A phase IIa trial studying the safety and tolerability of IRL752 in patients with Parkinson's disease dementia

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Session Information

Date: Monday, September 23, 2019

Session Time: 1:45pm-3:15pm

Session Title: Clinical Trials, Pharmacology and Treatment

Location: Agora 3 West, Level 3

Objective: The primary objective was to investigate the safety and tolerability of IRL752 in PD patients with dementia in a randomized controlled trial. Secondary outcome measurements related to efficacy on cognitive, motor and emotional symptoms.

Background: IRL752 is a novel small molecule compound which acts to enhance monoaminergic prefrontal cortical neurotransmission. It is developed as a potential treatment for symptoms and signs associated with cortical impairment in Parkinson's disease (PD).

Method: PD patients with dementia were randomized to IRL752 or placebo treatment (3:1 ratio) for 4 weeks. Study drug was given as an adjunct treatment to the patients' regular stable antiparkinsonian medication. Dosing was individually titrated for 14 days after which dosing was kept stable for an additional 14 days.

Results: Thirty-two patients were randomized to treatment and 29 patients completed the four-week treatment. Adverse events were generally mild and transient and were mostly reported during the titration phase of the trial. There were two serious adverse events, none of the related to the experimental treatment. The average dose achieved in the stable dose phase was 600 mg daily, yielding a 2-hour post-dose plasma concentration of about 4 μM on Day 28. Exploratory assessment for efficacy outcomes indicated that IRL752 treatment may improve apathy, executive function, postural and axial control, symptoms known to be unresponsive to L-dopa in patients with PD.

Conclusion: IRL752 can be safely administered to patients with PD and dementia. Exploratory efficacy outcome measures indicate that IRL752 could be used to treat L-dopa unresponsive symptoms. These results will be of guidance for the design of further efficacy studies.

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