Interview: José María Fernandéz Sousa-Faro, President, Zeltia, Spain

14.05.2014

Tags: Internationalization, Oncology

José Fernández, president of the Zeltia Group, outlines the company's strategy for developing oncology drugs through marine-based organisms with the group's subsidiary PharmaMar.

With €550 [SG1] million invested in research and development in total, Zeltia was finally able to commercialize a novel product. Would you say that this investment was worth the effort?

The investment Zeltia made has been worth the effort, and I would also say that we have yet to see the complete return on investment as there are still many goals to achieve that will result in our continual growth. Zeltia's first major success was Yondelis, which has been approved for treatment of soft tissue sarcoma and ovarian cancer and has been commercialized in nearly 80 countries worldwide. But the two major markets of the United States and Japan are still without approval, which respectively represent 42 and 12 percent of the world oncology market. The FDA has asked for another trial, which we have completed and are awaiting for the data to mature in order to present the file. In Japan, the health authorities wanted to do another series of trials to reproduce the data but only with Japanese patients, and so far the results have been positive. We are therefore confident that Yondelis will soon obtain approval in both countries. In any case, Yondelis has been licensed for the rest of the world to Johnson and Johnson, who has been able to register the drug in most countries with the same dossier used for Europe. This demonstrates that we have yet to reap all the benefits that Yondelis has to offer. Moreover, we have other marine

drugs in development; we have a drug for non-solid tumors that is now in Phase III, and we have a second generation of Yondelis that has been presenting very good results. We might not necessarily be developing blockbusters here, but there are certainly marine compounds in development that have significant potential.

What would be the full revenue potential of Yondelis after approval in the US and Japan?

If you look at other drugs where there has been an important delay between the approval in the US and in Europe, there tends to be a revamp in sales in Europe after American approval is received. This leads one to believe that most of oncology handbooks and publications originate in the US from FDA-approved drugs. Oncology congresses like that of the American Society of Clinical Oncology always have doctors from countries like Colombia, India or Turkey looking for books, none of which have Yondelis because it has not yet been approved by the FDA. Therefore we expect an FDA approval to not only generate American sales but to boost European sales. As Europe represents 25 percent of the world oncology market, our current European sales of €100 million could increase up to €400 million worldwide after an FDA approval.

What is your internationalization strategy?

PharmaMar has kept Europe as a territory for its sales. We have indeed created a sales force throughout Europe that is currently only selling Yondelis, but we are looking for other anticancer drugs that I believe our sales force could market very well. PharmaMar represents a great opportunity for American biotech businesses or Japanese pharma companies that do not have a European affiliate in terms of licensing. If a drug has sales between €50 and 100 million, we are probably a better option for smaller companies looking to license a drug; big pharma would not spend that much effort as there would be “peanuts” for them. We are actively looking for such licensing opportunities and we also expect to register Aplidin and PM1183 in the next few years. Essentially, PharmaMar will become an oncology company, with first-in class drugs that work through a different mechanism of action than other drugs in the market. We think that is a very important contribution to the therapeutic arsenal, not only because we are killing cancer cells differently from other drugs in the market, but also because more and more cancers are treated with a combination of drugs to better kill the tumor. In order to combine your drug with other drugs, it has to be a drug that works by a different mechanism of action.

Does the novelty of your drugs allow you to compete as a mid-sized company with big players?

Competition today has become very strong because of the frequency of mergers and acquisitions. The companies that remain are very big and strong, and sometimes they can allocate more money to achieve the goals, while we are quite small. But we do things differently; we are looking at marine anticancer drugs, and they are not. We then select those molecules that kill the cancer cell using a different mode of action. In that sense, we have competition because we are also competing in treating cancer patients. But our drugs are different. So in that sense, we minimize the problem of competing with big players.

Earlier this month, four of your products were mentioned at the AGM of the American Association for Cancer Research. Is this the breakthrough that you have been looking for?

The potential of marine compounds for treating cancer patients has been confirmed. Not only because of Yondelis, but in 2011 Eisai obtained approval for a marine-derived compound for treating breast cancer. But Eisai's strategy is different from PharmaMar's, as it was licensed from a Japanese professor at Harvard who had developed the drug in a laboratory and then established an agreement with Eisai. But it does prove that there are many interesting compounds in the oceans for treating cancer. I think the next possible marine-derived successes could be Aplidin and PM1183, but of course everything in the pharma business needs many years to reach the market. That being said, we are proving that our strategy is right and I believe that the best is still to come. Looking at our past, proof-of-concept for marine drugs was only a hypothesis. We did not have experience or capital for many years, and now that we have more of both we can finally make a profit. PharmaMar has demonstrated that oceans can provide very interesting drugs that kill cancer differently, which is very good for our therapeutic arsenal.

Several types of cancer that were incurable are now being cured very well. For example, in many civilized countries almost 80-85 percent of breast cancer patients can now be cured. Contrastingly, there are still many other cancers, such as pancreatic cancer, that we have yet to find a solution. We need to find weapons that use a novel mechanism of action previously unthought-of. PharmaMar is very open to unique opportunities to kill cancer cells that can be used alone in monotherapy or in combination with other drugs or different sequences of treatment, such as surgery, radiotherapy, immunotherapy, chemotherapy.

Do you think that the success of your company can change the paradigm for oncology research in the future?

PharmaMar is not the only company that has had success with cancer research, and there are of course many angles to this area of research; we simply represent one corresponding part of that

paradigm. Comparing cancer treatments from 50 years ago to today, perhaps we are not as developed as one would like, but at least life expectancy is higher today. That is due to every single actor that has made an advance in detection, surgery, chemotherapy, radiotherapy, or immunotherapy. Combined altogether, these advances have helped improve oncology research; the breakthroughs that the scientific community has made cannot be attributed to a single person or strategy.

[SG1]Nowadays we have invested €550 million. On the other hand, the day we obtained the EMA approval for Yondelis we had invested €350 million. Take the figure you want but explaining the circumstances

To read more articles and interviews on Spain, and to download the latest free report on the country, click here.

See more interviews