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GSK files for approval on melanoma drug combo

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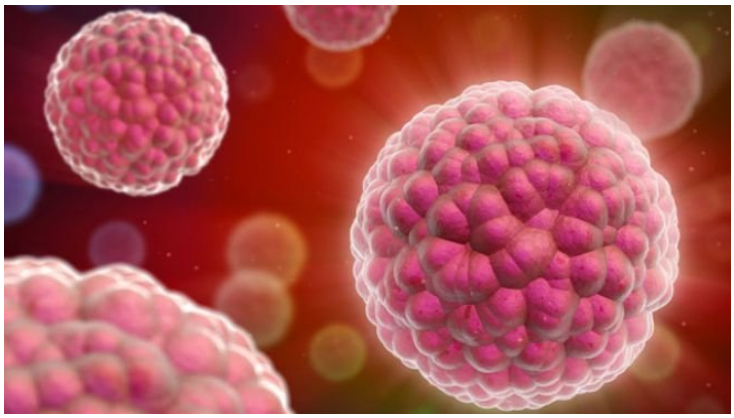

Singapore: Britian's leading drug maker, GlaxoSmithKline has filed for US Food and Drug Administration (US FDA) approval for its melanoma drug combo earlier than other competitors.

Using data from a mid-stage clinical trial, the pharma major submitted the combination of dabrafenib and trametinib to the US FDA. The two-drug combination against melanoma approval has been filed by the company much ahead of analyst expectations. Analysts reiterated that this move highlights a growing belief among drug companies that highly specific cancer drugs can prove their worth after relatively small-scale testing, speeding their path to market.

Making the announcement, GSK said that the submissions were made based on data from a randomized Phase I/II study.

The results of the final-stage Phase III data on the drug combination are expected towards the end of this year.

In May this year, the US FDA had approved the use of these two drugs separately and both the drugs are given as pills and are marketed under the brand names Tafinlar and Mekinist.