ABSTRACT – ISCTM FALL 2016

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

Authors: Bain, EE[1]; Shafner, L[2]; Walling, D[3]; Othman, A[1,4]; Chuang-Stein, C[5]; Hinkle, J[6]; Hanina A[2].

Methodological questions being addressed: Accounting for and minimizing subject nonadherence is critical to clinical trial design, particularly in CNS where high rates of nonadherence are observed.

Introduction: Accurately monitoring and collecting drug adherence data can allow for a better understanding and interpretation of the outcomes of clinical trials. The majority of clinical trials use a combination of pill counts and self-reported data to measure drug adherence, despite the drawbacks of relying on these types of indirect measures. It is assumed that doses are taken, but the exact timing of these is often incomplete and imprecise. The objective of this pilot study was to evaluate the use of a novel artificial intelligence (AI) platform on mobile devices in measuring medication adherence compared with modified directly observed therapy (mDOT) in a substudy of a Phase 2 trial of the α7 nicotinic receptor agonist, ABT-126 in subjects with schizophrenia.

Methods: Ten out of 31 US sites participated in the substudy adherence program. Subjects were allowed to choose between the AI platform or mDOT (three times per week). Subjects monitored by the AI platform were assigned a device with the AI application downloaded. Subjects used the application for each dosing administration. A total of nine phamacokinetic blood samples for analysis of ABT-126 plasma concentrations were collected. The main adherence measures for

the analyses were based on scheduled pharmacokinetic sampling results and AI platform adherence data.

Results: A total of 75 subjects were enrolled in the substudy; 22 chose to be monitored by mDOT. The early discontinuation rate in the AI group (32.1%) was similar to the early discontinuation rate at the 21 US sites not participating in the AI substudy (27.2%). The mean (SD) cumulative pharmacokinetic adherence over 24 weeks was 89.7% for subjects receiving ABT-126 and monitored using the AI platform compared with 71.9% for subjects monitored by mDOT. The US sites not participating in the AI substudy had cumulative adherence over 24 weeks of 78.1% (n = 69).

Conclusions: Subjects receiving ABT-126 and monitored using the AI platform had higher cumulative adherence (89.7%), as measured by study drug concentrations above the lower limit of quantification (LLOQ) over 24 weeks, compared with subjects monitored by mDOT (71.9%). Using drug levels, this substudy demonstrates the potential of artificial intelligence platforms to increase adherence, rapidly detect nonadherence, and predict future nonadherence. Subjects monitored using the AI platform demonstrated a percentage change in adherence of 25% over the mDOT group. Subjects were able to use the technology successfully for up to 6 months in an ambulatory setting with early termination rates comparable to subjects outside the substudy.

Disclosures and Acknowledgements: We thank George M. Haig, lead investigator Department of Neuroscience Clinical Development, Abbvie, and Deli Wang, employees of Abbvie for their help in preparing and assisting with the primary dataset.

David Walling, PhD, reports grant and research support from Novartis, J&J PRD, Sunovion, Janssen, Pfizer, Shire, Eli Lilly, Abbott, Abbvie, Forest, Allergan, Eisai, Takeda, Otsuka, Zogenix, Omeros, CoMentis, IntraCellular and is consultant to Otsuka, Eli Lilly, Janssen, and Acadia. John E. Hinkle, PhD, has active consulting agreements with AiCure and several drug discovery, pharmaceutical, medical food and contract research organizations. Christy Chuang-Stein, PhD, reports consulting agreements with AiCure, AstraZeneca, Abbvie, TEVA, Amgen, and Merck Serono. Earle Bain, MD, and Ahmed A Othman, PhD, are employees and shareholders of Abbvie.

[1]Abbvie Inc., North Chicago, IL, USA

[2] AiCure, 19 West 24th Street, New York, NY, USA

[3] CNS Network, LLC., Garden Grove, CA, USA

[4]Faculty of Pharmacy, Cairo University, Cairo, Egypt

[5] EarlyPhase Sciences, Inc.

[6] Principal Consultant, Chuang-Stein Consulting