Interview: Orlando Oliveira â?? SVP and General Manager International, TESARO, Switzerland

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Well-funded and with a stellar pipeline, TESARO is an up and coming Boston-based oncology biotech ready to launch their two first products in the European market in 2017.

Orlando, we understand your background in the biotech industry is with Amgen. After a career with the biggest of the biotechs, what was it that convinced you to join TESARO?

My first position after leaving Amgen was with another Boston-based biotech called Cubist Pharmaceuticals, and I was part of a great project which was to build an international infrastructure for the business here in Europe. Cubist was acquired by MSD in 2015, so it was a short but successful ride. After this experience, I really felt how empowering it was to work for a smaller biotech, where you can really see the impact that you have on the organization each day.

Thus, I was very interested in finding another exciting startup company to work with and when I came across TESARO, I was extremely excited by the companyâ??s pipeline and vision. Moreover, when I met Lonnie Moulder, TESAROâ??s CEO, Mary Lynne Hedley (President and COO) and the rest of the leadership team it was clear that this is really a great company in terms of culture and mindset, with a fantastic pipeline and the ambition to become a major global oncology player by offering innovative cancer treatments to patients bravely facing cancer. Because of all this it was with great enthusiasm that I took on the challenge of establishing and building up TESAROâ??s footprint in Europe.

You mentioned TESAROâ??s exciting pipeline and ambitions to become an important company in the oncology space: could you give us an overview of this pipeline and its potential?

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Our two products currently being reviewed by EMA are Varuby *(rolapitant)* and *niraparib*. Varuby is an anti-emetic for the treatment of chemotherapy-induced nausea and vomiting (CINV), and is already approved in the US and was launched in September 2015. At present Varuby is under final stages of review by with the CHMP and we are actually expecting an approval during the first half of 2017. Depending of reimbursement and pricing discussions, we are hoping to begin launching Varuby, Germany, Austria, Switzerland, the UK, Netherlands and Nordics starting in shortly after that.

Our second product *niraparib* is an exciting compound, one of a new class of oncology treatments known as PARP inhibitors. PARP inhibitors like *niraparib* have a lot of potential to treat various types of tumors, however thus far the strongest evidence for their efficacy is as a treatment for ovarian cancer. The results from our phase III NOVA trial for *niraparib* as a recurrent ovarian cancer maintenance therapy were really impressive, showing benefit across all patient groups. With these results, we have submitted *niraparib* to the EMA for review, and we are hopeful that we may get approval during 2017.

Next up in the pipeline will be additional indications for *niraparib*, as we already have a phase III trial underway investigating efficacy in breast cancer, as well as a phase III trial with *niraparib* as a first line treatment for ovarian cancer. We also have licensed the worldwide rights for *niraparibâ??s* use in prostate cancer to Janssen, who have already begun their trials for this indication. Beyond that, we also have a study underway for the use of *niraparib* in combination therapy with MSDâ??s Keytruda *(pembrolizumab)* and Rocheâ??s Avastin *(bevacizumab)*: these studies are looking at the efficacy of combinations of established products with a PARP inhibitor. Next we might look at *niraparib* trials for lung cancer for instance.

Looking a bit further down the road we have an exciting pipeline of our own immuno-oncology candidates. We have two compounds currently in phase I trials, an anti-TIM-3 mAb (TSR-022) and an anti-PD-1 mAb (TSR-042). Then we have an anti-LAG-3 mAb which we will soon be submitting to the FDA as an IND, with a few other pre-clinical assets also in development.

For Varuby (*rolapitant*), we are aware that there are several treatments already on the market for chemotherapy induced nausea and vomiting (CINV). In this case, what is the unmet medical need that Varuby will address?

There are actually two types of CINV, acute CINV occurring within 24 hours of chemotherapy, and delayed CINV which occurs from 24 to 120 hours after chemotherapy. Since patients come home after chemotherapy, doctors do not see them during the delayed phase and many patients suffer these symptoms at home in silence; often patients just assume that it is a part of chemotherapy that they have to deal with, and donâ??t realize that these symptoms can be treated.

