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P2456 Intravenous fosfomycin for treatment of severely infected patients (FORTRESS): first insights from a European, multi-centre, non-interventional and prospective clinical study

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Background: Despite its clinical use for almost five decades, prospectively obtained data on the use of i.v. fosfomycin in clinical routine is still limited. FORTRESS is the first multinational study to evaluate the efficacy and safety of i.v. fosfomycin in the treatment of severely infected patients under real-life conditions.

Materials/methods: Prospective, non-interventional and monitored European multicenter study including 500-1,000 patients (NCT02979951). The primary objective is clinical success, defined as clinical cure or improvement at end of fosfomycin treatment (EOT). Secondary objectives are microbiological cure and clinical success at different time points, adverse events and dropouts. Eleven patients with involvement of fungi were excluded from this interim efficacy analysis.

Results: Currently (November 2018), 124 patients from 10 German study centers have been enrolled, of which documentation has been finalised for 92 patients (43 females, 49 males; mean age 63 (27-91) years). Seventy-one of them (77%) were treated in intensive care units. Where documented, the mean APACHE II score at fosfomycin treatment start was 21 (range 11-36). Many patients (80/92) received fosfomycin in combination therapy, most often as 2nd line treatment (48/92). Documented indications for fosfomycin use were bacteremia/sepsis (12/92) and osteomyelitis (18/92), nosocomial lower respiratory tract infection (12/92), cUTI (10/92), bacterial meningitis/CNS infection (10/92), SSTI (10/92), endocarditis (9/92) and other infections (11/92) (each ± bacteremia/sepsis). The majority of infections were caused by at least one Gram-positive pathogen (60/92), only 30 (33%) included Gram-negative pathogens. The median targeted daily fosfomycin dose was 15 g over 14 days on average. Clinical success at EOT was favourable in 75% (61/81) of all cases and 70% (28/40), 80% (8/10) and 88% (7/8) in patients with sepsis/bacteremia, bacterial meningitis/CNS infection and nosocomial lower respiratory

tract infection, respectively. Microbiological cure was achieved in 84% of all patients (68/81). 28% (33/117, September 2018) of all patients showed adverse drug reaction(s) during fosfomycin therapy (26 non-serious, 7 serious).

Conclusions: These first results show high clinical and microbiological efficacy of i.v. fosfomycin treatment in severely infected patients and support the use of i.v. fosfomycin across different indications. Data from other European countries currently starting the study implementation is highly anticipated.