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EU nod for Novartis' skin cancer drug

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Novartis has announced that the European Commission has approved Odomzo(sonidegib, formerly LDE225) 200 mg capsules for the treatment of adult patients with locally advanced basal cell carcinoma (laBCC) who are not amenable to curative surgery or radiation therapy.

The EU approval of Odomzo was based on data from the Phase II randomized, double-blind, multi-center BOLT (Basal cell carcinoma Outcomes in LDE225 Trial) study in patients with laBCC not amenable to local therapy or metastatic basal cell carcinoma (mBCC). In patients with laBCC treated with Odomzo 200 mg, the objective response rate (ORR) was 56 percent per central review and 71 percent per investigator review. The median duration of response per central review has not been reached.

The median progression-free survival was 22 months per central review and 19 months per investigator review. The most frequent grade 3 and 4 adverse reactions occurring in at least 2 percent of patients treated with Odomzo 200 mg were fatigue, decreased weight and muscle spasms.

"We are pleased to have a new treatment option for European patients living with advanced basal cell carcinoma," said Mr Bruno Strigini, president, Novartis Oncology. He added, "This milestone follows the recent approval of Odomzo in the US and is the latest example of our commitment to precision oncology and developing targeted treatments to address unmet needs."

The EU approval follows a positive opinion adopted by the Committee for Medicinal Products for Human Use (CHMP) in June 2015 and applies to all 28 EU member states, plus Iceland, Norway and Liechtenstein. Outside the EU, Odomzo is approved in the United States, Australia and Switzerland. Additional regulatory submissions are being reviewed by health authorities worldwide.