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Press Release

Aurisco Pharmaceutical's Oral Dydrogesterone Tablets Get Marketing Authorization Approval in China Under The Brand Name AUXITON®



Aurisco Pharmaceutical has good reasons to celebrate. On its 25th anniversary, the high-tech pharmaceutical company dedicated to innovation has received its **first Marketing Authorization Approval in China for AUXITON®**, the oral finished dosage form of **Dydrogesterone**, from China's Health Authority, the NMPA. Aurisco is the only company holding both an active USDMF and a valid CEP – the Certificate of compliance with the European Pharmacopoeia, issued by the EDQM for the drug substance.

Aurisco's Chairman and founder, Mr. Peng Zhien said "After getting listed at the Shanghai Stock Exchange in 2020, this approval is another very important milestone for Aurisco. However, this is even more important for women with certain medical conditions that prevent them from having a healthy and successful pregnancy. These patients were the driving force for Aurisco to integrate the manufacturing of the active pharmaceutical ingredient with the development and manufacturing of the oral tablet finished dosage form. We hope to contribute to the happiness of many couples, by making possible their dream of having a baby".

As explained by Vivian Shan, MD - Aurisco Pharmaceutical's Medical Manager for this program, "AUXITON® provides doctors a safe and convenient, orally bioavailable dydrogesterone - a highly selective progesterone receptor agonist. With an equivalence dose 10–20 times lower than progesterone due to its better bioavailability and the progestogenic nature of the metabolites, dydrogesterone has multiple advantages over natural progesterone, ensuring efficacy and safety to establish the adequate levels for luteal support during natural pregnancy and in-vitro fertilization (IVF)."

"Since its foundation, Aurisco has been developing complex generic molecules, including steroids like dydrogesterone and more recently peptides like semaglutide or oligonucleotides such as nusinersen. Integrating the production of API, formulation and finished dosage, Aurisco ensures product quality, productivity, and cost advantages throughout the entire industrial chain, to guarantee adequate productivity

and stable supply to meet new clinical programs. Following international cGMP and EHS standards, our product quality is in line with China, Europe, and United States standards. We have been working with the best generic pharmaceutical companies in the world, supplying them safe, sustainable, affordable and high-quality products. Leveraging on our technologically advanced and differentiated capabilities, we also work with innovators, offering contract research, development and manufacturing services (CRDMO)” – says Alessandro Ricci, President of Aurisco USA, based in New York.

Rafael Antunes, Aurisco’s Vice-President for Business Development in Europe stated “The company has always been a pioneer in the API space. We were the first company in China to develop the phytosterol technology or to pass a RX360 supply-chain security audit. Being Ecovadis ranked, we have embraced ESG and Sustainability, by joining the Science Based Targets initiative (SBTi), the Manufacture 2030 and Energize initiatives to decarbonize the pharmaceutical supply-chain and adopt renewable energies, just to mention a few. We are based in China but export to over 100 countries, so we have a global responsibility”.

“The development and manufacturing of AUXITON® is a good example of some of our technical capabilities. As a science-based company, we have developed recombinant strains for fermentation, we produce and use selective enzymes for biocatalysis and chiral catalysts for asymmetric hydrogenation or industrial-scale photochemistry to make processes more sustainable and economical. Our dydrogesterone is produced with very low impurity levels, with consistent pharmacokinetic and human bioequivalence profiles when compared with the originator, essential prerequisites for clinical efficacy and safety. We are fast, very innovative and work with the best Universities to attract and retain top talent in the company. Aurisco has filled over 80 patents worldwide and offer customers the confidence of a IP-safe partner in China.” – said Prof. Li Jinliang, CEO of Aurisco’s Biotech subsidiary, in Shanghai.

To learn more about Aurisco Pharmaceutical and its products and CRDMO services, please contact info@auriscopharma.com.

About Dydrogesterone

Dydrogesterone is a potent orally active progesterone receptor agonist that was developed in the 1950s and that has been widely used since the 1960s for menstrual disorders such as premenstrual syndrome, cycle irregularity, endometriosis, threatened miscarriage, and habitual miscarriage, and for postmenopausal hormone therapy. It is estimated that the cumulative exposure for all indications from 1960–2017 is >113 million patients.

About Aurisco Pharmaceutical

Aurisco Pharmaceutical is a listed company on the Shanghai Stock Exchange (Stock code: 605116). With 25 years of experience in the development and manufacturing of complex APIs for regulated markets and with 6 R&D centers and 3 cGMP inspected manufacturing sites, it is focused on semi-synthetic and synthetic APIs, including steroids, peptides and oligonucleotides and hormone-based finished dosage forms, offering CRDMO services to the Global Pharmaceutical Industry.