Interview: Olivier Pilley â?? General Manager, ARIAD Pharmaceuticals France

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Olivier Pilley, French GM of the Swiss-American biotech company with a pioneering computational approach to anti-cancer therapies, presents ARIADâ??s fascinating R&D model, his optimistic assessment of the competitiveness of the French clinical research environment as well as his personal motivations for working in a rapidly growing biotech company.

ARIADâ??s niche is the use of computational and structural approaches to design small-molecule drugs to overcome resistance to existing cancer medicines, which is touted as a â??more efficient, less costly and lower-risk approachâ?•. Can you tell us more about this unique approach to anti-cancer therapies?

At ARIAD, we pursue a best-in-class, not first-in-class approach that is academically very rigorous, with a unique computational approach to drug discovery and scholarship. This proprietary model is at the heart of what we do. Using an iterative approach, we examine the pathology to figure out why a drug is ineffective, why a relapse occurs or why a cancer becomes drug-resistant. A virtual drug is created using computer software to address the issue and tested through thousands of simulations. Once we have found an effective therapy, we produce it in the laboratory and we test it on cell lines. This is an extremely efficient process of designing drugs, because the trial-and-error process is done virtually.

Speed is of paramount importance in R&D, particularly in the area of oncology, where there is now so much development and competition that even the slightest delay could result in a significant lag behind our peers, who are developing similar compounds and therapies.

Our model allows us to explore and design compounds for successful clinical trials as efficiently and quickly as possible.

How do you assess the success of ARIADâ??s business model thus far?

The science behind our business model is very academically rigorous. We are also very proud that we have already begun to see concrete successes. No other company has been able to produce as many drugs that have successfully entered clinical trials and achieved market approval in as short a period of time as we have. First and foremost, the fact that three original compounds â?? IclusigÂ® (ponatinib), Brigatinib and AP32788 â?? have already been discovered through our in-house R&D is testament to the strength of our model. We have also had major partnerships with pharmaceutical companies. Most recently, we signed a licensing deal with Otsuka. It is remarkable that we were able to command milestone payments from a Big Pharma company, which is indicative of Otsukaâ??s interest in and commitment to IclusigÂ®. It is a vote of confidence in us.

In addition to this unique business model, what are ARIADâ??s other strengths?

There are three main features of ARIAD I would like to highlight. Firstly, as our model demonstrates, we are very focused on academic rigor and the quality of our scientific research. Haematology is intrinsically one of the most academic areas in medicine and pharmaceuticals, and we are expressly dedicated to the pursuit of quality academic results. This guarantees the effectiveness of our therapies. Secondly, our main concern is to improve the quality of medical care for patients, and this is reflected in our slogan: â??no patient left behindâ?•. For instance, in the US, we have a program called â??ARIAD Passâ?•, which allows US patients without insurance to access IclusigÂ®. There is even a special team dedicated to helping patients find insurance. Finally, we have a very unique infrastructure, being jointly headquartered in Cambridge, Massachusetts in the US and Lausanne, in Switzerland. This departs from the usual paths taken by biotech companies, who usually launch their products through Big Pharma or are acquired by Big Pharma. With this dual approach, we are well-positioned to penetrate both American and European markets. For American companies, it can be difficult to access European markets because of its diversity, and they usually have to license with European suppliers. For ARIAD, its affiliates can be very streamlined. In France, for instance, we benefit from EU-mutualized functions such as HR and Finance.

What is ARIADâ??s current development strategy and what key goals would you like to achieve in the next few years?

Very concretely, ARIAD will have expanded into the field of solid tumors as our second drug , brigatinib, just finished enrollment for its pivotal trial and will aim for market approval in 2017. We would ideally also have two to four new drugs in clinical studies, developed from our in-house R&D. In addition to this, as part of our plans to develop into a fully-fledged biopharmaceutical company, we would also like to have a few licensing agreements with other companies for drugs in our specialty areas. We conduct visits to haemotology and oncology centers every day so we have a power of distribution in this field. Ultimately, we are striving to become a self-developed biopharma success story along the likes of Amgen or Celgene.

What has been the main project for ARIAD France?

