Antonio Francesco Di Naro – President & Founder, ADIENNE

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Swiss-headquartered ADIENNE has made recent headlines after being announced as the first European company to manufacture Russia's Sputnik V COVID-19 vaccine. President and Founder Antonio Francesco Di Naro explains how the company's deal with the Russian Direct Investment Fund happened and some of the challenges related to the manufacturing process. In addition, he highlights the company's technological expertise and dozens of patents around the world.

We understand that you have a scientific background and many years of experience in the industry. Can you begin by talking about the founding of the company and its current capabilities?

I have spent most of my career dedicated to orphan drugs; the area in which ADIENNE has focused since its founding in 2004. On a personal level, I began my career as a researcher at the Pharmacology Laboratory of Research Institute Mario Negri in Milan before joining Pasteur Mérieux at the age of 27. In 1998 I joined SangStat, where I held various positions, and in 2003 I was appointed VP Europe and International of Genzyme. The final stage in this journey came when I decided to start my own company, ADIENNE.

Today, I am the sole owner of the company, which has been profitable since its inception over 16 years ago. We have registered products with the EMA, US FDA, and many other regulatory

agencies in the world. Our manufacturing is dedicated to the production, purification and aseptic filling of biological products, especially monoclonal antibodies, including for the Sputnik V vaccine.

Our 20,000 square metre manufacturing facility is divided into two parts, one for biological products like monoclonal antibodies and vaccines and the other for highly-potent chemical drugs. ADIENNE has also patented a method to lyophilize cytotoxic products in multichamber flexible bag rather than glass vial, which is quite an innovative advancement. The multichamber flexible bag allows to avoid compliance problems related to the reconstitution of the cytotoxic products. Very few companies in Europe can boast such a footprint.

Today, ADIENNE's focus is on biological and onco-haematology products and we have over 90 patents registered across the world. The company conducts a large amount of research, starting from cells all the way to finished products and has all the integrated services in-house, including R&D, manufacturing, regulatory, and commercialization, and our products are sold in over 40 markets via distributors.

What do you mean by innovative advancement and what is the problem you are solving with that patented technology?

Onco-haematologists today are obliged to use cytotoxic products to treat patients. These products are manufactured and filled in glass vials that carry a risk to nurses and healthcare delivery professionals. We patented a way to lyophilize those products in a multichamber flexible bag that is ready to use. This is a ready to use system solving all compliance problems from the point of view of patient and healthcare professional safety.

With our product, it is no longer necessary for the healthcare professional to use syringes and needles, with the associated risks, as it is sufficient to activate the bag with simple movements and reconstitute the drug ready for infusion. With these innovative systems, leakage of toxic liquid is absolutely excluded as is microbial contamination. We invested over EUR 40 million to make this technology a reality and ADIENNE is the first company in the world commercializing the bag. This multichamber flexible bag is used for our products and we offer also a CMO service.

Can you walk us through ADIENNE's R&D process and how you select programs to develop?

To select our R&D programs, we look at unmet medical needs; first examining the science and then turning to the market. It is crucial to decide how much time and resources to invest because there may be an unmet medical need but no patients available. It is untenable to spend ten years enrolling patients for clinical trials.

We have people working in R&D internally, but we also work with universities and research centres in the US, Europe, Asia, and Russia.

In 2020, vaccines, which usually take many years to develop, were brought to market in months in response to the COVID-19 pandemic. As a scientist, were you surprised by the speed? What do you see as some of the challenges ahead?

I was not surprised but was heartened to see companies and organisations joining forces to develop vaccines in record time. However, there needs to be better and more accurate information disseminated to the public about these vaccines and how their benefits far outweigh their associated risks.

The issue is that many companies have the capability to fill and pack millions of doses, but very few can actually manufacture the drug product. We need to invest more because vaccines are not manufactured in one month and you need people with expertise to grow cells, do the chromatography, and other steps.

We should help universities and academic centres to release people with the necessary background to do the job. Today we are talking about COVID-19, but there may be another virus in five or ten years, and we must be prepared.

ADIENNE is now an important part of that COVID-19 vaccine manufacturing process. How did the decision to manufacture the Sputnik V come about?

The Russian Direct Investment Fund (RDIF) contacted us through the Russian-Italian Chamber of Commerce during the selection process of companies in Europe to manufacture Sputnik V. We appeared on their radar because they were looking for a company with a strong research footprint that could start from the cell all the way to the commercial product. Given that few companies in Europe are able to fit this bill as well as the fact that ADIENNE has all services integrated in-house, we were selected as the first European company to manufacture Sputnik V.

There has been some controversy surrounding the Sputnik V development process, particularly on the data behind the clinical trials. Scientifically, do you have any concerns or are you just waiting from the EMA to do its job?

I do not have any concerns. I am very pleased that there is a COVID-19 vaccine with 91.6 percent efficacy. This data was published in *The Lancet*, a peer-reviewed general medical journal. Another plus point for Sputnik V is that it can be stored at a temperature of 2°-8° C.

There are also challenges specific to Sputnik V as it is a two-shot vaccine that uses two adenoviruses called Ad5 and Ad26. This means that manufacturing the vaccine is almost like manufacturing two different vaccines.

How much investment and preparation do you need and how can you ensure that this vaccine push not distract ADIENNE from its other activities?

We do not need that much investment since we have the manufacturing capacity for monoclonal antibodies. We have our own bioreactor and our own upstream and downstream division. We are not involved in the commercial activity so we will focus on what we do best and continue working on our products and technology.

As you are personally responsible for the creation of the company and the technology it has developed, where do you want to take ADIENNE on the wave of the attention it is currently receiving?

I am still young and have many years in front of me! We are an agile, family company with good management and we have been able to build a sustainable business without external investment. 16 consecutive profitable years of business is a remarkable achievement and one we are looking forward to building on moving forward.

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