler instrument. Then, depending on the take-up of the product, we will develop a second generation test on molecular diagnostics instrument platform.

Participant

What were some of the delays caused by for this test?

Heino von Prondzynski

There has been a lot of work gone into determining how to provide DNA- or RNA-free reagents, as this impacts on manufacturing of the reagents for the kits. It has been quite a challenge, I think, in development, which also has delayed the project by say, at least a year.

Participant

What are some of the main areas where you cooperate between Pharma and Diagnostics?

Heino von Prondzynski

If we take today's business in testing, best practice in terms of Pegasys and HCV genotyping, HIV treatment and HIV viral load testing, even around cardiovascular, and of course oncology which is the main focus in pharma, there are a couple of corporations which are interesting for both divisions. But even before sales and marketing, I believe there is information which is arising on the collaboration through the biomarker discovery programme. This is combining Roche Pharma preclinical development, with diagnostic expertise from the very beginning. This means that diagnostics could be included in the drug development plans as well as in the trials. It is difficult to grab the demand that this could generate for a test, but should improve the processes.

Participant

Will there be something solid to talk about in the coming years?

Heino von Prondzynski

I would say there will be something solid to talk about in the next few years. You cannot estimate - there will be an overlap in some areas. If you asked me how much synergistic sales could be generated in a decade or 15 years from now, I would say somewhere around 5-10% growth in each of the divisions.

Participant

Is Oncology the main focus area for Diagnostics? Is that where you see the most benefits?

Heino von Prondzynski

Absolutely. The main focus of new markers is in Oncology and here the focus is breast cancer, colorectal cancer, to some extent on lung cancer and prostate cancer. But these are the main ones.

Participant

Does that mean, in a sense, there is an information gap in terms of some areas of oncology? There is a lot of work that has to be done now if we aim for you getting those things out. Some of your diagnostics business is not actually in Oncology at all?

Heino von Prondzynski

The Oncology programme is quite substantial. If I take, for example, the proteomics part which I presented with the results on the market profile chart, there are a couple of approaches in Oncology and we need to distinguish between various segments. The main purpose in diagnostics is early detection. Early detection will not only also result in improved patient care but could in fact lead to more customers for pharma. This approach is not specifically for a specific drug, but in general to help diagnose earlier, which will also bring people earlier therapeutic options. The genomic approach of patient specification is a much smaller segment on the diagnostic front. If you take early detection, the market for breast cancer and others is something around $4-4.5 million. If I take colorectal cancer, it might be around $3-3.5 million. If I take patient specification, the market is significantly lower because, also from the business model, the diagnostics part will never able to charge the high prices, like we could potentially be able to do in a very distinct early detection marketing model.

Participant

What would the next step be with the proteomic markers that have been tested on 800 samples?

Heino von Prondzynski

We first need to finish the validation process. We have a very well-developed validation process where we take, for example in the colorectal part, a sample of the main data from 800 samples. They are all extremely well defined. There are a number of colorectal samples and there are different kinds of cancers, also healthy people and symptom-related diseases. These 800 samples are very distinctive and very well defined, and the testing validation procedure follows a 20 page protocol. I have to say that is also very difficult to get 800 samples. It took us almost three years to get these 800 samples. This is a time-consuming effort.

Participant

To what extent do you think your gains in market share are due to Abbott's weakness?

Heino von Prondzynski

Most of the marketing gain in Immunochemistry was considerable. We have gained a lot of market share in the US, although in the US we have somewhere around 8-9% market share so there is still room for improvement. In Europe, we have around 23-24%. Here, we have gained around 5% over the last four years. Luck does not have anything to do with this. We have certainly benefited from Abbott's weakness in the US, as Abbott has significantly reduced its market share. But all the other companies in the US, like Dade, Beckman and Bayer have benefited and I would say that all of the companies in the US have had similar gains.

Participant

To what extent are you sourcing your cancer markers from deCODE?

