



SKIN CANCER (OTHER THAN MELANOMA)

ADVERSE EVENTS OF SPECIAL INTEREST IN PATIENTS WITH ADVANCED BCC RECEIVING SONIDEGBIB: LONG-TERM 42-MONTH RESULTS FROM THE BOLT STUDY

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Introduction: Based on the primary results of the phase 2 BOLT study (NCT01327053), 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 the incidence and impact of HHI class-effect AEs from the BOLT 42 month results.

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. Secondary endpoints were duration of response (DOR) and disease control rate (DCR), and). Results for the approved 200 mg dose at 42 months are reported here.

Results: In patients receiving sonidegib 200 mg QD at 42 months, ORRs were 48% (laBCC/mBCC) and 56% (laBCC); DCR was 91% and DOR was 24 months (mBCC) and 26 months (laBCC). All cause/Grade 3-4 AEs (incidence $\geq 30\%$) were muscle-related (68%/9%), alopecia (53%/0), nausea/vomiting (49%/5%), dysgeusia (46%/0), decreased appetite (42%/6%), asthenia (44%/5%) and diarrhea (33%/1%). Of these discontinuation/dose adjustment rates were low: muscle-related (5%/1%), alopecia (1%/1%), nausea (4%/0), dysgeusia (4%/1%), decreased appetite (5%/0), asthenia (6%/1%), and diarrhea (0/0).

Conclusions: Patients receiving sonidegib 200 mg experienced consistent and robust





efficacy and manageable tolerability with infrequent Grade $\frac{3}{4}$ AEs and discontinuations.

