EXECUTIVE SUMMARY

Introduction

This report is the first Development Safety Update Report (DSUR) for IMX-110, summarizing safety data received by IMMiX Biopharma Australia Pty Ltd., (referred to as IMMiX hereafter) from 03 January 2018 to 03 January 2020 from the ongoing Phase 1/2a, open-label, dose-escalation/dose-expansion study of IMX-110 in patients with advanced solid tumors. The Development International Birth Date (DIBD) for IMX-110 is 03 January 2018.

Investigational drug

IMX-110 combines the well-established anti-cancer effect of the anthracycline doxorubicin (DOX) with a Curcumin C3 complex® (CUR). CUR is derived from turmeric and contains 3 polyphenolic curcuminoids (curcumin, demethoxycurcumin and bis-demethoxycurcumin) and has been shown to inhibit various resistance-related pathways in cancer cells, including downregulation of NF-κB.

IMX-110 is a PEG-PE polymeric micelle encapsulating CUR, and low-dose DOX. Using less than 50% of the typical clinical DOX dose, IMX-110 has shown preclinical proof of concept in cellular models of colorectal cancer, triple-negative breast cancer, ovarian cancer, pancreatic cancer and glioblastoma models.

Exposure

Since DIBD (03 January 2018) up until 03 January 2020, a total of 9 patients have been enrolled and treated with IMX-110 in an ongoing, Phase 1/2a study (IMX-110-001), open-label, clinical study sponsored by IMMiX., in patients with advanced solid tumors.

Marketing approval(s)

IMX-110 is not authorized for marketing in any country in any dosage form at the time of this report.

Summary of overall safety assessment

The review of safety data collected during the report period do not alter the anticipated favorable benefit-risk profile for IMX-110.

Summary of important risks

There were no important risks nor new potential risks identified for IMX-110, other than what is already known and anticipated for doxorubicin.

Actions taken for safety reasons

As there was no change to the risk-benefit profile of IMX-110, the Investigators Brochure was not required to be updated in 2019. Similarly, there has been no cause for amending the clinical study protocol or patient informed consent forms on safety related grounds. The Study Sponsor will continue to monitor safety issues assisted by the established Safety Review Committee (SRC) to assure continued safety for the duration of the trial.

Conclusions

No safety concerns relating to IMX-110 were identified in the reporting period and continuation of the study as planned is justified by the anticipated benefits of IMX-110.

Considering the measures taken to minimize risk to patients participating in the IMX-110 clinical study, potential risks associated with IMX-110 are justified by the anticipated benefits that may be afforded to study participants.