Zanamivir aqueous solution in severe influenza: A global Compassionate Use Program, 2009–2019

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Abstract

Background Zanamivir is a neuraminidase inhibitor effective against influenza A and B viruses. In 2009, GlaxoSmithKline (GSK) began clinical development of intravenous (IV) zanamivir, and initiated a global Compassionate Use Program (CUP) in response to the evolving H1N1 global pandemic. The goal of the CUP was to provide zanamivir to critically ill patients with limited treatment options. Methods Zanamivir was administered to patients with suspected or confirmed influenza infection, who were not suitable for other approved antiviral treatments. Reporting of serious adverse events (SAEs) was mandatory and recorded in the GSK safety database. A master summary tracking sheet captured requests and patient characteristics. A case report form was available for detailing medical conditions, dosing, treatment duration, and clinical outcomes. Results In total, 4033 requests were made for zanamivir treatment of hospitalized patients from 38 countries between 2009 and 2019. Europe had the highest number of requests (n=3051) followed by North America (n=713). At least 20 patients were aged [?]6 months, of whom 12 were born prematurely. The GSK safety database included 466 patients with [?]1 SAE, of whom 374 (80%) had a fatal outcome. Drug-related SAEs were reported in 41 (11%) patients, including hepatic failure (n=6 [2%]) and acute kidney injury (n=5 [1%)]. Conclusions The CUP fulfilled the need to provide global access to zanamivir prior to product approval. No new safety concerns were identified in the CUP compared with IV zanamivir clinical studies.

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