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[Drug safety management compliance]

SK Biopharmaceuticals Co., Ltd. and its subsidiary SK Life Science, Inc. maintains the core principle of patient safety through monitoring of quality, efficacy, and safety of the entire drug development cycle from clinical development to marketing authorization, and observation of side effects is managed through pharmacovigilance.

Pharmacovigilance is defined as the science and activity relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems¹. All safety information related to drugs collected are used for benefit/risk analysis of drugs.

The primary objectives of pharmacovigilance include · early detection of unknown adverse events and interactions · monitoring the frequency of adverse events and identification of risk factors associated with adverse events, and the ultimate goals of pharmacovigilance include · improvement of patient safety through the correct and safe use of drugs · quantitative assessment of benefit/risk through updated safety information.

SK Biopharmaceuticals Co., Ltd. is responsible for globally managing pharmacovigilance duties and activities for all products from SK Biopharmaceutical Co., Ltd. and its subsidiary SK Life Science, Inc. For systematic pharmacovigilance operation, relevant information is collected based on safety, ethics, regulation and science and take action for detections for all product related side effects and adverse events in compliance with regulations of each health authority and other regulatory agencies including Korea Ministry of Food and Drug Safety and US Food and Drug Administration.

SK Biopharmaceuticals Co., Ltd. aims to maintain the objective of corporate social

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responsibility by proceeding with the continuous plan to manage product benefit/risk and transparently sharing all information related to product safety with patients, medical professionals and regulatory agencies.

1 World Health Organization. (2002). The importance of pharmacovigilance. World Health Organization.