Use of an Artificial Intelligence Platform on Mobile Devices to Assess Dosing Compliance in a Phase 2 Schizophrenia Study

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ABSTRACT

Objective: Accurately monitoring and collecting drug adherence data can be a labor-intensive process during a schizophrenia clinical trial. The primary objective of this substudy was to determine the utility of the artificial intelligence (AI) platform on mobile devices in measuring medication adherence compared with modified direct observation (mDOT) for the assessment of adherence in subjects with schizophrenia.

Methods: The use of an AI platform was assessed in a Phase 2 study using the AI platform to measure medication adherence and to examine the feasibility of using the platform in a 6-month, Phase 2 study. The study was a 24-week, randomized, placebo-controlled, parallel-group, dose-ranging, multicenter study in subjects with schizophrenia. The primary objective of this substudy was to evaluate the use of the AI platform compared with modified DOT (mDOT) 3 times per week during a clinical study (Study M10-855) of an investigational antidepressant and placebo in subjects with schizophrenia.

Conclusions: Medication adherence results from an AI substudy using the AI platform were compared with mDOT results. The AI platform demonstrated high adherence rates for all study groups, with a rate of 79.4% for subjects monitored using the AI platform compared with 77.5% for subjects monitored using mDOT.

RESULTS

The present report describes medication adherence results from an exploratory pilot substudy using the AI platform compared with mDOT (n = 16 subjects) as part of a 24-week clinical study to assess the feasibility of using the AI platform to monitor medication adherence. The study included 16 subjects (n = 16) randomized to placebo or ABT-126. Subjects were dosed once daily (QD) 25, 50, or 75 mg ABT-126 or matching placebo, and 3 (15.8%) subjects in the morning for 24 weeks. Adherence was measured by review of returned study drug blister packs and by collection of pharmacokinetic blood samples for analysis of ABT-126 plasma concentrations.

CONCLUSIONS

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REFERENCES


2. AUTHORS DISCLOSURE

We wish to report the following author relationships and conflicts of interest: Earle Bain, MD, holds the Chair Investigator of Neuroscience Clinical Development, Abbott, and Dali Wang, employees of Abbott for their help in preparing and assisting with the primary database.

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