Heino von Prondzynski

None of the cancer marker candidates are from deCODE; they are all from internal development and a few other companies such as Epigenomics. We have marker candidates for cystic fibrosis from deCODE, and also cardiovascular disease for predisposition. Most of the cancer marker approach, from marketing development and research is done internally. What we also do through this validation process is search for useful clinical markers in the literature. However, not all of these markers are defined efficiently.

Participant

What new acquisitions are you looking into?

Heino von Prondzynski

That is something about taking opportunities where they are. Everything needs to make strategic sense; you cannot do it just for adding compounds. When you look at the three latest acquisitions, we made them to fill a gap in the blood gas electrolytes, in molecular diagnostics for highly sensitive virology tests, a market we have built. With Disetronic we wanted to fill our offering in the diabetes arena. We are also building the bridge towards the automated pancreas. The dynamic of the market for us has developed because we now have the technology, the number of instruments, the critical size and mass and also menu.

Participant

Do you think it is possible to improve margins further?

Heino von Prondzynski

In clinical chemistry, you can only make a difference if you are able to reduce instrument costs significantly and have critical mass of placements. Also, we have projects running for which we use consolidated instruments in clinical chemistry and immunochemistry. This will make a difference. You have to have good ideas; those concepts put us in the market. But we will consolidate in the market, not through acquisition, but just through pure market evidence.

Participant

So what is happening with Immunochemistry?

Heino von Prondzynski

In Immunochemistry, part of the market is close to becoming commoditised. If I take thyroids and such areas, a couple of the new markets are coming but these segments are relatively complete. The Oncology market on the other hand, has a lot of potential, especially if you can come up with very specific new tests. Take breast cancer markers, the gold standards show quite low sensitivity. However, new marker profiles that are being developed will really make a difference. Within proteomics, there are a number of markers in development that can ideally be put on the Immunochemistry platform to improve on current methods. Single markers, or profiles of say three markers will make a difference. If you have more than three markers, we are developing protein arrays which are completely different from the DNA-grade system. That is an internal development which started four years ago. It is quite advanced now.

Participant

You are seriously outspending competition on R&D at the time, so perhaps you could out-compete them technologically in the future?

Heino von Prondzynski

That is true in terms of technology in pharma, but it is also true in terms of technology in diagnostics. Because we see that technology is much more of a decisive factor in competitiveness. We are focusing on technologies that are much more specific and much more reliable than other technologies on the market. We are doing this for a diabetes care, with Accu-Chek Aviva and also with the new product for insulin delivery called Accu-Chek Spirit. If I look to the feedback from the German market where Spirit has recently been launched it is getting huge enthusiasm and up-take. And here we did a pilot program in the Netherlands first to make sure we delivered what the market wanted. So from that point of view, outspending the market has produced results. However, there is always room for improvement. We also need to be faster, more productive, and have more innovation coming out of them.

Participant

Do you think in Molecular Diagnostics Virology is becoming commoditised?

Heino von Prondzynski

In Virology, if I take HCV, HIV, I would not say Virology has become commoditised, but it is coming under significant price pressure, because competition is becoming more aggressive, with Bayer and a couple of other players. If I compare price development, it is not as dramatic as it was in the early 1990s in diagnostics, but there are certainly price pressures. So, this is the point where we need to addition tests and an additional menu. Also, market places for this will also need to make our business more sustainable.

Participant

What do you think will drive the molecular testing market?

Heino von Prondzynski

One very distinctive aspect, I believe, is having an integrated system. Combining sample preparation and detection process, so you do everything in one system. Look at all of our technologies. They are, so far, balanced areas and have a window of opportunity of somewhere between three or five years So when you integrate all of the technology standards we supply it keeps us ahead of the market. One last question.

Participant

What do you think will be the growth rate of the diagnostics business in the future?

Heino von Prondzynski

The market has grown over the last five years somewhere around 4-6%. We expect market growth this year to be around 5%. If we take our projections and compare this with others, they also have an average component growth rate projected to a maximum of 6% for the next five years.

Heino von Prondzynski

Thank you very much.