Interview with Marco Caligiuri, Country Manager, Celgene Turkey

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What were the first challenges you have faced as the new General Manager of Celgene turkey?

In all humility, I have to say that even though it is always challenging to work in a new country, new culture, and new position, our company values have really helped me adapt to my new environment. Passion for patients, courage, trust, excellence, those values help me make the right decisions towards all stakeholders, customers, colleagues, authorities, scientific societies, and most importantly patients.

Your actions result from your capacity to integrate all these values. If you stick to the core values you believe in, adapting to a new country and a new culture is suddenly not that difficult. I have the fortune to work for a company where values drive people's actions.

What's exciting for you in Turkey?

.. Concerning the healthcare environment, I see two main dynamics. As in other countries, the industry faces issues related to cost saving, budget constraints, delays in market access, and etc… On the other hand, Turkey has a growing economy and especially is a country where all stakeholders, the state, the academies, the physician community, and the pharma industry, seem to share common goals: better healthcare – i.e. focus on innovative drugs -, and growth…..and these aspects make Turkey an ideal country to be in for Celgene.

How do you assess your own potential as a manager?

The best leaders are those who are humble and have an incredible will and passion. I have always search to improve my managing skills and to share this mindset with the team. I like the idea of being part of challenging experiences. I like to take risks, and to see the results and what I do together with my colleagues…our dream is to ‘make the difference’.

Celgene is today the ideal organization for that.

Celgene is a preeminent company in the haematology space; could you start by describing it’s profile?

Celgene is changing the course of human health through bold pursuits in science and a promise to always put patients first. For example, 7 to 8 years ago, the deadly blood cancer myeloma would take your life approx two years after diagnosis, Today as a result of innovative therapies , including our own, care givers have greatly increased survival rates.

Celgene is a mid-sized global biopharmaceutical company, founded in 1986 and operating in Europe since 2006. It discovers, develops and commercializes innovative therapies for patients with cancer and severe inflammatory diseases with unmet medical needs.

Traditionally, Celgene focused on HAEMATOLOGY, becoming a leader in this space thanks to transformational science and life-enhancing therapies that utilize the body’s immune system (IMiDs) as well as epigenetic agents, which target the disease at its source at the genetic level. Currently, Celgene is expanding its unique science platforms to address unmet medical need in SOLID TUMORS, including Nanotechnology for metastatic breast cancer (MBC) and pancreatic cancer – and INFLAMMATION & IMMUNOLOGY. Pipeline drugs include innovative pluripotent immunomodulators, kinase inhibitors and placenta- derived cellular therapies for diseases like psoriasis, psoriatic arthritis, and more.

How did Celgene become a leader in onco-haematology in such a short period of time?

Celgene believes that in order to make a meaningful difference in patients’ lives and to reduce the burden on healthcare systems you must be willing to take enormous risks and deliver transformational innovation that changes the way medicine is practiced. That said, our INNOVATIVE THERAPIES, which extend survival and reduce disease symptoms of patients with rare and fatal haematological malignancies, are transforming the landscape of:

- Multiple Myeloma (MM) – with thalidomide, lenalidomide
- Myelodysplastic Syndromes (MDS) – with azacitidine
- Breast with nanotechnology based treatment

Moreover, we have a rich pipeline of products in development for MM, MDS, lymphomas’ and other tumours.

What makes this company different?

Mainly four things:

• Our PROMISE to ALWAYS PUT THE PATIENT FIRST
• We ensure, to the best of our ability, that patients who can benefit from our therapies have safe and appropriate access to our innovative treatments.
• A research focus grounded in COMMITMENT to areas of great medical need, enormous risk taking, significant INVESTEMENT well above the industry average and a continuous cycle of INNOVATION enabling us to change the course of critical diseases such as cancer.
• Our innovation is key to improving quality of life, reducing healthcare costs, increasing productivity and driving economic growth.
• We are pioneers in the field of safety ensuring that all patients have safe access to the clinical benefits of our novel therapies.

Let me give you some examples of our commitment to patients, to R&D and to innovation.

Between 2005 and 2010, we reinvested more than 30% of our revenues into R&D; this figure is more than twice as much as the pharmaceutical industry average. In fact, at the moment, we have four R&D centres worldwide (including one in Europe) and 17 pre-clinical programs, as well as 20 compounds in clinical development and more than 30 phase III and pivotal clinical trials, with hundreds more clinical trials ongoing across our portfolio. This means that with our on-going studies, more than 50,000 patients will access our innovative therapies.

It is mainly for these reasons that, last year, Celgene was recognized by Forbes as the most innovative pharmaceutical company worldwide.

As the head of Celgene Turkey's operations, what would you say have been the company's chief milestones since its establishment in the Turkish market?

We have been operating in Turkey since 2008 and immediately initiated a drug access program, according to local regulations, to ensure patient access to lenalidomide.

At the beginning of 2010, we also obtained regulatory approval in Turkey for our lenalidomide risk management plan and, immediately thereafter, market authorization and reimbursement for later lines of treatment for relapse and refractory multiple myeloma (rrMM).

This month we have obtained a label expansion for patients after first relapse.

Last, but not least, we have initiated since 2008 an important clinical program, with both company-driven and investigator-initiated clinical trials, investing in it more than 30% of our revenue 2008 and 2011.

In fact, we have involved in our clinical program hundreds of Turkish patients, not only in haematological malignancies (such as MM, MDS and lymphomas) with lenalidomide and azacitidine – but also in immuno-inflammatory diseases, such as Behcet's syndrome with apremilast, a TNF-alpha inhibitor. This trial can represent an important example of our R&D commitment in Turkey, considering that here we can find the highest prevalence in the world, and more than 80% of patients enrolled in this international trial are Turkish.

