## INTRODUCTION

The Advanced Systemic Mastocytosis Symptom Assessment Form (AdvSM-SAF) was developed to assess the signs and symptoms of advanced systemic mastocytosis (AdSMa), a rare condition characterized by neoplastic cell infiltration of tissues and chronic untreated survival. The AdSM-SAF is a 10-item diary that assesses eight symptoms of AdSM including abdominal pain, nausea, diarrhea, itching, flushing, and fatigue. Using a 24-hour recall period, eight items assess symptom severity with an 11-point numerical rating scale, where 0 is no problem and 10 indicates the worst health imaginable. Of the eight items, vomiting and diarrhea are scored as frequency items (vomiting and diarrhea) assess symptom frequency by asking subjects to enter a specific numerical value. The remaining six items (abdominal pain, nausea, itching, flushing, and fatigue) are scored as severity items. These items are measured using a 11-point numerical rating scale asking subjects to rate the severity of each symptom on a scale of 0 to 10, with 0 being no problem and 10 indicating the worst health imaginable.

Psychometric analysis of the AdSM-SAF is supported by other clinical and PRO studies. Four-week and PRO measures in BLU-285-2101 indicated a high degree of internal consistency when 11 items shown in the measure are uniformly measured. Chronic mastocytosis (α>0.70) was investigated by calculating Cronbach’s alpha coefficient. Cronbach’s alpha coefficients for all four-week and PRO were all reliable (>0.7), except the vomiting frequency item. Weekly PRO measures in BLU-285-2101 indicated a high level of internal consistency when items shown in the measure are uniformly measured. Weekly PRO measures in BLU-285-2101 indicated a high level of internal consistency when items shown in the measure are uniformly measured. Weekly PRO measures in BLU-285-2101 indicated a high level of internal consistency when items shown in the measure are uniformly measured. Weekly PRO measures in BLU-285-2101 indicated a high level of internal consistency when items shown in the measure are uniformly measured. Weekly PRO measures in BLU-285-2101 indicated a high level of internal consistency when items shown in the measure are uniformly measured.