Press Release / Aug 11, 2023

Successful FDA inspection at Aurisco's manufacturing site in Yangzhou, China

Aurisco Pharmaceutical today announced that its cGMP manufacturing plant in Yangzhou has successfully passed a USFDA inspection.

Front view of Yangzhou Aurisco Pharmaceutical Co. Ltd

Yangzhou, China, August 11th, 2023 – Aurisco Pharmaceutical announced today that its API and FDF plant in Yangzhou, China has successfully passed a cGMP inspection by the US Food and Drug Administration (USFDA).

The inspection, carried out by the FDA Consumer Safety Officer, Mrs. Michele Glendenning, lasted 5 days (7–11.Aug.2023) as initially planned. The FDA inspection confirmed the site to be compliant with the principles and guidelines of Good Manufacturing Practices (GMP) and no Form 483 observations were issued. At the closing meeting the inspector informed that she was satisfied with the workshops and labs she had seen and complimented Aurisco on its GMP system and documents, inspection organization and the knowledge of its team members.

Dr. Wang Guoping, General Manager of the Yangzhou site, said "This successful FDA inspection is very important for our customers, as it confirms the cGMP status of this site, where we offer CDMO services, manufacture generic APIs like Dydrogesterone, Brivaracetam, Bempedoic acid, Dolutegravir sodium, Rimegepant, Vibegron and will soon produce

peptides such as Semaglutide. This site also manufactures Auxiton®, the first NMPA approved generic dydrogesterone tablets, with a Marketing Authorization for the Chinese Market".

A view from the QC Lab of Yangzhou Aurisco Pharmaceutical Co. Ltd

Dr. Li Jinliang, Board Director of Aurisco, said "We are pleased to have another successful FDA inspection. Quality is very important for us, and this inspection demonstrates the safety of our products and cGMP compliance of our quality system. This successful result is a team effort and I congratulate the entire team for being so committed."

About Aurisco. Aurisco serves global markets with over 25 years' experience in the development and cGMP manufacture of Active Pharmaceutical Ingredients. With 6 R&D centers, 3 FDA inspected sites and building its 4th site in China, and sales offices in USA, Portugal and Brazil, the company focuses on complex products for the most demanding customers in the most regulated markets. With a broad portfolio of complex generic APIs, the company is broadening its offer from small molecules to peptides and oligonucleotides and offering innovators an IP safe and cGMP and ESG compliant environment for research, development and manufacturing of their innovative molecules. With over 80 patents filled worldwide and 250 scientists, the company pays special attention to IP, innovation and sustainability. Being Ecovadis ranked, Aurisco has joined the SBTi, M2030 and the sustainable procurement pledge. Aurisco was the first pharmaceutical company in China to pass a RX360 supply chain security inspection and has been audited by the Pharmaceutical Supply Chain Initiative (PSCI), a group of pharmaceutical and healthcare companies who share a vision of better social, health, safety and environmental outcomes in the communities where they buy.

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