



## ALZHEIMER'S DISEASE & RELATED AGITATION

Of the approximately 5.5 million people in the U.S. with dementia, it is estimated that 60-80 percent have Alzheimer's disease.<sup>1,2</sup> Behavioral symptoms develop in the majority of people with Alzheimer's disease and many of these symptoms are clinically diagnosed as agitation; including wandering, restlessness, significant emotional distress, aggressive behaviors, and irritability. It is estimated that agitation symptoms affect nearly 50 percent or more of patients with Alzheimer's disease.<sup>3</sup>

Symptoms of agitation place a serious burden on the people afflicted with the disease and their caregivers, significantly affecting the quality of life for all concerned. Agitation is often a determining factor in the decision to place patients in high-level residential care facilities, contributing to the ~\$259 billion cost associated with Alzheimer's disease in the U.S. for 2017.<sup>1</sup>

### CLINICAL RESEARCH STUDY

Otsuka Pharmaceutical Development & Commercialization, Inc. (Otsuka) has started a Phase 3 study of brexpiprazole in the treatment of agitation in patients with dementia of the Alzheimer's type. This study will compare the efficacy of 2 doses of brexpiprazole with placebo in subjects with agitation associated with Alzheimer's disease.

Approximately 300 patients are expected to be enrolled in this 12-week study. The study population will include subjects between 55 and 90 years of age (inclusive) with a diagnosis of probable Alzheimer's disease, who are residing either in an institutionalized setting or in a non-institutionalized setting and have been diagnosed with symptoms associated with agitation.

### BREXPIRAZOLE

Brexpiprazole is an atypical antipsychotic co-developed by Otsuka and Lundbeck. Brexpiprazole is approved in the United States for use in adult patients for the treatment of schizophrenia and as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD). It is also approved in Canada and Australia in adult patients for the treatment of schizophrenia.

### PREVIOUS CLINICAL RESEARCH EXPERIENCE

Two phase III clinical studies were previously conducted evaluating the efficacy, safety and tolerability of brexpiprazole in the treatment of agitation in patients with Alzheimer's disease. Improvements were seen against both the primary and secondary endpoints; change from baseline total score in the Cohen-Mansfield Agitation Inventory (CMAI) and change from baseline score in the Clinical Global Impression-Severity of Illness (CGI-S), respectively. Following the completion of the studies, results confirmed the safety and tolerability profile obtained from studies for schizophrenia and major depressive disorder (MDD).

## ADDITIONAL INFORMATION

If you have any additional questions please contact Michael Ward:  
michaeljames.ward@syneoshealth.com, or visit the link below for a study pre-  
screener to review potential patient eligibility,

[leapcurealzag.studies.leapcure.com/?lang=en-us&utm\\_source=AAGP&utm\\_medium=article&utm\\_campaign=ALZ](http://leapcurealzag.studies.leapcure.com/?lang=en-us&utm_source=AAGP&utm_medium=article&utm_campaign=ALZ)

## SITE INFORMATION

SITE NAME	CITY	STATE	ZIP
Research in Miami Inc	Hialeah	FL	33013
ATP Clinical Research, Inc.	Costa Mesa	CA	92626
Premier Clinical Research Institute, Inc	Miami	FL	33122
Maxblue Institute Inc.	Hialeah	FL	33018
Galiz Research	Hialeah	FL	33016
Richard H Weisler, MD, PA	Raleigh	NC	27609
Arocha Research Center	Coral Gables	FL	33134
Neurology Center of North Orange County	Fullerton	CA	92835
Michigan Clinical Research Institute PC	Ann Arbor	MI	48105
Arch Clinical Trials, LLC	St. Louis	MO	63118
Advanced Clinical Research	Coral Gables	FL	33134
Clinovation Research, LLC	Weston	FL	33327
Centex Studies, Inc.	Houston	TX	77058
Allied Biomedical Research Institute	Miami	FL	33155
IMIC Inc	Palmetto Bay	FL	33157
Bio Behavioral Health	Toms River	NJ	08755
Shreenath Clinical Service	Lakewood	CA	90805
Georgia Neurology and Sleep Medicine Associates	Suwanee	GA	30024
MD First Research, LLC	Chandler	AZ	85226
Alzheimer Disease Center	Winchester	MA	01890
Territory Neurology & Research Institute	Tucson	AZ	85704
Gadolin Research, LLC	Beaumont	TX	77702
UWF Clinical Trials	Pensacola	FL	32514
Bio Pharma Informatic Inc.	Houston	TX	77084
SC3 Research	Pasadena	CA	91105
Nova Clinical Research, LLC	Bradenton	FL	34209
Global Clinical Trials	Costa Mesa	CA	92627
Precise Research Centers	Flowood	MS	39232
Integrative Clinical Trials LLC	Brooklyn	NY	11229
Axis Clinical Trials	Los Angeles	CA	90036

<sup>1</sup> Alzheimer's Association. 2017 Alzheimer's disease facts and figures. 2017;13:325-373 <sup>2</sup> Alzheimer's Disease International, The world Alzheimer's report 2015; 30

<sup>3</sup> Bergh, S. and Selbæk, G. The prevalence and the course of neuropsychiatric symptoms in patients with dementia. Norsk Epidemiologi 2012; 22 (2): 225-232