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Results of Analysis of the OASIS Study, a Large-Scale Health-Related QOL Study in Patients with Chronic Cerebral Infarction

Tokyo, Japan—Feb. 21, 2008—Having completed the OASIS Study,*¹ Japan's first large-scale study with respect to health-related quality of life (below, "health-related QOL"*) in Chronic Cerebral Infarction , Kyorin Pharmaceutical Co., Ltd. (Tokyo, President: Ikuo Ogihara), a subsidiary of Kyorin Co., Ltd., presented the study results at the International Stroke Conference 2008 at New Orleans, Louisiana, USA on February 20 local time.

*Health-Related QOL: Quality of life (QOL) used in the assessment of medical care, defined as a concept limited to issues stemming from personal health and not encompassing financial matters or other factors arising from the social environment

The OASIS Study aimed at 1) assessing health-related QOL and 2) investigating the relationship between health-related QOL and dizziness in patients with chronic cerebral infarction in Japan. This epidemiological study was performed at 162 institutions from July 2005 to June 2007, with Yukito Shinohara MD, PhD, (a director of Federation of National Public Service Personnel Mutual Aid Associations Tachikawa Hospital and chair of The Japan Stroke Society) chairing the study. The study population consisted of 2069 Japanese patients with chronic cerebral infarction. Verification of health-related QOL relied on the SF-36v2*² score, an index used worldwide, in addition to a survey covering a range patient information.

A summary of the presentation follows:

* Japanese patients with chronic cerebral infarction exhibited a low health-related QOL score, as did their counterparts in other countries. The results suggested that patients require therapies oriented to health-related QOL.

* The determination of health-related QOL in Japanese patients with chronic cerebral infarction with SF-36v2 revealed a number of characteristics:

- A close relationship was recognized between the severity of cerebral

infarction and the physical health-related QOL score.

- Female with chronic cerebral infarction patients exhibited an inferior degree of physical and mental health in comparison with male patients.

* Japanese patients are more prone to dizziness as a subjective symptom. It was clarified that treatment of dizziness was important, since the symptom adversely affected health-related QOL.

Kyorin Pharmaceutical Co., Ltd. will clarify details of health-related QOL in Japanese patients with cerebral infarction by means of a sub-analysis of the study results and will also verify the significance of the use of Ketas (common name: ibudilast), a drug for cerebrovascular disorders. The results will be reported at relevant academic meetings in Japan and overseas. Kyorin Pharmaceutical Co., Ltd. will continue to contribute to the treatment of chronic cerebral infarction from the perspective of health-related QOL.

*¹: OASIS Study: Outcome Assessment using SF-36v2 in stroke patients

*²: SF-36v2: MOS Short-Form 36-Item Health Survey. A scientifically reliable and valid scale for determining health-related QOL. SF-36v2 is characterized by a structure based on a common concept of health-related QOL for everyone, without being limited to specific illnesses. It enables the determination of health-related QOL, both for patients having different illnesses and generally healthy people. Following a comprehensive discussion from the stage of the construction of the concept through computational-psychological verification, SF-36v2 is used widely around the world, having been translated into over 60 languages.

OASIS Study Summary

Subjects: 2069 patients with cerebral infarction more than 1 month after onset
Period: July 2005 to June 2007
Observation time: Enrollment, Week 8 and Week 24
Study type: Epidemiological study (based on observation)
Study items: 1) Backgrounds (e.g., symptoms, presence of rehabilitation and concomitant medication)
2) Effects of therapy (for dizziness, depression and others)
3) QOL survey (with SF-36v2)

Ketas

Ketas (common name: ibudilast) is a drug for asthma and cerebrovascular disorders developed internally by Kyorin Pharmaceutical Co., Ltd., which released it in 1989. In the treatment of cerebrovascular disorders, the drug is indicated for dizziness caused by chronic cerebral circulatory disorders accompanying the aftereffects of cerebral infarction. The usefulness has been shown in re-evaluation in a placebo-controlled double blind comparative study.

Cerebral infarction

Cerebral infarction is a variation of stroke. It hinders blood circulation because brain blood vessels are blocked or narrowed. Stroke is the third leading cause of death in Japan, following cancer and heart disease. According to statistics by the Ministry of Health, Labour and Welfare, around 1,500,000 patients are hospitalized or attending hospital because of stroke (there are about 1,130,000 patients with chronic cerebral infarction). The average number of days of hospitalization is longer for stroke patients than for patients presenting with any other diseases or disorders. Stroke is a very significant disease since it has the highest mortality rate of all afflictions and once it occurs, it imposes a heavy physical and economic burden on the patient and the patient's family.

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