**Supplemental Table 4**. Frequency of Patients With Shifts in Hematology, Lipid, and Endocrine Values Outside the Predefined Limits of Change by Treatment Group From Baseline to Endpoint in the All-Treated Set.

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| --- | --- | --- | --- | --- | --- |
| Parameter | PDLC criteria | PBOn=101 | ASN2.5 mg bidn=97 | ASN5 mg bidn=113 | OLZ15 mg qdn=46 |
| n assesseda | n (%) | n assesseda | n (%) | n assesseda | n (%) | n assesseda | n (%) |
| Hemoglobin | Male: <115 g/LFemale: <95 g/L | 5245 | 1 (1.9)1 (2.2) | 5439 | 0 (0.0)0 (0.0) | 6440 | 3 (4.7)1 (2.5) | 2818 | 0 (0.0)0 (0.0) |
| Hematocrit (%) | Male: <0.37%Female: <0.32% | 5245 | 3 (5.8)2 (4.4) | 5439 | 1 (1.9)0 (0.0) | 6440 | 4 (6.3)2 (5.0) | 2818 | 0 (0.0)0 (0.0) |
| White blood cells | <2.8 x 109/L>16 x 109/L | 9797 | 0 (0.0)1 (1.0) | 9393 | 1 (1.1)0 (0.0) | 104104 | 0 (0.0)1 (1.0) | 4646 | 1 (2.2)0 (0.0) |
| Neutrophils | <1.5 x 109/L | 97 | 1 (1.0) | 93 | 2 (2.2) | 104 | 2 (1.9) | 46 | 1 (2.2) |
| Total lymphocytes | <0.5 x 109/L | 97 | 0 (0.0) | 93 | 0 (0.0) | 104 | 0 (0.0) | 46 | 0 (0.0) |
| Eosinophils | >1.2 x ULN | 97 | 1 (1.0) | 93 | 1 (1.1) | 104 | 0 (0.0) | 46 | 1 (2.2) |
| Platelets | <75 x 109/L>700 x 109/L | 9696 | 0 (0.0)0 (0.0) | 9191 | 1 (1.1)0 (0.0) | 104104 | 0 (0.0)1 (1.0) | 4646 | 0 (0.0)0 (0.0) |
| Creatine kinase | >5 x ULN>10 x ULN | 9797 | 1 (1.0)0 (0.0) | 9393 | 1 (1.1)0 (0.0) | 104104 | 8 (7.7)3 (2.9) | 4646 | 2 (4.3)0 (0.0) |
| Aspartate aminotransferase | >3 x ULN>5 x ULN>10 x ULN | 979797 | 0 (0.0)0 (0.0)0 (0.0) | 939393 | 0 (0.0)0 (0.0)0 (0.0) | 104104104 | 1 (1.0)0 (0.0)0 (0.0) | 464646 | 0 (0.0)0 (0.0)0 (0.0) |
| Alanine aminotransferase | >3 x ULN>5 x ULN>10 x ULN | 979797 | 1 (1.0)0 (0.0)0 (0.0) | 939393 | 1 (1.1)0 (0.0)0 (0.0) | 104104104 | 1 (1.0)0 (0.0)0 (0.0) | 464646 | 3 (6.5)0 (0.0)0 (0.0) |
| Total bilirubin | >2 x ULN | 97 | 0 (0.0) | 93 | 0 (0.0) | 104 | 0 (0.0) | 46 | 0 (0.0) |
| Total cholesterol | >50% above ULN | 97 | 2 (2.1) | 93 | 1 (1.1) | 104 | 0 (0.0) | 46 | 0 (0.0) |
| LDL | >50% above ULN | 96 | 0 (0.0) | 92 | 0 (0.0) | 104 | 0 (0.0) | 46 | 0 (0.0) |
| Triglycerides | >5.65 nmol/L | 94 | 0 (0.0) | 84 | 1 (1.2) | 93 | 1 (1.1) | 45 | 0 (0.0) |
| Glucose | >20% below LLN>20% above ULN | 9797 | 1 (1.0)7 (7.2) | 9393 | 0 (0.0)7 (7.5) | 104104 | 0 (0.0)7 (6.7) | 4646 | 0 (0.0)3 (6.5) |
| HbA1c | >7.5% | 97 | 0 (0.0) | 93 | 3 (3.2) | 104 | 1 (1.0) | 46 | 1 (2.2) |
| Prolactin | >4 x ULN | 97 | 0 (0.0) | 92 | 2 (2.2) | 104 | 4 (3.8) | 46 | 0 (0.0) |
| ASN, asenapine; bid, twice daily; HbA1c, glycosylated hemoglobin; LDL, low-density lipoprotein; LLN, lower limit of normal; OLZ, olanzapine; PBO, placebo; PDLC, predefined limit of change; qd, once daily; ULN, upper limit of normal.an assessed is the number of patients with at least one post-baseline laboratory measurement during the treatment phase; n is the number of patients who had a post-baseline laboratory value that met PDLC criteria during the treatment phase.LLN and ULN were defined by a central laboratory. Levels of PDLC are met irrespective of baseline values. |