

Interview: Ahu Yazici - General Manager, BMS, Turkey



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BMS Turkey's new general manager discusses Opdivo (nivolumab) their revolutionary new product for squamous non-small cell lung cancer, their registry of 1200 patients in Turkey with melanoma, potential developments in pharmaceutical pricing through alternative reimbursement models, and BMS' role in helping to shape health policy around oncology given their revolutionary immuno-oncology products.

BMS has product lines in immunology, oncology and virology therapeutic areas. How does BMS Turkey reflect BMS's global portfolio?

We have BMS's main specialty product lines, in virology, immunology and hematology-oncology. The most promising area for BMS globally is our line of immuno-oncology products, which is projected to grow from 13 percent of our global revenues today to 40 percent in the next ten years. In Turkey, we started our oncology business with Taxol many years ago, followed in 2007 with Sprycel in hematology-oncology, and most recently we received marketing approval for Yervoy in June 2014, which is being reviewed for reimbursement presently. Our goal is to launch the entire immuno-oncology portfolio in Turkey with full reimbursement.

Could you please give our readers a current update regarding the pricing system in Turkey and any prospects of change?

Our reimbursement system imposes mandatory discounts, which start at 11 percent in the first year for original drugs which bring innovation to the treatment, and progress up to 41 percent, upon a reference price which is the lowest price in reference countries, converted into Turkish Lira at an outdated fixed exchange rate of 2.0 while the market rate is over 3.0 at the moment. The resulting prices are the lowest in Europe, and in addition the registration process takes much longer than in Europe, up to four to five years to get marketing authorization and full reimbursement approval. The biggest buyer is the Social Security Institution who reimbursed 80% of prescription cost of active workers and 90% of pensioners. The national insurance covers almost 99 percent of the population.

However, a special/early access program exists for drugs that serve an unmet medical need; the Turkish pharmacists association is authorized to import such products from another country if there is no direct alternative available on the Turkish market. We are also seeing the possibility of change for the pricing for certain product types, as the Social Insurance Institution (SGK) is now discussing alternative reimbursement models with the industry and other government stakeholders, and they are also seeking to make agreements with the companies to make products available before the full reimbursement process. In fact, starting in mid-July, public hospitals except university hospitals will introduce a tender process for oncology products administered intravenously.

What is the IP timeline like in Turkey?

Data exclusivity is valid for six years after launch, yet the complete regulatory and reimbursement process takes at least four years, leaving two years for a product to be sold with exclusivity. For some of our products like Sprycel (Dasatinib) we have patent protection, while with others such as Baraclude (entecavir) for Hepatitis B, there are generics on the market due to the expiration of data exclusivity.

Yet, Turkey is an interesting market. In markets like the US, once you lose patent protection, sales disappear overnight. In Turkey, generics are priced at 60 percent of the reference price and you can successfully compete against generic competitors, or even achieve some meaningful sales growth, after a product loses exclusivity.

Former Minister of Health Professor Akdağ says that it is now time to negotiate a new “win-win” situation; what are your minimum conditions for a win?

The exchange rate will be updated regularly, because the cost of the products we import is steadily increasing in Turkish Lira terms as the currency loses value, yet the price we receive is nominally

fixed. This situation is discouraging investment and interfering or delaying the launch of innovative products. Turkey is the sixth largest market in Europe, has an aging population of 77 million with rising prevalence of chronic diseases; the healthcare system must be innovative and use innovative treatments now to help maintain patients' health. This will mean incremental increases in costs now, but will help prevent drastic and unsustainable increases in costs later.

As it is, the system has spread itself very thin by trying to invest in all areas of healthcare, and therefore is not able to invest meaningfully in any area. Current copayment levels are not a realistic, as there are lower priority healthcare expenses that the government shouldn't necessarily pay for, and the payer should have more freedom to increase investment in critical areas. Ideally, all healthcare costs must be controlled and balanced, including hospital costs, treatment costs, and other categories, with drug costs as only one component. For example, Turkey is one of the few country in the world not implementing OTC.

What are some adaptations that BMS Turkey has made relative to other countries to succeed in this environment?

