**Adverse events of special interest in patients with advanced basal cell carcinoma receiving sonidegib: Long-term 42-month results from the BOLT study**

**Alexander Guminski,1,2 Nicholas Stults,1 John T Lead*1**

Royal North Shore Hospital, St Leonards, NSW, Australia;*University of Sydney, Sydney, Australia; Sun Pharmaceutical Industries, Inc., Princeton, NJ, USA; *Manchester Academic Health Science Centre, University of Manchester, Manchester, UK

**BACKGROUND**

Sonidegib (DE225, sonidegib) is approved in the US, the EU, and Australia for the treatment of adult patients with locally advanced basal cell carcinoma (laBCC) not amenable to surgery (for which all other treatment options had been exhausted) or metastatic (mBCC) disease, including those patients with previously treated metastatic disease. Sonidegib is indicated for the treatment of adult patients with metastatic or locally advanced refractory (nonaggressive vs aggressive), and geographic region.

**OBJECTIVES**

- To report the incidence and impact of 48 selected adverse events (AEs) seen in the BOLT study

**METHODS**

- **BOLT** is a randomized, double-blind, phase 3 trial that included 1,032 patients across 32 countries

**RESULTS**

- **Safety and tolerability of sonidegib at 42 months** was consistent with reports at 30 months

**CONCLUSIONS**

- **Patients receiving sonidegib at 42 months** had consistent and robust efficacy and safety outcomes, comparable to those at 30 months

**REFERENCES**


**ACKNOWLEDGMENTS**

Medical writing and editorial support provided by Jennifer McCreary, MS, CCDF, of Allegiance, LLC, and funding by Sun Pharmaceutical Industries, Inc.

**DISCLOSURES**

All authors participated in advisory boards for Bristol-Myers Squibb, Pfizer, and Sanofi. O.A. and J.L. are employees of Sun Pharmaceutical Industries, Inc. J.L. was a consultant for Novartis and received personal non-financial benefits from Biogen-Idec Pharmaceuticals, Inc.