and improved adherence among the top treatment benefits. Barriers to LAI use commonly cited by patients/caregivers included side effects and lack of effect on negative symptoms, while common barriers cited by HCPs included patient access/cost and limited knowledge around best prescribing practices. Treatment comparisons and/or switching were more commonly mentioned among patients/caregivers (51%) than HCPs (30%), suggesting a greater interest in optimizing treatment among patients. Patients/caregivers often compared individual LAIs with oral antipsychotics (OAs) or different LAIs, whereas it was more typical for HCPs to compare LAIs with OAs than to distinguish between different LAIs.

Conclusions. Based on social media posts, patients/caregivers and HCPs had different primary treatment goals/concerns and generally used different lexicons, which may affect communication. Overall, HCPs were more positive and less negative toward LAIs than patients/caregivers. Top benefits noted (relapse and adherence) were similar between groups, while top treatment barriers differed. These differences highlight the need to improve communication between patients/caregivers and HCPs in order to increase treatment satisfaction and potentially improve treatment outcomes.

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EMPOWERing the Next-Generation: A Phase 2 Program to Evaluate Emraclidine, a Selective M4 Positive Allosteric Modulator (PAM), for the Treatment of Schizophrenia

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Background. Emraclidine is a novel, highly selective positive allosteric modulator of M4 muscarinic acetylcholine receptors currently in development for the treatment of schizophrenia and Alzheimer's disease psychosis. By selectively activating M4 receptors, emraclidine may reduce excess dopamine signaling in the striatum, potentially leading to a reduction in psychotic symptoms. Unlike current antipsychotics, emraclidine does not interfere with signaling at dopamine, serotonin, or histamine receptors, which can lead to adverse events. A previous phase 1b study supports further investigation of emraclidine. The phase 2 EMPOWER program will fully evaluate the efficacy, safety, tolerability, and dose-range of once-daily (QD) emraclidine in schizophrenia.

Methods. EMPOWER-1 and EMPOWER-2 are two adequately powered, multicenter, randomized, double-blind, placebo-controlled, parallel group, 6-week inpatient studies of emraclidine monotherapy (10 mg QD, 15 mg QD, 30 mg QD). The trials are enrolling adult participants with schizophrenia who are experiencing an acute exacerbation of psychosis. Eligible participants will have a Positive and Negative Syndrome Scale (PANSS) Total Score between ≥85 and ≤120 and a Clinical Global Impression – Severity (CGI-S) score ≥4 at baseline. Both de novo participants and those who complete EMPOWER-1 or EMPOWER-2 will be eligible to participate in EMPOWER-3, a 52-week open label extension trial to evaluate the long-term safety and tolerability of emraclidine in adult participants with stable schizophrenia.

Results. Detailed study designs for the EMPOWER program will be presented. Primary outcome measure for EMPOWER 1 and 2 is change from baseline in PANSS total score at week 6. Other outcome measures include change from baseline in CGI-S score at week 6. Data from EMPOWER-3 will contribute to the overall evaluation of safety and tolerability of emraclidine in adult participants with schizophrenia.

Conclusions. The development of emraclidine is promising, as it selectively activates M4, a novel target that has been implicated in reducing psychotic symptoms while potentially avoiding many of the side effects currently associated with antipsychotics. The EMPOWER program aims to establish the efficacy, safety, tolerability, and appropriate dose-range of emraclidine in the treatment of schizophrenia.

Funding. Cerevel Therapeutics

Use of the Modified Functional Status Questionnaire to Assess Functioning in Patients with Parkinson's Disease Psychosis Treated with Pimavanserin

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Introduction. Patient-reported outcomes (PROs) are increasingly collected in clinical trials and real-world studies as they provide valuable information on the impact of a treatment from the patient's perspective. Studies in Parkinson's disease psychosis (PDP) have focused on hallucination and delusions, however individuals with PDP also face functional limitations associated with worsening psychosis. Assessing activities of daily living (ADLs) and functioning of PDP patients can help inform PDP treatment. The International Parkinson and Movement Disorder Society has recommended the use of the Functional Status Questionnaire (FSQ) which has been infrequently utilized. Prior results were reported from a Phase 4 open-label study examining the impact of pimavanserin on ADLs and

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