**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.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | PDLC criteria | PBO n=101 | | ASN 2.5 mg bid n=97 | | ASN 5 mg bid n=113 | | OLZ 15 mg qd n=46 | | |
| n assesseda | n (%) | n assesseda | n (%) | n assesseda | n (%) | n assesseda | n (%) | |
| Hemoglobin | Male: <115 g/L Female: <95 g/L | 52 45 | 1 (1.9) 1 (2.2) | 54 39 | 0 (0.0)  0 (0.0) | 64 40 | 3 (4.7)  1 (2.5) | 28 18 | 0 (0.0)  0 (0.0) | |
| Hematocrit (%) | Male: <0.37% Female: <0.32% | 52 45 | 3 (5.8) 2 (4.4) | 54 39 | 1 (1.9) 0 (0.0) | 64 40 | 4 (6.3)  2 (5.0) | 28 18 | 0 (0.0) 0 (0.0) | |
| White blood cells | <2.8 x 109/L >16 x 109/L | 97 97 | 0 (0.0) 1 (1.0) | 93 93 | 1 (1.1) 0 (0.0) | 104 104 | 0 (0.0) 1 (1.0) | 46 46 | 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 | 96 96 | 0 (0.0) 0 (0.0) | 91 91 | 1 (1.1) 0 (0.0) | 104 104 | 0 (0.0) 1 (1.0) | 46 46 | 0 (0.0) 0 (0.0) | |
| Creatine kinase | >5 x ULN >10 x ULN | 97 97 | 1 (1.0) 0 (0.0) | 93 93 | 1 (1.1) 0 (0.0) | 104 104 | 8 (7.7) 3 (2.9) | 46 46 | 2 (4.3) 0 (0.0) | |
| Aspartate aminotransferase | >3 x ULN >5 x ULN >10 x ULN | 97 97 97 | 0 (0.0) 0 (0.0) 0 (0.0) | 93 93 93 | 0 (0.0) 0 (0.0) 0 (0.0) | 104 104 104 | 1 (1.0) 0 (0.0) 0 (0.0) | 46 46 46 | 0 (0.0) 0 (0.0) 0 (0.0) | |
| Alanine aminotransferase | >3 x ULN >5 x ULN >10 x ULN | 97 97 97 | 1 (1.0) 0 (0.0) 0 (0.0) | 93 93 93 | 1 (1.1) 0 (0.0) 0 (0.0) | 104 104 104 | 1 (1.0) 0 (0.0) 0 (0.0) | 46 46 46 | 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 | 97  97 | 1 (1.0)  7 (7.2) | 93  93 | 0 (0.0)  7 (7.5) | 104  104 | 0 (0.0)  7 (6.7) | 46  46 | 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. | | | | | | | | | |