BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Daiichi Sankyo seeks approval for Diagnogreen

February 23, 2018 | News

Daiichi Sankyo Submits Application for Additional Indication and Dosage for DiagnogreenÃ¢â??â?¡ for Injection 25 mg in Japan



Daiichi Sankyo has has submitted a supplemental New Drug Application (sNDA) to Japan's Ministry of Health, Labour and Welfare (MHLW).

It is done for an additional indication and dosage for Diagnogreen for injection 25 mg (indocyanine green, ICG) for evaluation of blood circulation in vascular and tissues.

ICG is presently marketed in Japan with indications for liver function testing, cardiovascular function testing, and near-infrared fluorescence angiography during cerebrovascular surgery, and identification of sentinel lymph nodes in breast cancer and malignant melanoma.

However, a petition calling for the indication, "evaluation of blood circulation in vascular and tissues", was submitted by related scientific societies, and on December 22, 2017, the 33rd Review Committee for Unapproved or Off-label Use of Drugs with High Medical Needs recommended that a public knowledge-based application should be made concerning this indication.

Since ICG emits fluorescence in blood when exposed to near-infrared light, it is currently used for the purposes of confirmation of blood circulation during cerebrovascular surgery, etc.

The knowledge-based application has been already approved in European countries (including UK and Germany).

The drug is expected to be used widely in Japan as a means for visual and real-time confirmation of blood circulation during operation in various fields of surgery (vascular, cardiac, gastrointestinal, plastic etc.).

Daiichi Sankyo is committed to making unapproved and off-label drugs with high medical needs available to patients who are waiting for them to be approved.