Zafer ToksÃ¶z â?? Founder & President, Arven Pharmaceuticals

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Arven Pharmaceuticals is the Turkish R&D-based company behind the first biosimilar drug developed and manufactured from cell to final product in the country, and the first patented and produced dry powder inhaler in Turkey. Its founder and president, Zafer ToksÃ¶z, explains the companyâ??s pioneering journey and the circumstances that have led the company to transform into a CDMO, offering its unique biosimilars development and production expertise to the global industry.

Can you begin by introducing the ToksÃ¶z Group, owner of Arven Pharmaceuticals, its presence in the Turkish market, and the role of Arven for the larger organization?

The ToksÃ¶z Group is a group of three companies, not a holding structure, which encompasses three different organizations: Arven Pharmaceuticals, Verano Pharmaceuticals and Montero. In addition, the Group currently owns 35 percent of Sanovel Pharmaceuticals, a manufacturer of generic medicines, after selling shares to a venture capital fund last year. Arven, Montero and Verano are fully owned by me and operate in three different sectors.

Verano focuses on veterinary health pharmaceuticals for livestock, which is a relatively small sector in Turkey but where we have a prominent market position.

Montero focuses on high quality nutrition and care products for infants. The company owns the Evolvia brand which is produced in Spain and Norway and distributed in Turkey; we will soon be exporting to 72 countries after a strategic partnership we have made with Ordesa, a Spanish company. Besides infant nutrition, Monteroâ??s core business, we have just after an agreement with a Turkish dairy producer this year to compete in the enteral nutrition business, whose products are reimbursed in many countries, including Turkey.

The third company is Arven Pharmaceuticals, the growth driver of the Group, whose primary focus is development and production of high-technology inhaler and biotechnology products.

Arven succeeded in developing the patented and produced dry powder inhaler DPI in Turkey, Arvohaler, as a result of long-lasting R&D activities. Our main competitors in that space are GlaxoSmithKline for our Salmeterol/Flutikazon DPI and Boehringer Ingelheim for our Tiotropium Bromide DPI.

Those products are not exactly generics; in the United States, they qualify for the 505(b)(2) drug approval pathway, which means that they are registered as a semi-original product because the drug delivery system is different.

Arvenâ??s main expertise is research and development, so we choose products that are difficult to produce as evidence by the fact that we are one of only 15 companies in the world competing in the DPI sector.

While the company excels in R&D and manufacturing, it is lacking global commercialization capabilities.

Arven is also known as the company behind the first biosimilar drug, developed and manufactured from cell to final product in Turkey. Can you explain your presence in the biosimilar space?

Arven owns a production facility for two different types of biosimilar products: monoclonal antibodies predominantly produced in mammalian cell culture bioprocesses, and bacteria-based biosimilars.

In 2016, the company obtained marketing authorization for the biosimilar of Neupogen (filgrastim), marketed under Fraven, which is the first biosimilar drug, developed and manufactured from cell to final product in Turkey. Filgrastim is used by almost every oncological patient going through chemotherapy and we are the market leaders in Turkey for that biosimilar. For this product, we have been able to increase by ten the efficiency of the cell.

Our advantage is due to unparalleled investment in biosimilar R&D and production; no other company in Turkey has invested as much as Arven. The main challenge in biosimilar production is the know-how, which is what we have been doing for the last 15 years.

Today, Arvenâ??s team is capable of developing from cell line, called upstream, to industrialization, what the industry calls scale up. Many of the Turkish companies with investments in biosimilars have not looked at the strategic value of the overall process but rather at the fill and finish side only. The technological infrastructure required for biosimilars is also used for recombinant DNA vaccines, for example, which is why Arven invested on the new injectable lines for high-scale products this year.

With an already successful business for your DPI products, what is your strategy moving forward in the biosimilars space?

Arven is currently a small-scale company, not a big scale one; financially, we have to adapt our investment in accordance with the Turkish marketâ??s reality.

Two years ago, we invested in trastuzumab and bevacizumab, two monoclonal antibodies, which were ready for the scale up process and first clinical studies, but unfortunately the reimbursement system in Turkey made prices for those products too low for us to consider it a feasible investment.

The government is buying most of these products through tenders and a low pricing strategy. The issue is that companies that own the originator product see Turkey as 1 percent of the global market and can sometimes sell it at cost, with extremely low margins or none at all. But Turkey is 100 percent of the market for Arven.

We tried to explain to the authorities in Ankara that such low prices would make it hard for us to sell them in Turkey since clinical trials would have cost too much. The alternative is selling them abroad but globalizing one biosimilar product requires USD 30-40 million investment for clinical studies.

For this reason, we have decided to stop our own development of biosimilars, changing our strategy in order to become a CDMO, offering our capabilities to develop and manufacture for other companies.

Our strategy is to offer our unique set of biosimilars capabilities to any organization that wants to enter the business but does not have its own manufacturing or development know-how in Turkey. The investment in new sterile injection lines that I mentioned allows Arven to offer a full package for companies in search of a CDMO.

This is a great opportunity today since many global CDMOs are running at capacity with pandemic-related projects, and because Turkey remains a very cost-effective country to manufacture. We are also looking for a strategic partners that can carry our company to international platforms.

Turkeyâ??s Scientific and Technological Research Councilâ??s (TUÌ?BIÌ?TAK) president, Hasan Mandal, explained that they funded 35 healthcare projects during the pandemic. Is Arven currently collaborating with them or other public institutions?

Both TUSEB and TUBITAK are very friendly and helpful, always trying to support and invest in different projects, but their budget is limited. Creating one monoclonal antibody cannot be done with USD 500,000, it is not possible because you need to invest millions in clinical studies. In addition, both institutions are currently concentrated on the vaccine projects.

Finally, can you tell us about your background and how you got involved with the biopharma industry?

I studied chemical engineering at BoÄ?aziÃ§i Ã?niversity in Turkey and did a two-year MBA afterward. My father was a well-known pharmacist and founder of Sanovel, and I worked with in the pharmaceutical sector until he passed away in 2012. I have always been involved in the R&D part because of my passion towards solving difficult problems.

Of course, my background in chemical engineering has helped but none of the success would be possible without our great team filled with Turkeyâ??s best talent.

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