SKIN CANCER (OTHER THAN MELANOMA)

LONG-TERM EFFICACY AND SAFETY OF SONIDEGIB IN ADVANCED BASAL CELL CARCINOMA ACROSS 42 MONTHS: FINAL RESULTS FROM THE BOLT TRIAL

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Introduction: Based on phase 2 BOLT data (Migden 2015; NCT01327053), sonidegib, a hedgehog pathway inhibitor (HPI), was approved in the US, EU, Switzerland, and AU for adult patients with locally advanced basal cell carcinoma (laBCC) not amenable to curative surgery or radiation therapy. Sonidegib was also approved in patients with metastatic BCC (mBCC) in Switzerland and AU.

Objective: Here we report efficacy and safety through 42 months from the phase 2 BOLT study, the longest follow-up data available for an HPI clinical trial in advanced BCC (aBCC).

Methods: BOLT was a randomized, double-blind, multicenter, phase 2 study where HPI treatment–naïve patients with laBCC or mBCC not amenable to curative surgery/radiotherapy were randomized 1:2 to sonidegib 200 mg or 800 mg QD, respectively. Tumor responses were assessed using BCC-modified Response Evaluation Criteria In Solid Tumors (mRECIST) for laBCC and RECIST v1.1 for mBCC. The primary endpoint was objective response rate (ORR) per central review as well as safety/tolerability. Data analyses were performed at the primary, 12, 30, and 42 months. Data for the approved 200 mg dose are reported here.

Results: The ORRs (central review) for laBCC 200 mg (n=66) were 47% at 6 months, 58% at 12 months, and 56% at 30-, and 42-months; per investigator review, ORR rates were higher: 65% (6 months) and 71% (12, 30 and 42 months). In patients with mBCC receiving 200 mg (n=13), the ORRs per central review were 15% at 6 months, and 8% at 12-, 30-, and 42-months; per investigator review, rates were higher: 23% at the 6-, 12-, 30- and 42-month analyses. Safety/tolerability was consistent through 42 months with no new AEs emerging following the primary analysis.

Conclusions: In patients with laBCC and mBCC, patients receiving 200 mg experienced consistent and robust efficacy and manageable tolerability over 42 months.