SKIN CANCER (OTHER THAN MELANOMA)

SUBANALYSES OF OBJECTIVE RESPONSE RATES: FINAL 42-MONTH RESULTS FROM THE BOLT STUDY

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Introduction: Based on the primary results of the phase 2 BOLT study (NCT01327053; Migden 2015), sonidegib 200 mg was approved in the US, EU, Switzerland, and Australia for the treatment of adult patients with locally advanced basal cell carcinoma (laBCC) not amenable to curative surgery or radiation therapy. In addition, sonidegib was also approved for the treatment of metastatic BCC (mBCC) in Switzerland and Australia.

Objective: Here we report subanalyses data from the final 42-month results.

Materials and Methods: BOLT was a double-blind phase 2 study where hedgehog inhibitor treatment–naïve patients with laBCC not amenable to curative surgery/radiotherapy, or mBCC were randomized 1:2 to sonidegib 200 or 800 mg QD, respectively. The primary endpoint was objective response rate (ORR). Analyses were performed at 6, 12, 30, and 42 months.

Results: At 42 months per central review, ORR for 200 mg QD (laBCC and mBCC) were consistent for patients with laBCC aggressive and nonaggressive histologies (60% vs 52%); male and female (44% vs 55%); patients aged <65 years and ≥65 years (60% vs 40%); for patients receiving and not receiving gastric pH agents (52% vs 39%). ORR analyses by disease strata (laBCC [56%] vs mBCC [8%]) and ECOG PS (0 [60%] vs ≥1 [30.6%]) showed diverse results. In patients with no dose reduction/delay vs those with ≥1 dose reduction/delay, ORRs were 49% and 46%, respectively. In laBCC 200 mg patients with a change in response assessment category, 80% achieved a better response (ie, stable disease to partial response [PR] or from PR to complete response). The safety/tolerability profile at 42 months was consistent with prior timepoints with no new AEs emerging.

Conclusions: These results confirm the consistency of treatment effect for sonidegib 200 mg at 42 months across several subgroups including age, disease histology, dose modifications, and gender.