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Focus on RoActemra®

Q What led you into arthritis research?

My current position as a life cycle leader for RoActemra® within Roche is not 100% research focused. I oversee the whole span of a product's life cycle – from production to future development, encompassing the commercial features, and medical and clinical aspects as well. Therefore, I cover all these areas; I try to be a project steward. I am very close to the clinical and medical development and as a life cycle leader, I steer the resources we put behind RoActemra. So, for example, we are currently looking into new indications. We have a giant cell arthritis trial running, and a trial for systemic sclerosis as well; we are also looking into other smaller indications where the IL-6 mode of action may play an important role. I am very close to research.

We have also received European approval for the new subcutaneous formulation, which was already launched in Japan and the USA and is now available to another whole group of patients. One part of my role was to be behind that approval process so that we can deliver on promises to patients where we have an indication.

It is a good mixture of different activities. I am handling development of the drug with multiple teams all over the world within the company.

Q What does the approval of this new formulation of RoActemra mean for patients?

The European approval of the subcutaneous formulation of RoActemra expands the number of patients who have access to RoActemra and is another important step towards providing patients and physicians more flexibility to choose the right treatment.

RoActemra is an anti IL-6 receptor biologic and therefore has a different mode of action compared with the other biologics in the RA therapeutic field. Over the past couple of years we have seen that, with this IL-6 mechanism of action, we have a specific advantage with regard to monotherapy. We are learning more every day but it looks like the drug addresses monotherapy in a different way from the TNFs, for example. For the patient, and also for physicians – RoActemra provides a biologic for RA, which is able to be effective alone or in combination depending on patient's needs.

What stands out for RoActemra is that we have this differentiation potential. We have also gained new data over the past few years. I started in the German affiliate 3 years ago, and at that time we thought that maybe 20% of patients were ineligible or were not tolerating methotrexate. Today, when we look at the registries and the data we have, we observe many more patients who are not taking methotrexate (more than 30%). Therefore, those patients, and we are now talking about a third of the total, have a need, and the need is to get an effective and long-lasting therapy; this is where RoActemra comes in. It helps the physician and the patients to have more targeted therapies. This has also been recognized by the European League Against Rheumatism who have added RoActemra to their guidelines as a first-line biologic therapy and have highlighted the evidence to support the use of RoActemra in monotherapy patients. It is great to see this. RoActemra is also in the French and German guidelines; medical societies are gaining more confirmation that

Ralf Keil
Life Cycle Leader, Roche, Basel, Switzerland

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RoActemra can be efficacious alone, without a disease-modifying antirheumatic drug (DMARD). This then meets the need of those patients we talked about who are unable to take the combination. This is our main focus and we are very proud to be able to deliver this benefit to the patient and to the physician societies.

Q Where in the treatment pathway is RoActemra prescribed?

At the moment we still have a clear treatment algorithm within rheumatoid arthritis (RA). We start with a DMARD, and after DMARD failure, the physician and patient decide how to continue. If the decision is made between the patient and the physician that the patient is treated with a biologic, then they have a choice of a set of available therapies. With regard to the treatment pathway, RoActemra is a first-line biologic in patients who are either intolerant to or who have failed to respond to a DMARD, which is also highlighted in the European League Against Rheumatism guidelines, along with the TNFs, so there is no difference with regard to the TNFs or RoActemra. Then, as mentioned already, when it comes to the monotherapy, we have demonstrated with our head-to-head trial that we are doing better than one of the most prescribed TNFs. We have also been able to show with some of our own data, which compared monotherapy and combination therapy, that monotherapy is as efficacious as the combination therapy, we delivered the proof of that and this is one of the reasons RoActemra is also recommended as a monotherapy drug.

We hear from the market that confidence is growing. In the beginning, physicians are always a little bit conservative and do not rush in to prescribe a therapy since it is new. It has taken 5 years now, we launched in Japan in 2008, in Europe in 2009 and in the USA in 2010, within RA. RoActemra was launched first in Japan for Castleman's disease, so it already had a long history; with regard to RA, we have been on the market for 5 years and during these 5 years, we have been able to treat – our company estimate is – 275,000 patients since the launch, this has resulted in physicians and medical societies having growing confidence in recommending and prescribing RoActemra. The treatment certainly delivers a positive benefit–risk ratio.

Q The subcutaneous formulation can be administered by patients at home. What effect does this have on patients and how can they be trained to use the new formulation?

Yes, certain patients can use the new subcutaneous formulation at home, following training from their healthcare professional. We recognize that, for some patients, the intravenous formulation is less convenient and there can be stigma for patients to have to reach out to their employer to ask for holiday or time off to go to the hospital to get the infusion. Home use is much easier for some patients as it meets their needs. With regard to dosing, the first application should be in the clinic in order to train the patient, for safety reasons and to ensure everything is carried out correctly. Then if the patient and physician feel it is safe to carry out the procedure at home, then they will be able to do this. This is the situation in the USA and we expect the same from the European authorities, that after the first application together with the physician in the clinic, from then onwards, the RoActemra subcutaneous formulation can be used at home.

Q What are your expectations as to how many people will be prescribed this new formulation of RoActemra?

The decision is with the patient and the physician which drug and formulation they choose for treatment, but what we know is that, from a current market perspective, more patients prefer a subcutaneous formulation, so we would expect more patients will benefit. There will be some switchovers from the intravenous formulation, but the new formulation will also expand the number of patients who now have access to RoActemra.

Q The side-effect profile is a lot more favorable than other RA drugs. However, there is a risk of infection. Is the development of serious infections a real threat with this drug?

With the information that we have so far from the market and from physicians, the side-effect profile of RoActemra is well understood and data from databases and registries reveal that it is very manageable. It has been previously reported that there may be an increased risk of infection with RoActemra however we have no evidence that it is more serious than with the other drugs available on the market. In 2011 a meta-analysis from the Cochrane Collaboration did not show RoActemra being significantly different from other biologics available on the market for the treatment of RA in risk of infection.

Comparing the intravenous and subcutaneous formulations, we have a recently published study, which was one of the trials used for approval of the subcutaneous formulation. In this trial, we studied more than 1200 patients. There was an intravenous arm and a subcutaneous arm; there was no difference regarding the side-effect profile. The only difference was the injection reaction that was seen, which is common with subcutaneous drugs. There was no difference in hypersensitivity and immunogenicity between the intravenous and subcutaneous arms.

Q Finally, what do you see in the future of RA treatment?

What we see at the moment and with the new and upcoming drugs or potential treatment opportunities is a very positive trend with regard to RA. There will be more and more treatment options available for the physician and for the patient, which will be increasingly targeted towards the needs of the patient. We can also target the different diseases within RA, for example, systemic disease or more chronic disease; it is clear that these different forms require different treatments. There will also be enrichment of the available therapies, and I think we can very positively look to the future.

At Roche, we are happy that we have completed one of the first steps to introduce a new mechanism of action in order to provide an additional treatment opportunity. This additional treatment opportunity with a different mode of action that clearly works better than other options for a large subset of patients is something we are proud of. Although we are a long way from a cure, we can at least offer patients a more normal life, and this is most important.

Disclaimer

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