Official Title: An Open Label, Proof-of-Principle, Pilot Study to Evaluate Pimavanserin for the Treatment of Motor and Behavioral Symptoms of Tourette Syndrome.

NCT Number: Pending

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Data at baseline and scheduled follow up visits per study protocol will be collected in the form of standardized rating scales used to measure symptom severity in Tourette syndrome as described below.

The primary endpoint is the change in the Total Tic Score (TTS) of the Yale Global Tic Severity Scale (YGTSS) from baseline to week 8 in TS patients treated with pimavanserin. The goal is to see if pimavanserin has an effect on this score. A reduction in score would indicate a clinical benefit and vice versa.

If this score is reduced from baseline to week 8 while taking the study drug, this will suggest clinical benefit. Any degree of reduction in this score will be described as a suggestion of clinical benefit. A similar approach will be applied to the other scales mentioned in the study protocol. If there is suggestion of clinical benefit, we will consider this an indication of feasibility for a larger study.

Secondary endpoints include changes from baseline to week 8 in: - Yale-Brown Obsessive Compulsive Scale (Y-BOCS) - Tourette Syndrome-Clinical Global Impression (TS-CGI) score - Tourette Syndrome-Patient Global Impression of Impact (TS-PGII) score - Gilles de la Tourette syndrome-quality of life scale (GTS-QOL) - Global Severity Score (GSS) of the YGTSS - Motor Tic Severity Score (MTSS) of the YGTSS - Vocal Tic Severity Score (VTSS) of the YGTSS - YGTSS Impairment score - Proportion of patients who have a reduction of 6 or more points in the TTS of the YGTSS - Proportion of patients who have a TS-CGI reduction of 2 or more points - Observed values and change in patient-assessed Tic-free Interval assessment.

All these variables will be analyzed over the 8 week treatment period. The data will be analyzed using standardized software and statistical tools as indicated. The data will be presented in the form of graphs/tables showing the change in scores over the 8 week treatment period.

Safety Analyses: All adverse events will be coded using the Medical Dictionary for Regulatory Activities. Summaries will be presented for all adverse events, adverse events determined by the investigator to be related to study treatment, serious adverse events, and adverse events causing withdrawal from the study. Patient listings of serious adverse events and adverse events leading to withdrawal will be presented. Observed values and changes from baseline in laboratory results, vital signs and EKG parameters will be summarized descriptively. The use of concomitant medications will be monitored and will include all medications taken while the patient is treated with IMP.

Observed values in the C-SSRS will be monitored for all patients.