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As such, there is still a big unmet need for treatment in the area of delayed CINV, and here we believe Varuby can have a big impact on patientâ??s quality of life. This product is an NK-1 inhibitor, and there are a few other compounds of that class already on the market that are effective treatments against CINV. However, for delayed CINV Varuby does have some particular advantages versus these other compounds, the biggest being that it is long acting and has the longest half-life of

any of the compounds in this class at 180 hours potentially addressing the late part of delayed CINV in an efficacious way.

Your task at present is to build up an international infrastructure to commercialize these products here in Europe. Why did TESARO decide to take this route rather than license out these products to partners?

We considered the option of licensing out our products to partners for international markets, but it was decided that we would bring our products to market ourselves. Few startup companies take the approach of going to market directly due to the risk, but TESARO was confident however that we could do it for the US and Europe initially. For the rest of the markets we will have to look at each opportunity individually. We have already found two partners in China, but we still have yet to determine the right entry model for key markets like Canada, Australia and Japan.

As for why we decided to take this route, we thought that with two products to start, TESARO, being fully dedicated and focused in oncology has a really massive incentive to ensure these drugs are launched well and successfully. Anytime you license a product out to a big pharma player, your product will become just one of many products they have in a given portfolio (with many times conflicting priorities), and there is a possibility that they would not receive the same degree of attention as they will within a fully dedicated organization. This was the biggest incentive for us to commercialize Varuby and *niraparib* ourselves, however there are certainly other advantages to being small like speed and flexibility.

What is the role of this office in Zug within TESAROâ??s organization?

Zug is the headquarters for TESAROâ??s international business, meaning everything outside the US, and to begin we are focusing strongly on Western Europe. At this office we are centralizing some of the support functions (HR, Regulatory, Finance, etc.) to support our new European affiliates, which will primarily be lean customer facing organizations composed of key account managers, medical scientific liaisons, a medical director and general manager. So far we have established entities in Rome, Munich, London, Paris and Madrid, and we are on track to reach about 120 people by the end of 2017, with one third at the office here in Zug and two thirds in the field. The focus will be initially on the DACH countries, Nordics, UK and France early on due to market access considerations, and then starting towards the end of 2017 and in 2018 we will launch Southern Europe.

Why was Switzerland as a country, and Zug as a pharma and biotech hub, selected as the site for TESAROâ??s international headquarters versus other hubs across Europe?

There are certainly a lot of strong biotech hubs across Europe, and at the beginning we considered locations in the UK, the Netherlands and Switzerland as the three broad options. We concluded that Switzerland offered the best package to us overall given its central location, fantastic infrastructure, business friendly environment, easy collaboration with the local authorities, and the massive pool of talent for the pharma and biotech sector that is frankly just incredible and diverse in Switzerland.

When we looked to select a site within Switzerland, we looked at the Zurich area, Basel, and Zug predominantly. With companies like Novartis, Johnson & Johnson, Roche, Amgen, Shire, and Biogen with significant presence in Zug the pool of talent is just very attractive. Zug has great connectivity to ZÃ¼rich airport, itâ??s incredibly easy to get Swiss and foreign talent to locate here due to the quality of life, and Zug is also becoming more and more of a hub for small- and mid-sized biotech companies which gives it a very specific feel. In my view it is becoming a something of a Boston or San Francisco of Europe.

And to wrap up, where would you like to see TESARO in five years?

I would like to see TESARO become a well-known and respected global oncology player, and honestly I think that with our pipeline and the preparation weâ??ve done weâ??re well on the way already. Certainly in five years Iâ??d like to see Varuby and *niraparib* well positioned and successful in markets across Europe, perhaps with an additional indication or two for *niraparib.* We very much decided to make this effort ourselves, and looking around our organization its clear this decision was made for the right reasons because everyone is incredibly committed to making this company succeed and also making TESARO a very special place to work. All I have to do myself is try to ensure we maintain the right culture, work to attract the best talent, and keep the organization on course to provide patients across Europe access to our innovative drugs.

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