

NCCN Guidelines for Basal Cell Skin Cancer V.1.2018 – Follow-Up on 01/19/18

Guideline Page and Request	Panel Discussion/References	Institution Vote*			
		YES	NO	ABSTAIN	ABSENT
<p><b>MS-13</b></p> <p>External request: Submission from MD Anderson clinician to include in the Discussion the recently published long-term (30 month) data from the sonidegib phase II BOLT trial (Lear 2017), by adding the following to MS-12: “With long-term follow-up data by central review from the BOLT trial, sonidegib 200 and 800 mg continued to demonstrate sustained efficacy in patients with localized advanced basal cell carcinoma (laBCC) and metastatic basal cell carcinoma (mBCC), regardless of tumor histology, as well as manageable tolerability (Lear 2017). At 30 months, tumor responses were durable: median duration of response was 26.1 months for 200 mg and 23.7 months for 800 mg in patients with laBCC, and for mBCC, 24.0 and not reached for the 200 and 800 mg doses, respectively (all central review; (Lear 2017). Since the time of the primary analysis, objective response rates in the 200 mg arm improved in patients with laBCC and decreased (200 mg) or remained similar (800 mg) for those with mBCC (Lear 2017). At 30 months, the estimated 2-year overall survival was &gt;90% and 69% for patients with laBCC (200 and 800 mg) and mBCC (200 and 800 mg), respectively. The safety/tolerability profile at 30 months was consistent with the primary analyses with few grade 3-4 adverse events and no new side effects emerging (Lear 2017; Migden 2015).”</p>	<p>This request has been sent to the chair and vice-chair of the panel* and is under consideration for the guideline update for Basal Cell Skin Cancer v 2.2018.</p>	N/A	N/A	N/A	N/A

\* Discussion section updates for web publication require the review and approval of the Panel Chair, and in some instances, the Vice-Chair (not the entire panel). Submissions related to the Discussion are typically NOT included in the transparency because they are not subject to a panel vote.