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To all media outlets

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**Revaluation of Cerebrovascular Uses for
Bronchial Asthma and Cerebrovascular Agent KETAS Capsules 10 mg**

Kyorin Pharmaceutical Co., Ltd. (Head office: Tokyo, President Ikuo Ogihara) has conducted post-launch, extraordinary clinical trials and submitted the results to the authorities for its bronchial asthma and cerebrovascular agent KETAS capsules 10 mg (Japanese generic name: Ibudilast). This activity comes in response to a government request to reevaluate the efficacy in cerebrovascular Uses. According to a notification by the authorities to Kyorin Pharmaceutical today (December 20, 2001), the Drug Revaluation Commission convened on November 27, 2001 found improvements in efficacy for vertigo in patients with chronic cerebral circulation impairment associated with sequelae of cerebral infarction.

Background

KETAS Capsules 10 mg received approval for anti-bronchial asthma and cerebrovascular disorders in January 1989. On September 28, 1999, the company was requested to conduct a revaluation of the cerebrovascular uses in terms of efficacy. The effect on the subjective symptoms of chronic cerebral circulation impairment associated with sequelae of cerebral infarction (main evaluation: vertigo; secondary evaluation: paresthesia and dysesthesia) was investigated by means of a randomized, placebo-controlled, double- blind, comparative study with a placebo run-in period. The revaluation application based on the results of clinical testing was provided to authorities (deadline of September 28, 2001).

Results

The KETAS patient group was found to have statistically higher, significant improvements in response to the subjective symptom of the main evaluation of vertigo compared to the placebo patient group. The clinical results are shown in Table One. The special clinical tests involved cerebral infarction and insufficient testing was done on sequelae of cerebral hemorrhage to allow for evaluation and was rejected from efficacy.

Table One: Improvement of vertigo * p ; risk rate () indicated Number of cases

	KETAS Group	Placebo Group	² test p value
Improvement rate(%)	50 . 0 (47 / 94)	18 . 7 (20 / 107)	p < 0 . 001

Follow-up actions

Within two weeks of notification from the authorities, Kyorin Pharmaceuticals will submit a modified request: improvements to vertigo due to chronic cerebral circulation impairment associated with sequelae of cerebral infarction

End of release

Inquiries

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