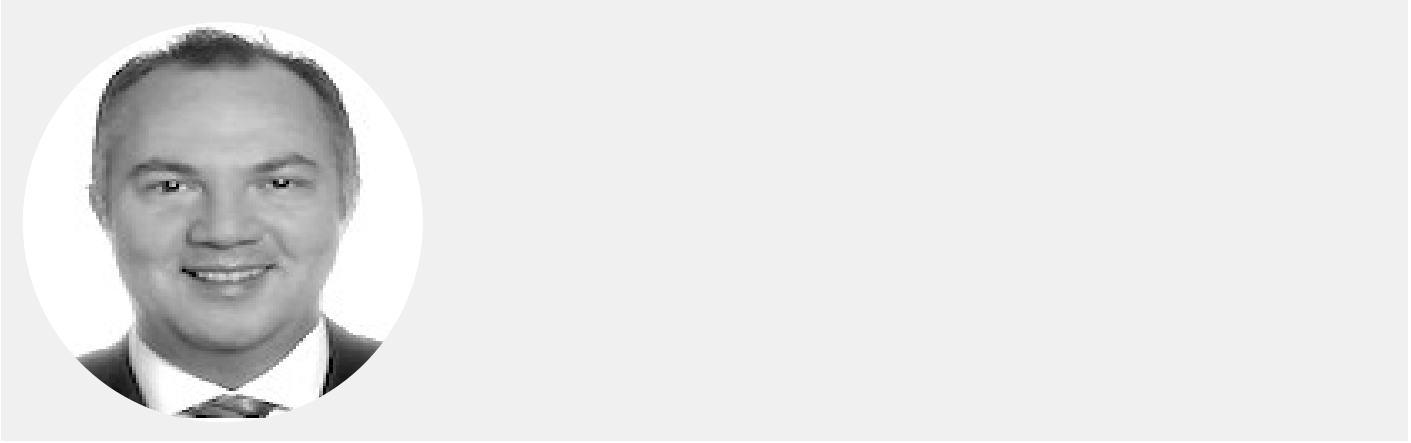
Interview: Murat Uslu – General Manager, Actelion Turkey



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Turkey has been a high priority market for Actelion since the company's relatively recent beginnings, and the general manager of the local affiliate discusses his affiliate efforts to improve awareness around this rare disease through open communication with health authorities, and the need for formal recognition of orphan drugs by regulators.

What role has Actelion Turkey and the Turkish market come to play for Actelion globally?

Turkey has always been a priority for Actelion . Actelion's lead product, Tracleer, was approved by the FDA in late 2001 and the EMA in mid 2002; the Turkish affiliate was started two years later, in May 2004. To my knowledge, this was, and still is, the fastest decision ever made by an international company to enter the Turkish market. The reasons behind treating Turkey as such a high priority market are very clear; the country had a population of over 70 million people at the time, was an emerging economy with a pharmerging market, and the healthcare system was in the early phase of a transformation that was supposed to increase access to healthcare and provide universal coverage. This represented a fantastic growth opportunity, not only for the company's sales but also in terms of making an impact.

Actelion believes that the first priority is the patients, and that the first investment should be for the patients. We live this value as a company, and we have had a strong impact on patients'

quality of life, and lifespan, since we entered the Turkish market eleven years ago with Tracleer. We have prolonged lives that would have perished otherwise, and this is the only gain or reward that we work to achieve, because we know there are patients who had a life expectancy of two to three years who are still alive now, after ten years.

Actelion has a very well managed portfolio of treatments for Pulmonary Arterial Hypertension (PAH), which started with our groundbreaking oral therapy Tracleer (bosentan). Over the last 10 years we have introduced other products that are effective at various stages of the disease progression and give physicians a spectrum of PAH specific drugs so that they can achieve the best outcomes for patients, which include Veletri (epoprostenol) and soon Opsumit (macitentan), which is currently in the registration process.

Is the Turkish medical community excited by Actelion's pipeline?

