Qualification of Symptoms of Major Depressive Disorder Scale, a Patient-Reported Outcome Instrument for Measurement of Symptoms of Major Depressive Disorder

Date: November 27, 2017

DDT Type: Clinical outcome assessment (COA)

DDT Tracking Number: DDTCOA-00008

Referenced COA: Symptoms of Major Depressive Disorder Scale (SMDDS)

Type of COA: Patient-Reported Outcome (PRO) Instrument

The Center for Drug Evaluation and Research has determined that the SMDDS is qualified for exploratory use to measure symptoms of major depressive disorder (MDD) in the context of use described below.

Section I: COA Concept of Interest

The SMDDS total score measures overall symptoms of MDD.

Section II: Context of Use

This qualification statement supports exploratory use of the SMDDS as a measure of symptoms of MDD in drug development. Further evaluation is needed on the instrument's longitudinal measurement properties and the interpretation of clinically meaningful within-patient change in score. This information can be obtained in early phase studies in drug development programs.

Sponsors seeking to use the SMDDS as a primary or secondary endpoint in confirmatory studies should discuss with the appropriate CDER review division. The instrument's longitudinal measurement properties will need to be evaluated prior to consideration for labeling. As further supportive experience with the SMDDS accumulates, the qualification statement could be expanded to include use of the SMDDS as part of a primary or secondary efficacy endpoint in confirmatory studies.

A. Study population

The recommended target patient population is described as follows:

- Adults aged 18 years and older
- Clinical diagnosis of MDD
- Treated in an ambulatory setting
- Experienced a major depressive episode within the last 6 months

- HAM-D score >18
- Meets the DSM-IV or DSM-V criteria for MDD

The SMDDS has not been assessed in patients with a history of:

- Personality disorder
- Bipolar disorder
- Schizophrenia or other psychotic disorder
- Cognitive impairment (e.g., dementia)
- Significant risk for suicide
- Evidence of recent history (past 12 months) of drug or alcohol abuse

B. Labeling or promotional claim(s) based on the COA

After the SMDDS's longitudinal measurement properties and the interpretation of clinically meaningful within-patient change have been evaluated, the SMDDS total score is intended to support labeling claims related to change in overall symptoms of MDD.

Section III: Interpretation of Change

Information to support thresholds for clinically meaningful within-patient changes in the SMDDS total score is needed. We recommend that data to interpret clinically meaningful within-patient change in the SMDDS total score be gathered and evaluated in early phase development prior to its use in confirmatory studies.

Section IV: Contact Information for Access to the Qualified COA

Patient-Reported Outcome Consortium
Critical Path Institute

1730 E. River Road
Tucson, AZ 85718
For more information, please send email to: procadmin@c-path.org; Subject: SMDDS Inquiry

Instructions for Use in a Regulatory Submission: Please reference DDT # 00008 in your regulatory application.