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The Role of Bedaquiline in Effectiveness of Treatment of the Patients with M/XDR-TB and Clinical Data Monitoring Plan

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Objectives: The new drug bedaquiline applies used to treat multidrug and extensively drug-resistant tuberculosis (M/XDR-TB) since then 15/06/2017 in Azerbaijan. Regimens containing bedaquiline, delamanid, linezolid and clofazimine as backbone drugs were used in patients with laboratory confirmed M/XDR-TB. Estimated number of RR/MDR-TB cases in 2017 -N=1300. Number of RR/MDR-TB cases detected in 2017, N=1007.

Methods: Our study evaluated 64 patients with pulmonary XDR-TB and with cavernous lung lesions on chest X-ray treated with bedaquiline (n=64) combined with a World Health Organization recommended regimen. 16 (25%) patients had: fluoroquinolone-resistant (13 patients) and 3 patients had aminoglycoside-resistant MDR-TB, 48 (75%) patients had extensively drug-resistant XDR-TB. Of these, 49 (76.5%) were male and 15 (23.5%) were female.

Results: In all patients were developed adverse events. The most frequent adverse events were the following: cQT prolongation, hypercalcemia, liver function tests elevation, myelosuppression, deficiency of potassium in the bloodstream.

Conclusion: Treatment was halted in four patients (6.25%) because of prolonged Fridericia's corrected QT interval. This fact, bedaquiline as well as other, drugs such as delamanid, fluoroquinolones and clofazimine, may increase the QT interval. All treatment duration we were monitored, electrolytes (potassium and magnesium) disturbance and/or hypoalbuminemia and any problem need to be adequately managed to prevent QTc prolongation.

Keywords: M/XDR-TB, BDQ, LZD, treatment of drug-resistant tuberculosis