Our team works together as a cross-functional metrics group, and when we start planning a product launch, we bring together our medical, regulatory and market access groups. We must work with different stakeholders including the payer, regulatory, and medical community, and must convince them all of our products' value, both in medical and economic terms. But we are adapting to constant change in this environment, there is cost containment, a global budget, and we are adapting our work style based on the requirements and regulations.

Also, while BMS has been in Turkey for 20 years and used to be a large pharmaceutical player with our entire portfolio, including our legacy antibiotic products, two years ago we made the decision to divest our mature products portfolio. Now we only focus on our specialty products in this market, focusing on areas of unmet medical needs to more efficiently deploy our resources.

What do you foresee as the biggest sources of growth in your portfolio for the coming few years?

What we are seeing with Yervoy, a product which targets metastatic melanoma, are survival rates of up to ten years, where the normal lifespan for an untreated patient with this phase of cancer would be six to nine months. Our new products, which we call immune checkpoint inhibitors, can stop tumor growth and trigger an immune response from the patient that attacks the cancer cells. One example is Opdivo (nivolumab), which is indicated in melanoma, and since March for squamous non-small cell lung cancer in the US. This is a revolution because this is the first new

product in this indication for 15 years, and we are seeing a 41 percent survival rate in the first year. The new generation of treatments that BMS is introducing have relatively few side effects, and can potentially achieve an actual cure.

I am personally very sensitive and passionate to developments in the area of lung cancer because my mother passed away from non-small cell lung cancer nearly three years ago. Due to the side effects, she was unable to undergo chemotherapy, and she battled with the cancer for 16 months, spending the last three mostly in hospital. Lung cancer is a critical health issue for Turkey as a whole because we still have very high rates of smoking, and the government has prioritized fighting the consequences of smoking with strong smoking prevention initiatives. Fighting something like lung cancer takes a comprehensive approach, ranging from prevention and education to early detection programs, diagnosis, and treatment regimes for various stages of cancer. BMS Turkey wants to be involved in this whole regime, and we are engaging the relevant specialty associations and government figures to help shape healthcare policy in these areas, from prevention all the way through to treatment.

Given the benefits and the challenges of the Turkish market and industry, is Turkey an attractive investment environment for BMS at present?

Turkey is definitely worthwhile investing in, and at present we are investing in R&D through clinical trials and named patient programs. Beyond the usual benefits of exposing Turkish physicians to new products, giving some patients access to innovative products, and collecting medical data based on the local population, we are using these studies to collect general patient data for certain medical indications. While there is reasonable patient data for some illnesses, no one has any relevant information or a patient registry for illnesses such as melanoma. So, in conjunction with our clinical trials and named patient programs, we are sponsoring and supporting registry programs, and have built a registry of 1200 patients in Turkey with Melanoma for example.

How strong is BMS's commitment to Turkey's Vision 2023, and what are the steps you are taking to help achieve this vision?

Certainly, we are committed to Turkey, as is made apparent by our numerous clinical trials, name patient programs and our close involvement with key stakeholders in oncology and our other key therapeutic areas. Furthermore, we are a member of both the research based association, and the local manufacturers' association because we are looking for potential partners and are evaluating localization projects. However, convincing our head office to invest in Turkey will of course take time, as will finding and planning the best opportunity for us.

How do you like your new role as general manager?

After a year in the role, I am still very excited and definitely proud of being part of BMS Turkey organization. . After spending two years in a European role I am very happy to be part of the Turkish team again, where I used to work as a business unit director. I enjoy the role because I trust my team here, and given Turkey's variable environment it makes each day exciting, challenging, and new, however this makes my job particularly difficult since I must be conscious of the big picture for the entire affiliate today, and in the future.

As for the future, I would like to have the chance to work in our immuno-oncology business, perhaps as part of a group outside of Turkey working on developing new products. I am personally sensitive to the oncology topic as my mother passed away after a relatively short battle with lung cancer, and I want to be a part of our efforts to help patients and patients' families with treatments that were not available at the time my mother was sick. I know that my individual efforts, when combined to support our mission, make a huge impact on patients' lives.

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