Yes, most certainly. I love to go into the field, and so far this year I have done eight full day double visits. Every time we discuss our upcoming products with physicians there is a twinkle of hope in their eye. PAH is a very difficult condition for patients and physicians alike, because despite all of our treatment options and the amazing progress that Actelion has brought, the disease is still not curable, yet. Each time we bring a new product to market, the physician is better able to combat this disease and is able to give their patients more time, more hope.

To what extent are healthcare authorities and medical professionals aware of PAH, and how is Actelion engaging stakeholders to promote positive change?

When Actelion entered the Turkish market, there was no structure for PAH diagnosis and treatment and very limited awareness of the condition, close to none in actuality. Since we effectively had a blank slate to build upon, we evaluated various other systems that had been developed for other diseases, and came to the conclusion that developing a network of PAH diagnosis centers would be very difficult as it would take five or six such centers at a minimum to adequately cover Turkey's population. Furthermore, doing so would have taken a lot of investment and progressed slowly, with only incremental achievements in terms of diagnosis capabilities.

Instead, we have devoted our time and efforts to awareness initiatives and constant and open communication with government stakeholders. From day one we have been very open with the authorities, showing them the effects of the disease and its impacts, discussing our objectives and objectives for patients, and explaining how these patients and their physicians can benefit from our products. We also worked closely with SGK, and the previous reimbursement structures prior to their unification. As an outcome of this, SGK has been the first authority to formulate combination

therapy in reimbursement system globally. After ten years; there is now huge awareness of PAH amongst specialists and the regulatory and reimbursement institutions, and these specialists, be they cardiologists, pulmonologists, or rheumatologists, are dedicating significant amount of time to PAH during their practice routine. Patients are benefiting greatly from the increased attention that they are giving this disease in general, and every year we are doing our best to show more patients and physicians that while the disease isn't yet curable, it can be managed and lives can be prolonged significantly as it has been demonstrated with our newest product Opsumit was shown to reduce the mortality rate for PAH patients by up to 50 percent.

Of course, there are still areas to improve. The Turkish healthcare system has a lot of excellent facilities, while some others have quite a way to go in term of equipment and work-load, and this of course affects physicians' ability to efficiently diagnose patients. The number of physicians, and the number of specialists, per capita is very low in Turkey, making it difficult for physicians to dedicate sufficient time to each patient. It is not clear that international pharmaco-economic standards are met in the daily routine of the pharmaceutical industry at large, and within the healthcare system itself, so there is also ground to be covered there.

For Actelion, is Turkey an attractive investment environment?

We have made substantial efforts to bring R&D investments to Turkey in the form of clinical studies, and at present we have Turkish sites participating in three ongoing global clinical studies and 2 large-scale local registries. Our previous trials have been extremely successful in terms of quality and productivity, the experience and professionalism of the investigators, and the quality of the data they collected, so Turkey is now known within Actelion as a high potential research site, and we work hard to be considered for all clinical trials going forward.

On behalf of Actelion and PAH patients, what are your priorities for the coming three to five years?

Actelion is the leading company in PAH, and our top priority is securing that position and further developing our leadership by introducing our new and innovative products to the Turkish market. In the longer run, Actelion is developing into areas outside of PAH such as immunology and oncology, and developing a business in this area with the same degree of specialization, focus, and expertise as we have in PAH will be another top challenge.

From an orphan drugs point of view, we have invested a lot of time and effort while working in the rare diseases space since this affiliate was started. There has been some significant progress in terms of how orphan drugs are treated by the Turkish regulatory and reimbursement authorities,

while we have not been able to transform these gains into legislation, regulations, or even guidelines at the national level. The Turkish healthcare system needs definitions and designations for orphan diseases and orphan drugs, protocols for patient treatment and orphan drug regulation and reimbursement, etc. It is our hope that within three to five years Turkey will introduce regulations in line with EU standards, so that at that point Turkey can become a key player in the orphan disease area.

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