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Investigator-assessed efficacy and safety of sonidegib 200 mg QD in patients with locally advanced basal cell carcinoma: Results of the BOLT 30-month analysis

Statement of the Problem: The 200-mg dose of sonidegib, a selective smoothened inhibitor that blocks hedgehog pathway signaling, was approved in Europe and the United States for the treatment of patients with locally advanced basal cell carcinoma (laBCC) who are not amenable to curative surgery/radiation. Approvals were based on results from the pivotal BOLT study (NCT01327053). Investigator-assessed efficacy and safety data of sonidegib 200 mg QD from the 30-month analysis are reported here.

Methodology & Theoretical Questions: Patients with laBCC were randomized to receive sonidegib 200 or 800 mg daily; here we discuss the 200-mg dose. Investigators evaluated objective response rate (ORR); complete response [CR]+partial response [PR]), duration of response (DOR), and progression-free survival (PFS) per modified response evaluation criteria in solid tumors (mRECIST; laBCC) and RECIST v1.1 (mBCC); overall survival (OS) was also assessed.

Findings: In patients with laBCC who received sonidegib 200 mg (n=66), the investigator-assessed ORR was 71%. Disease control rate was 91%; median DOR was 15.7 months, with 25/47 responders maintaining an objective response. The median PFS was 19.4 months and the median OS was not yet reached. One death was reported; it was not considered related to study treatment by investigators. The safety profile of sonidegib 200 mg was manageable; however, grade 3/4 adverse events (AEs; 43%), AEs requiring dose interruptions/reductions (43%), and/or discontinuations due to AEs (30%) were reported. Commonly reported AEs included muscle spasms (54%), alopecia (58%), and dysgeusia (60%).

Conclusion & Significance: In the BOLT 30-month analysis, sonidegib 200 mg QD provided sustained efficacy and long-term safety in patients with laBCC. Notably, these data were investigator-assessed, which are typically higher than data that are centrally reviewed. These data support the use of sonidegib 200 mg in difficult-to-treat patients with laBCC according to local treatment guidelines.

Biography

Michael Migden is a distinguished US-based Dermatologist and an Associate Professor, Departments of Dermatology, Division of Internal Medicine, and Head and Neck Surgery, Division of Surgery, at the University of Texas MD Anderson Cancer Center, Houston, TX, USA. At MD Anderson, he is a Program Director of the ACGME Fellowship: Micrographic Surgery and Dermatologic Oncology. He also serves as a Faculty Member in the Department of Ophthalmic Plastic and Reconstructive Surgery. He has served as a Principal Investigator for studies on the smoothened inhibitors sonidegib, vismodegib, and taladegib, and on immune therapy trials in non-melanoma skin cancer. He has published numerous primary and expert review articles on basal cell carcinoma.

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