In first for EU, anti-skin cancer drug approved

26 April 2019

French pharmaceutical giant Sanofi's new tumour-reducing drug is aimed at patients with the second most common form of skin cancer whose cancer is advanced and are who are not candidates for surgery or radiation therapy

French pharmaceutical giant Sanofi on Friday said the European Medicines Agency had conditionally approved its anti-cancer drug Libtayo, the first drug of its kind to be authorised for use in the EU.

The tumour-reducing drug is aimed at patients with the second most common form of skin cancer—cutaneous squamous cell carcinoma (CSCC)—whose cancer is advanced, and who are not candidates for surgery or radiation therapy.

Confirming the conditional approval, the agency added in a statement that it had "adopted a positive opinion, recommending the granting of a conditional marketing authorisation for the medicinal product Libtayo, intended for the treatment of advanced cutaneous squamous cell carcinoma".

"The benefits with Libtayo are its ability to reduce tumour size and to prevent progression of the tumour for longer," it said.

No drugs for the treatment of CSCC are currently approved in the EU, according to Sanofi.

Final approval of the drug will be given subject to Sanofi providing further results from clinical trials.

The US Food and Drug Administration (FDA) approved Libtayo in September 2018 while Health Canada gave it the conditional green light earlier this month.