First and foremost, it has been to guarantee access to our innovative drug, for patients suffering from this terrible disease that is leukemia, and in the near future, patients suffering from other cancers. We want to live up to our mission: â??No patient left behindâ?•. Thus, we collaborate with physicians, pharmacists and patient associations so that all stakeholders of patient care and management can work in sync to provide the best treatment to each patient.

When I joined ARIAD France, my mission was to hire a team of key personnel to establish ARIAD France as a labeled pharmaceutical company (â??Laboratoire exploitantâ?•, as certified by ANSM).

Subsequently, it was to manage the transition of IclusigÂ® from ATU to post-ATU and proper market access. Typically, a drug obtains approval from the European Medicines Agency (EMA) approval,

and then it has three months to end the ATU process. During this post-ATU stage, there are multiple stages of regulatory assessment and discussions, for instance, with the Haute AutoritÃ© SantÃ© (HAS â?? French National Authority for Health), which is needed to obtain a drug rating, a prerequisite for reimbursement and pricing negotiations.

In addition to this, all general managers from European affiliates coordinate their approach with a best-practice sharing approach, constantly exchanging ideas and optimizing distribution.

What is the positioning of ARIAD France in terms of global operations?

France is a very important market for ARIAD. As an affiliate, we are very light and efficient, and we represent a significant percent of global operations.

Furthermore, in terms of clinical research, France is one of the top performers in Europe. In terms of patient recruitment, for instance, we are the top recruiter in Europe and we have consistently met or exceed recruitment targets. There is also an extremely high quality of clinical research, most notably oncology and haematology, and this is complemented by the excellence of French public institutions and hospitals. There is a lot of incentives for public centers to participate in clinical research. The pivotal studies for IclusigÂ® were conducted with a strong participation from France, and we have a few more studies planned for France.

The success of ARIAD France is evident in the strength of the HQ-affiliate relationship. An example of this is that I persuaded them to involve us in the selection of their worldwide CRO partners, and our Medical Director has been conducting interviews with the CRO candidates in France, because the quality of our partners is crucial to the success of our operations.

The tough regulatory environment is one of the most common complaints about the French healthcare industry. How significant a challenge has this been for ARIAD France?

France has many strong points. Its ATU system (pre-approval named patient access) is very structured and well-managed and this, particularly the quality of the system, is very unique in Europe. As long as a company has proof of efficacy and upcoming EMA approval, their therapies can be provided very easily to hospitalized patients through the ATU system. The company will also be reimbursed efficiently, which is a very critical aspect of a successful ATU program.

When it comes to reimbursement and pricing decisions, precedence is important. If we are slow to produce a drug, which may be as good as or even better as an existing one, the authorities may assign our drug a lower price, simply because it has come later or may not meet the required level of improvement on the existing one. This is a complex issue but at the moment, the regulations surrounding it are not sufficiently flexible or nuanced. Specifically, the Commission de Transparence assessment may be too subjective and/or not expert enough, and the ratings obtained hold too much weight in the subsequent price negotiation.

What have been challenging are the issues surrounding pricing; market access per se is not very difficult, though it is lengthy. But as a small company, we struggle most with the pricing decisions taken by the French authorities. From our perspective, it is difficult to understand how France can price drugs at a level 30 to 40 percent lower than other similar European markets, like Germany or Italy.

Another problematic element has to do with the regulatory environment surrounding clinical research. The recent *contrat unique* (Standard Unique Contract) is a welcome improvement that should expedite the clinical research process, but more can â?? and should â?? be done.

What motivates you every day?

ARIAD has a grand strategy for its long-term development, and I believe in it fully â?? it has the capacity to execute its profitability plan and continue its output of innovative cancer patient therapies.

I have worked in haematology since 2006 and oncology since 2004, and I absolutely enjoy ARIADâ??s entrepreneurial environment. There is not the weight of a big company with endless internal meetings and a lack of actual focus on health care professionals. At ARIAD, most of our work is focused on R&D, physicians, pharmacists, nurses and ultimately patient care, and I find this the most fulfilling aspect of my work. Finally, I am very impressed by ARIADâ??s patient-centric approach, particularly in an industry that has often been â?? and rightly so â?? criticized for insufficient focus on the patient.

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