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Netupitant-palonosetron: Safety profile of a novel fixed-dose combination drug in the prevention of chemotherapy-induced nausea and vomiting

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Chemotherapy-induced nausea and vomiting (CINV) remains a major adverse effect of cancer chemotherapy that may seriously impair patient quality of life, cause nutritional and metabolic disturbances and interfere with the motivation of patients to follow recommended treatment regimens. Of all the known predictive factors, the intrinsic emetogenicity of a given chemotherapeutic agent is the predominant factor in predicting the development of CINV. The netupitant-palonosetron combination (Akynzeo®) is an oral fixed dose combination of 300 mg netupitant and 0.5 mg palonosetron Hydrochloride with a safety profile comparable to that of its single components. Netupitant is a neurokinin-1 receptor antagonist (NK_1 RA) while palonosetron is a serotonin type 3 ($5\text{-}HT_3$) RA which has been used extensively for the prevention of CINV since 2003. To evaluate the most important identified and potential risks of the single active ingredients with those of the fixed combination, a conservative approach was adopted with the known and potential risks identified for palonosetron considered in the evaluation of the risks associated with netupitant. Thorough QT studies in healthy volunteers showed no sign of any effect on atrioventricular conduction or cardiac depolarization or any new clinically relevant morphological changes. Phospholipidosis and serotonin syndrome were considered potential risks; the former having only been observed in netupitant pre-clinical studies and the latter potentially related to palonosetron. No additional risks were generated by the combination of the two constituents. Routine risk minimization measures were considered adequate in the EU-RMP (Europian Union-Risk Management Plan) while REMS (Risk Evaluation and Mitigation Strategy) was not required by the FDA.

Biography

Mario Bertazzoli is a Physician and a Registered Specialist in Human Reproduction Pathology. He received both Medical and Specialization degrees from the University of Milan, Italy. He worked since 1995 for international pharmaceutical companies as Pharmacovigilance and Pharmaco-Epidemiology Physician. He is currently the Head of Corporate Drug Safety and Reference Physician to the EU Qualified Person for Pharmacovigilance for the Helsinn Group. He is Founder and Treasurer of the International Society of Pharmacovigilance, Swiss-Austrian Chapter.

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