US FDA expands use of Regeneron's Libtayo as add-on treatment for skin cancer

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Bengaluru: The U.S. Food and Drug Administration on Wednesday cleared Regeneron Pharmaceuticals' immunotherapy, Libtayo, as an add-on treatment for skin cancer patients at high risk of their disease returning after surgery and radiation, the drugmaker said.

Libtayo is already approved in the U.S. for advanced skin cancer, basal cell carcinoma, advanced non-small cell lung cancer and cervical cancer.

Regeneron said its approved application did not include contract drugmaker Catalent's Indiana facility as a fill-finish site for the drug. The FDA in August had declined to approve Regeneron's blood cancer therapy, odronextamab, citing its inspection of the facility.

The Bloomington, Indiana site handles the final stages of drug preparation and packaging for Regeneron's Eylea HD and odronextamab. The contract drugmaker was acquired by Novo Nordisk last year.

Following an inspection at the facility in June and July, the FDA issued six observations detailing a range of manufacturing lapses, including the improper investigation of contaminants - one of which was identified as cat hair.

Regeneron said in August it is working with regulators to resolve manufacturing issues at the site, which has delayed other drug approvals including Scholar Rock's muscle weakness therapy.

Libtayo was cleared Wednesday as an adjuvant treatment for adult patients with cutaneous squamous cell carcinoma (CSCC) - the second-most common form of skin cancer.

The approval is based on a late-stage trial with 415 patients, in which Libtayo reduced the risk of cancer recurrence or death by 68% compared with placebo.

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