**OLB26**
**2-hour Oral Session**
**Late breaker session: Other**

## Prolonged bedaquiline treatment for multidrug-resistant tuberculosis: first report of safety and long-term outcome

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**Background:** Bedaquiline is a new drug for the treatment of multidrug-resistant tuberculosis (MDR-TB), defined by resistance to rifampicin and isoniazid. It is currently recommended for a maximum duration of 24 weeks, and no published data exist on longer treatment courses.

**Material/methods:** A multicenter, national cohort was established including all patients who started MDR-TB treatment from 01/01/2011 to 31/12/2013 and received bedaquiline for at least 30 days.

**Results:** Overall, 44 patients were included: median age was 38 years (range, 18-70), 82% were male, and 98% were foreign-born. 52% of patients had additional resistance to fluoroquinolones and second-line injectables (XDR-TB), 39% had resistance to one of these drug classes, and 9% had no additional resistance to these drug classes. 77% were previously treated for TB. The strains were resistant to a median of 9 drugs (interquartile range (IQR): 7-11). Out of 43 patients with pulmonary TB, 88% had cavitary and 84% bilateral disease. 48% were HCV-positive and 5% HIV-positive. The most commonly prescribed drugs, in addition to bedaquiline, were: linezolid (96%), PAS (89%), cycloserine (73%), amikacin (70%), imipenem-amoxiciline/clavulanate (61%), moxifloxacin (52%). Surgery was performed in 25% of cases, after 167 days (IQR: 38-280) of treatment. Total treatment

duration was 627 days (IQR: 545–730) and bedaquiline treatment duration was 361 days (IQR: 196-590). Overall, 41 out of 44 patients (93%) received more than 24 weeks of bedaquiline and 15 (34%) received bedaquiline for all treatment. Adverse events led to discontinuation of one or more drugs in 36 patients (82%). QTcF>500ms values were recorded in 4 patients (9%) after a median of 3 months (range, 1-17) of treatment. No arrhythmias nor symptomatic cardiac side effects occurred. Bedaquiline was discontinued in two patients following QTcF prolongation. No other serious adverse events were attributed to bedaquiline. Out of 40 patients with positive sputum culture at treatment start, 25 (63%) and 39 (98%) achieved conversion after 3 and 6 months of therapy respectively, with a time to culture conversion of 88 days (IQR: 43-107). One patient reverted to positive culture after 449 days of treatment. 32 patients (73%) achieved successful treatment outcomes. Out of the 12 (27%) patients with unsuccessful outcomes, eight were lost to follow-up or not evaluated, three died and one failed.

**Conclusions:** Long-term bedaquiline treatment was safe and effective in this cohort of patients with advanced resistance patterns and extensive disease. Prolongation of bedaquiline beyond 24 weeks should be considered in selected MDR-TB cases.