A summary of safety outcomes is shown in Table 2.

Pseudobulbar affect (PBA) occurs secondary to certain neurologic diseases or injuries affecting the brain. These findings underscore the importance of careful neurologic and psychiatric evaluation and treatment. Such outbursts are often embarrassing, leading to social isolation and negatively impacting quality of life.

Objective

- Evaluate the prevalence of neurologic and psychiatric comorbidities in patients with PBA among PRISM II and PRISM III trial populations.

Methods

- Open-label, 90-day, US multicenter trial (NCT01799941).
- Eligibility:
  - >18 years of age
  - ≤12 months from the first onset of PBA symptoms
  - MMSE ≥20
  - If ≤20, CDR ≤2

- All patients have prior confirmatory neurologic diagnosis of stroke, TBI, or dementia
- No concurrent enrollment in another clinical trial
- Open-label, 90-day, US multicenter trial (NCT01799941)
- All patients have prior confirmatory neurologic diagnosis of stroke, TBI, or dementia
- No concurrent enrollment in another clinical trial

- Patients enrolled in either phase IIb/III trial were allowed to enroll in this study; however, PBA often goes undiagnosed or may fail to be differentiated from other conditions.

Results

- CNS-LS scores improved significantly at Day 30 and 90 compared with baseline (all P<0.05).
- Table 2 shows a significant reduction in depression (CNS-LS, episode count and PHQ-9) concomitant diseases and medications.

Primary Endpoint

- CNS-LS scores were significantly reduced from baseline at Day 30 and 90 compared with baseline (P<0.05; 90-day change: 26.0 (23.0%)).

Secondary Endpoints

- Table 1 shows a significant reduction from baseline at Day 30 and 90 compared with baseline (P<0.05; 90-day change: 12.2 (10.4%)).
- Table 1 shows a significant reduction from baseline at Day 30 and 90 compared with baseline (P<0.05; 90-day change: 12.2 (10.4%)).

Conclusions

- Neurological and psychiatric comorbidities assessment in the PRISM II study of dextromethorphan/quinidine for treatment of pseudobulbar affect.