FDA approves Xifaxan® for the treatment of Irritable Bowel Syndrome-D

US studies confirm the efficacy of Alfa Wassermann's drug

Valeant-Salix, partner of Alfa Wassermann (Alfasigma group) for the US market, announced that the U.S. Food and Drug Administration (FDA) approved Xifaxan® 550 mg for the treatment of IBS-D in adults. Irritable Bowel Syndrome, which is thought to affect approximately 35 million Americans, is a chronic gastrointestinal disorder characterized by recurrent abdominal discomfort or pain.

Xifaxan® is the first-and-only nonsystemic antibiotic approved for the treatment of IBS-D in adults. The FDA approval is based on data from three studies in over 3,000 patients. The studies demonstrated the efficacy and safety of repeat treatment following completion of a two-week course of treatment.

Although millions of people suffer from the condition, current treatments for IBS-D are limited to products aimed at relieving individual symptoms and fail to address the syndrome complex. "We are thrilled to offer patients this new option to manage their IBS-D symptoms," said Dr Pier Vincenzo Colli, General Manager of Alfa Wassermann. "The FDA approval in IBS-D extends the reach of Xifaxan® beyond hepatic encephalopathy to a population greatly in need of a different treatment approach. Besides, it's a further confirmation of the goodness of the research model that we developed with our American partners."

By now, Xifaxan® is approved for IBS-D in the USA. Alfa Wassermann is considering the opportunity to pursue approval also outside the United States in the future.

Alfasigma is the result of the merger of Alfa Wassermann and Sigma-Tau, two of the most important pharmaceutical Italian groups.

Alfasigma is ranking among the top five players in the Italian pharmaceutical market, both in prescription and over-the-counter products, with a turnover of more than 900 million Euro.

Alfasigma operates directly in 18 countries, among which the USA, China, Russia and several European countries, with a staff of about 2,800 employees, of whom 1,840 are in Italy and 960 in branches abroad. The operational sites in Italy will be: Milan, Bologna, Pomezia, Alanno and Sermoneta. The last three are production sites equipped with cutting-edge technologies.

Alfasigma, thanks to its extensive portfolio of products, holds a leading position in the Italian market in Orthopedics-Rheumatology, Cardiometabolic area, Diabetology and Gastroenterology.

Alfasigma invests a significant share of its turnover in R&D in order to identify therapies that can offer new treatment opportunities for those who have to cope with illnesses with high clinical and social impact. A significant outcome of this work has been Rifaximin-α (Normix), a product used for various gastroenterological diseases that is marketed in 39 countries around the world. In the USA, with the brand name Xifaxan, it is one of the leading 50 products in terms of turnover. The R&D Centre in Pomezia (Rome) concentrates mainly on immuno-oncology, specifically through the study and development of proprietary biotechnology platforms aimed at innovative - targeted therapies.