

of PGI-C responders: fasedienol 40.6% vs. placebo 18.6% ($p=0.003$). Fasedienol was well-tolerated with no treatment-emergent adverse events above 1.5% occurrence.

Conclusion. The Phase 3 PALISADE-2 trial results demonstrated that a single dose of fasedienol prior to a stressful PSC produced efficacy on patient-rated SUDS and PGI-C, as well as the clinician-rated CGI-I. The results also confirmed the nasal-amygdala neural circuits as a new portal for administration of pharmaceuticals. The data support continued development of fasedienol as a first-in-class, rapid-onset, well-tolerated treatment option for SAD without addictive properties.

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Feasibility of a Risperidone Implant for the Maintenance Treatment of Schizophrenia for up to 12 Months After a Single Administration

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Introduction. Disruptions of antipsychotic therapy lead to greater symptoms and increased likelihood of relapse. One way to improve medication adherence has been with long-acting formulations, usually administered by injection. Implantable technology has been used to support medication continuity in a few therapeutic areas, e.g., contraception. Despite the potential benefits from implants, this modality is not yet available for maintenance treatment of schizophrenia. Delpor, Inc. is developing an investigational risperidone implant (DLP-114) that releases therapeutic drug levels for up to 12-months. Initial clinical findings are reported below.

Methods. The DLP-114 implant is a titanium cylinder approximately 4-5 cm long and 5 mm in diameter. It has membranes mounted on each end and is loaded with a proprietary formulation of risperidone.

The clinical study (NCT04418466) was an open-label study in stable schizophrenia patients to evaluate the safety, tolerability, and pharmacokinetics (PK) of switching from oral risperidone to DLP-114. Schizophrenia patients ($N=28$), stable on a 2-3 mg dose of oral risperidone for ≥ 2 weeks were randomized to receive either 6- or 12-month DLP-114 implant devices. Each patient received two DLP-114 devices implanted in the abdomen. Device placements were conducted through a 10-minute procedure using local anesthetic and a custom placement tool. Plasma levels of risperidone and 9-hydroxyrisperidone were tracked over the treatment period, and patients were clinically monitored for signs of relapse. Patient safety (including local tolerance and emergent AEs) and PK were the principal endpoints. Secondary clinical endpoints included PANSS and CGI scores.

Results. The placement and removal procedures were well tolerated. Of 28 enrolled patients, two were lost to follow up and one asked to have the implant removed prior to the end of the dosing period. One nonrelated SAE (pulmonary embolism) was reported. Treatment-related AEs were generally mild, and included implant site pain/soreness/tenderness, drowsiness, ecchymosis, increased appetite, insomnia, and headache. The PK profile in both groups followed near zero-order kinetics with both dosing periods until the end of study. The average steady-state plasma concentration ranged between 7-13 ng/mL. One patient was removed from the study with signs of impending relapse. All other patients were clinically stable for the study duration, with average PANSS scores from 50-60 and CGI-I scores from 3-4. PANSS and CGI-I scores were comparable between the oral and the implant phases of the study.

Conclusions. DLP-114 was well tolerated for up to 12 months. Average PANSS and CGI-I scores were similar between the oral and implant treatment phases, suggesting that, for most patients, DLP-114 provided a comparable therapeutic benefit to 2-3 mg of daily oral risperidone over time. Plasma concentrations of risperidone and 9-hydroxyrisperidone were substantially constant for 6-12 months, but values for steady-state Cave fell slightly below the target of 10-14 ng/mL.

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A Veteran with PTSD and Bipolar Disorder Type I with Psychotic Features

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This case discusses a 33-year-old transgender Army Veteran, diagnosed with co-occurring Bipolar Disorder Type 1 (Bipolar I) and Post-Traumatic Stress Disorder (PTSD), both with psychotic features. The patient exhibited recurrent mood swings, delusions, auditory hallucinations, and passive suicidal thoughts. Concurrent symptoms, such as disrupted sleep, irritability, and intrusive thoughts, complicated diagnosis and treatment. The patient's medical history included migraines, chronic pain, medication-induced seizures, traumatic brain injury (TBI), and Borderline Personality Disorder.

During the assessment, the patient displayed mood fluctuations, cognitive issues, and intermittent tearfulness. They were averse to sedative medications and preferred non-pharmacological approaches. The Alpha-Stim (Cranial Electrical Stimulator – CES) was recommended for anxiety, depression, insomnia, and chronic pain.

Medication options (Aripiprazole, Lurasidone, and Risperidone) were discussed, and the patient chose Aripiprazole. The