How does Celgene Turkey maintain its position in this competitive and unpredictable market, especially concerning the challenging regulatory and pricing & reimbursement environment?

As you've stated, the Turkish market is still characterized by regulatory & reimbursement delays/restrictions and stringent pricing control. On the other hand, it is also characterized by a rising awareness to find a balance between resource optimization and appropriate access to innovative drugs, considering the advancement of medicine and evolving standard of care.

In this context, we have been collaborating with government authorities, scientific societies and the academic research community to create collaborations around a 'sustainable innovation' model. From this perspective, Celgene Turkey maintains an important position thanks to our:

• Innovative treatments
• R&D investments
• Efforts to implement strict pharmacovigilance programs for patient safety and appropriate prescribing

What will be the main strategies implemented this year?

Our strategy for 2012 is simple:

• Extend patient access to lenalidomide obtaining reimbursement in MM also for 2nd line and label approval for MDS del5q
• Optimize safe access to lenalidomide in the rrMM setting, initiating a Turkish Post Authorization Safety Study (PASS) and supporting world-class medical education programs
• Assess the possibility of additional future regulatory filings and clinical program with multiple products in different diseases (newly diagnosed multiple myeloma (ndMM), lymphomas, etc.)

This means that Celgene Turkey will bring value in terms of growth to the group's regional operations.

Despite growing cost-containment policies, innovative drugs will continue to gain importance in the Turkish pharmaceutical market due to the increasing needs of better healthcare and outcomes, which are also related to the positive results from the Health Transformation program. Celgene's

innovative drugs make it one of the most innovative companies in Turkey, and I think that we will reinforce this position in the near future due to our commitment to R&D.

What are the company's current and future strategic partnerships, licensing and distribution agreements?

In March 2008, Celgene acquired Pharmion, inheriting in Turkey a distribution agreement with a local distribution partner for azacitidine and thalidomide. For this reason, we have been collaborating with them to ensure strategic alignment and safe patient access to our drugs (eg. medical education and a risk management plan for thalidomide). However, we plan to re-integrate both drugs into the Celgene Turkey commercial portfolio by the start of 2014.

What is the main reason to believe in Turkey's pharmaceutical industry?

The Turkish pharmaceutical sector represents an increasingly important growth opportunity for pharmaceutical companies in the coming years, especially for innovative drugs, considering that it has an important market value (ranks 16th globally and 7th in Europe), but is still considered an emerging market (per capita pharmaceutical expenditure is significantly lower than average).

Government, academia and pharmaceutical industry are aligned on the following goals:

• Improving healthcare standards, especially by increasing patient access to innovative drugs
• Ensuring economic growth

To reach these goals, they are going to work together to turn the Turkish pharmaceutical sector into a leading R&D and production site and a regional management hub. This could accelerate market access to innovative drugs and improve the pricing & reimbursement environment.

What is your view on the importance of Turkish operations for Celgene globally?

Celgene Turkey will become increasingly important for our company. In fact, within the next 10 years, the Turkish pharmaceutical market will likely become one of the more interesting growth opportunities for an innovation-driven company like Celgene, considering that growth will be driven mainly by innovative drugs and an increasing focus on R&D.

What is your personal vision for the Turkish pharmaceutical industry in the next five years?

The next five years will be critical for the Turkish pharmaceutical industry's competitiveness and for its goal of becoming a leading player in R&D. The key success factor will be the capability of government, academia and pharmaceutical industry to realize the cooperation necessary to take advantage of the current potential 'growth platform' (know-how, infrastructure and geostrategic positioning) and to create an appropriate investment environment.

What objectives have you set for Celgene Turkey?

Our first goal is to achieve also in Turkey a leading position in hematology, i.e. to recover azacitidine and thalidomide in our commercial portfolio, and to work to have new indications with multiple products.

In MM we could consolidate our leading position by extending lenalidomide indications into the ndMM setting and launching pomalidomide in rrMM. Similarly for MDS, we could have new indications for lenalidomide in del5q patients and may extend azacitidine indications to include Acute Myeloid Leukemia (AML) patients with >30% blasts. Lastly, we could enter the lymphoma market with lenalidomide in Mantle Cell Lymphoma (MCL) and Chronic Linfocitic Leukemia (CLL) and romidepsin in Peripheral T-cell Lymphoma (PTCL).

Our second goal is to expand our therapeutic focus to other areas, for example inflammation and immunology, where we may launch apremilast in severe diseases such as psoriasis and Behcet's syndrome.

Lastly, we aim to reinforce our partnership with Turkish academic researchers, for both medical education and clinical programs, to generate data on existing and upcoming therapies, as well as optimise treatment practices.

Do you have a final message to the readers of Pharmaceutical Executive?

I am proud to work for Celgene Turkey in an environment where, together with academic researchers, governmental authorities and other companies, it is possible to bring value to Turkey through research, innovation and growth, with the ultimate goal of helping Turkish patients live longer and better lives.

I am sure that Celgene Turkey can play an important role in this ambitious project, not only because we are firmly rooted in science and innovation, but also thanks to our employees and our values:

• We always put patients first.
• We don't see a 'business perspective' unless there is a 'patient perspective'.
• We have the courage to face global challenges concerning healthcare, to ensure the best for patients.
• We trust each other and our stakeholders to create an alliance for our patients.
• We always strive for excellence at all levels, from both a scientific and an ethical perspective.

After all, this is what it means to be a part of Celgene.

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