**Real-world dataset demonstrates favorable safety profile of Liposomal amphotericin B primary treatment of invasive aspergillosis in haemato-oncology patients**

**Background**

Liposomal amphotericin B (Ambisome®) (LAmB) remains a cornerstone treatment for invasive fungal disease, due to its broad spectrum of activity, proven efficacy and low rof resistance. Evidence shows a reduced risk of adverse events (AEs) over conventional AmB and other lipid formulations. LAmB is an alternative to voriconazole (VOR) for treatment of invasive aspergillosis (IA), in cases of hepatotoxicity, dermatologic or visual adverse events (AEs) and QTc prolongation. Limited real-world evidence (RWE) is available.

**Objective**

This RWE study evaluates the AE profiles of LAmB and VOR as primary treatment for IA in high-risk haemato-oncology patients.

**Methods**

This retrospective non-interventional drug utilization study collected data from patient’s medical records. Adult haemato-oncology patients (pts) who received ≥1 dose of LAmB or VOR for primary treatment of proven/probable IA between January 2014 and December 2019 were included (15 clinical sites in Europe). Patients were included consecutively in the order they were prescribed either LAmB or VOR, according to local treatment guidelines

and clinical practice.

Pts were followed for 84 (±7) days or until lost-to-follow up or death.The following were collected: nephrotoxicity, hepatotoxicity, AEs leading to treatment modification or discontinuation (D/C), concomitant nephrotoxic or hepatotoxic medication, and baseline comorbidities (diabetes mellitus, renal disease/injury, liver disease/injury or other underlying immunosuppression). Nephrotoxicity was categorized as an event leading to new renal replacement therapy, persistent renal dysfunction or death. Hepatotoxicity was defined as an event leading to hepatic failure, jaundice cholestatic, cholecystitis or death.

**Results**

359 pts were included: 127 received LAmB, 232 VOR (70.3% intravenous).

Patient and treatment characteristics, haemato-oncological conditions, comorbidities and concomitant medication at baseline are in table 1. Table 2 provides detail about the treatment related renal and liver AEs.

Overall, treatment related AEs were seen in 12 patients (9.4%) in the LAmB group and 53 patients (16.4%) in the VOR group. Patients with treatment related renal AEs were 5.5% (7pts) with LAmB and 0.4% (1pt) with VOR. Patients with treatment related liver AEs, were 0 with LAmB and 12.1% (28 pts) with VOR. Of all pts treated, discontinuation due to any treatment related AEs was 6.3% (8 pts) with LAmB and 11.2% (26 pts) with VOR.

**Conclusion**

In this large multi-national RWE study in a very complex and poly-morbid populations, the absolute frequency of clinically relevant treatment related AE was low despite the severity of illness, The number of treatment-related renal adverse events was higher with LAmB. However, the absolute frequency was low, which positively contrasts with the adverse event profile of conventional Amphotericin B. A higher number of treatment-related hepatic adverse events was observed with VOR, which is consistent with available literature.