INTRAVITREAL SIROLIMUS EFFECTS ON ORAL CORTICOSTERIOD TAPERING IN SUBJECTS WITH NON-INFECTIOUS UVEITIS (NIU) OF THE POSTERIOR SEGMENT: SAKURA STUDY 1 RESULTS

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Purpose: To determine if intravitreal sirolimus, a local mTOR inhibitor, can reduce systemic corticosteroid needs while improving vitreous haze (VH) in subjects with active NIU of the posterior segment. Methods: SAKURA Study 1 is a double-masked, multinational monotherapy study in which 347 subjects with baseline VH 1+ were randomized to every-other-month injections of intravitreal sirolimus 440, 880, or 44 µg (active control). Subjects already receiving systemic corticosteroids at baseline started tapering these drugs at baseline. The proportion of tapering successes (prednisone-equivalent dose tapered to ≤5 mg/d) was assessed at Month 5. Results: 69 subjects (440 µg, n=26; 880 µg, n=21; 44 µg, n=22) entered the study at baseline corticosteroid doses of 5 mg/d. The highest percentage of tapering successes was observed in the 440 µg dose group (76.9%) vs the 44 µg active control (63.6%) and 880 µg (66.7%) dose groups. A total of 46.2%, 27.3%, and 33.3% of subjects, respectively, achieved tapering success along with a VH score of 0 or 0.5+. The mean observed corticosteroid doses at Month 5 were 3.7±10.4 mg/d (440 µg) compared to 2.9±7.7 mg/d (44 µg) and 1.1±3.7 mg/d (880 µg). Differences among the 3 treatment groups did not reach statistical significance due to the small sample size. Conclusion: In SAKURA Study 1, all but one subject who were on oral corticosteroids at baseline were successfully tapered to ≤5 mg/day with intravitreal sirolimus 440 µg. These results support the potential use of intravitreal sirolimus to help patients taper corticosteroids to below recommended maintenance doses.