Swati Jajodia – Managing Director, Swati Spentose, India



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Swati Jajodia, managing director of Swati Spentose discusses her commitment to tackling underserved diseases and the company's approach to bringing pentosan polysulfate to global markets while working with Key Opinion Leaders and CMEs in raising awareness about

interstitial cystitis (IC).

Could you please introduce Swati Spentose to our international audience?

Swati Spentose is a family owned company founded in 1970. Originally set up by my father-in-law, it is now owned and run by my husband and myself. When Jajodia Group, first started as a distributor over four decades ago, it was aimed towards supplying the Indian market with chemicals, including to various formulators such as Sun Pharmaceuticals, Intas, Micro Labs etc. However, the focus was shifted as the next generation stepped in.

We were interested in manufacturing, but we were clear that we did not want to manufacture simply for the sake of manufacturing a product: we were interested in molecules that other manufacturers were not producing. By chance, we came across a particularly unique molecule, a polysaccharide called pentosan polysulfate (PPS). At that time nobody in the world was working on polysaccharides, thus it offered us an opportunity to look into the molecule.

It was an especially difficult product as there was no data available and it was a very challenging molecule. However, our research into pentosan polysulfate shifted our focus towards treating orphan, neglected and underserved diseases. This became our passion and we consider this to be the point out of which much of our current work originated. The company is mainly a research driven company focused towards researching pentosan polysulfate and validating the science in the USA. Our pre-clinical trials have been done at the prestigious Mount Sinai Health System, New York City.

What role does pentosan polysulfate play in Swati Spentose's operations?

Pentosan polysulfate, is a polysaccharide used to treat a number of conditions and sold under the brand name Elmiron. The latter is only registered in the USA and the patent expired around eight years ago, although the price of the product jumped from USD150 to USD1000. This is largely due to the challenging nature of the molecule which is very difficult to characterise and manufacture by generics companies.

While pentosan polysulfate treats a number of diseases, it is most prominently used to treat interstitial cystitis (IC) a condition through which the lining of the bladder degenerates, thereby causing significant pain and an inability to hold one's bladder. As of now there are just 40,000 prescriptions per month for Elmiron in the US; however according to the RAND Drug Policy Research Centre study there are probably 3-8 million patients suffering from IC in the US only. The number of prescriptions is so low due to the prohibitively expensive pricing of Elmiron, while insurance companies are driven towards removing it from their lists as the drug has to be taken for six months and as such is unaffordable.

Pentosan polysulfate regenerates the lining creating a gag layer inside the bladder, and it therefore works as both a functional and a structural medicine. Two foundations, the Interstitial Cystitis Network (IC Network) and the Interstitial Cystitis Association (IC Association) from USA have contacted us repeatedly seeking the generic, which highlights the fact that this product is highly needed.

Previously, the business within the US had been enough for Elmiron's manufacturer and distributor while the cost of raising awareness about IC also seemed too large of an investment. As a result, IC has remained a relatively unknown disease. It is nonetheless crucial to raise awareness about the disease, with a special focus on doctors outside of the US, as the originator is not currently available in international markets outside the US.

We have top notch doctors who are now our Key Opinion Leaders (KOLs) and who now conduct CMEs daily. There is now real hope and we are determined to reach out to patients in the deepest pockets of India and around the world. We host seminars, Continuing Medical Education (CMEs) and talks by doctors from Europe and the United States. We send doctors around the world and we're a member of councils such as the European Council for Interstitial Cystitis (ESSIC) in an effort to raise international awareness.

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To what extent does an awareness and understanding of interstitial cystitis (IC) exist in India?

India does not have a universal healthcare system and there is no social security and so people do not have access to medicines for even life-threatening conditions. Widespread awareness of IC is a long way off. The government is focused on raising awareness of diseases in the likes of breast cancer, AIDS, polio and tuberculosis – thus IC awareness is not a priority.

India is a very large country with a massive proportion of its population living below the poverty line. Much of the population lacks education and so the government is dealing with a lot of poor people, a lot of uneducated people and a simply a lot of people. As such we cannot fault the government. However, it is important that pharmaceutical companies that are growing at a fast pace come together to tackle underserved issues.

The issues which India faces are in part due to the fact that neither the patients nor the government can afford the significant expenses that are associated with pharmaceuticals. This is where our company plays a critical role. As a second-generation company, Swati Spentose is able to sustain itself and thus we are able to focus on research and addressing underserved diseases such as IC.

While it was a tough journey at first, we are now able to achieve our aim of bringing our product to the market at an affordable price: our company manufactures pentosan polysulfate at competitive price in our United States Federal Drug Agency (USFDA) inspected site. The economies of scale and highest compliances make us the most sought for partner for PPS.

What approach has Swati Spentose taken towards developing internationally?

Significantly we are partnering with companies with very good distribution channels around the world. In Korea alone, we have over 6000 prescriptions month on month; that is a huge number for such a small country. We are currently in discussion with Japanese distributors and we have

already reached out to 20 different countries overall, including Russia and Turkey. We are going to make sure that the product is available in every country in which it was previously unavailable.

We are also filing to make the product available in Europe, where we are collaborating with a very strong partner, and we hope that the process will be completed within nine months to a year's time. We are also seeking to find a partner in the USA in order to reach the 3-8 million patients suffering from IC.

Overall, we are interested in partners who are passionate about meeting the needs of these patients: it is not easy money and resources must be allocated towards raising awareness and reaching out to doctors and insurance companies. In every country we would rather have two or three partners selling the product in order to further the medicine's reach and access. Just like in India we have our brand Comfora and we are also mfg for Sun and Cipla to reach the medicine to all those suffering. However, few companies are willing to make the leap, although this product is highly needed and having a niche product in their portfolio sets companies apart.

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Which other diseases have Swati Spentose focused on?

We are working on a number of rare diseases. We have been focusing on mucopolysaccharidosis type 6 (MPS) a condition through which children do not attain the average height due to enzyme deficiency which prevents the optimal growth of bones. We have undertaken pre-clinical trials at Mount Sinai in New York which were sponsored by a parent whose child suffered from MPS.

We have also been working on prions which relate to the degeneration of the brain, and particularly the degeneration of neurons, dementia and memory loss. We are developing a product which has demonstrated significant success in treating the human form of a prion disease, Bovine Spongiform Encephalopathy (BSE), commonly known as mad cow disease.

We have also been looking at diabetic kidney damage as diabetes awareness is very poor in India. While our primary focus is on underserved diseases we are currently moving towards becoming an exporter a polysaccharide company, and we are focused on identifying new polysaccharides.

Additionally, we have five facilities in which we manufacture steroids, hormones and Active Pharmaceutical Ingredients (APIs). We have an entire pipeline of urology products, whose revenues will allow us to sustain our research. We currently turn over USD100 million: USD25 million of that amount is derived from our manufacturing business, which allows us to maintain our commitment to the vision that we have created, while the other USD75 million comes from our import trading

business.

Any words to conclude?

By the year 2023 we aim to have pentosan polysulfate available in generic form in the USA and across the globe. We are working on new indications and hope to complete clinical trials and register for these new indications, which have the potential to make Swati Spentose a billion-dollar company. We aim to develop and open up new markets, an ambitious and arduous task that is however required to ensure more patients around the world can benefit from this life-changing product.

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