Approval for Additional Indication of Pheochromocytoma for Dacarbazine Injection 100

Tokyo, Japan, March 25, 2013 --- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Nobuo Hanai, “Kyowa Hakko Kirin”), announced today that Dacarbazine Injection 100 (generic name: dacarbazine), which is manufactured and marketed in Japan, has been approved for the additional indication of pheochromocytoma by Japan's Ministry of Health, Labour and Welfare (“MHLW”).

According to international guides and overseas clinical practice guidelines, combination therapy of cyclophosphamide, vincristine and dacarbazine (“CVD therapy”) is one choice for the treatment of pheochromocytoma. However, CVD therapy was not covered by the Japanese national health insurance system for the treatment of pheochromocytoma.

In this situation, groups including the Japan Endocrine Society and an association to consider pheochromocytoma requested an additional indication for each drug within CVD therapy. The Review Committee on Unapproved or Off-Label Drugs with High Medical Needs determined on March 23, 2012 that there is a high medical need for CVD therapy for pheochromocytoma. Kyowa Hakko Kirin received a request from the MHLW on April 6, 2012 to develop dacarbazine for the additional indication of pheochromocytoma. With a prior evaluation that allowed use of a public knowledge-based application, at the Second Committee on Drugs, within the MHLW's Pharmaceutical Affairs and Food Sanitation Council, on October 31, 2012, Kyowa Hakko Kirin submitted an application, together with the two companies that manufacture and market cyclophosphamide and vincristine, to expand the label of dacarbazine within CVD therapy, with the scientific basis using publicly available documents.

Kyowa Hakko Kirin believes that the approval of the additional indication will significantly contribute to the treatment of pheochromocytoma.

About pheochromocytoma

A tumor that develops from the adrenal medulla or extra-adrenal paraganglion, and secretes large quantities of adrenaline and other catecholamines. Common symptoms include hypertension, palpitations, headache and sweating.

About Review Committee on Unapproved or Off-Label Drugs with High Medical Needs

This committee was established, in relation to drugs and indications that are allowed to use in Europe and/or the USA, but not in Japan, in order to promote development by pharmaceutical companies of unapproved and off-label drugs, by evaluating the requirement with respect to medical care, and verifying the applicability of public knowledge-based applications, and the appropriateness of additional studies necessary for the application for approval.

About public knowledge-based application

A type of application for drug approval, for an additional indication. For example, the scientific basis is publicly available information, and the efficacy and safety of the drug is publicly known on a medical and pharmacological basis, so some or all of the new clinical studies can be omitted.

About companies that manufacture these drugs

Cyclophosphamide Hydrate (Endoxan): Shionogi & Co., Ltd.

Vincristine Sulfate (Oncovin for Inj. 1mg): Nippon Kayaku Co., Ltd.