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Novartis has announced that the US Food and Drug Administration (US FDA) has approved Odomzo (sonidegib, formerly LDE225) 200 mg capsules, for the treatment of adult patients with locally advanced basal cell carcinoma (laBCC), that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.

"The FDA approval of Odomzo offers a new and non-invasive treatment option for a potentially devastating disease that is hard to treat and can be disfiguring," said Mr Bruno Strigini, president, Novartis Oncology. He added, "Odomzo is an important addition to our growing portfolio of targeted treatments for advanced skin cancers and underscores our commitment to developing and bringing to market new options for patients."

The Odomzo approval was based on the demonstration of a durable objective response rate (ORR) in an international, multi-center, double-blind, randomized, two-arm, non-comparative trial in patients with laBCC not amenable to local therapy or metastatic basal cell carcinoma (mBCC).

Patients with laBCC treated with Odomzo 200 mg (n=66) were followed for at least 12 months unless discontinued earlier. The ORR was 58 percent(95 percent confidence interval: 45, 70), consisting of 5 percent (n=3) complete responses (CR) and 53 percent (n=35) partial responses (PR). A pre-specified sensitivity analysis using an alternative definition for CR, defined as at least a PR according to MRI and/or photography and no evidence of tumor on biopsy of residual lesion, yielded a CR rate of 20 percent. Among the 38 patients with an objective response, 31 patients (82 percent) have ongoing responses ranging

from at least 1.9 to 18.6 months and the median duration of response has not been reached.

The most serious risks of Odomzo are embryofetal toxicity and musculoskeletal adverse reactions including rhabdomyolysis. Musculoskeletal adverse reactions, which may be accompanied by serum creatine kinase (CK) elevations, may occur with Odomzo and other drugs which inhibit the hedgehog pathway. The incidence of musculoskeletal adverse reactions in patients with laBCC treated with Odomzo 200 mg was 68 percent, with 9 percent reported as grade 3 or 4.