

## Melanoma [2016]: Bulletin #2

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### Abstracts

This edition presents key opinion leader (KOL) views on recent developments in the malignant melanoma (MM) market. Topics covered include: Array BioPharma announcing that it has withdrawn its New Drug Application (NDA) in the US seeking approval of binimetinib for the treatment of neuroblastoma RAS viral oncogene homologue (NRAS) mutation-positive melanoma; NewLink Genetics reporting positive interim results from a Phase II study evaluating its IDO pathway inhibitor, indoximod, in combination with Keytruda (pembrolizumab); OncoSec Medical announcing data from a Phase II study assessing the combination of its investigational intratumoral therapy, ImmunoPulse IL-12, with Keytruda (pembrolizumab) in metastatic melanoma patients who are not expected to respond to anti-PD-1 agents.

#### Business Questions

Was the decision to withdraw the NDA for binimetinib as monotherapy in NRAS melanoma the right one?

Does binimetinib have a future in NRAS melanoma?

Is there room for the market to accommodate another BRAF and MEK inhibitor combination therapy to treat BRAF-positive melanoma?

If approved what will binimetinib/encorafenib's main competitors be, and what setting(s) will it be used in?

How do KOLs view current data from the indoximod/Keytruda programme?

If approved, how likely is indoximod/Keytruda to impact nivolumab?

Is the rationale behind ImmunoPulse IL-12/Keytruda's use in metastatic melanoma patients, who are not expected to respond to anti-PD-1 agents, justified?

How do KOLs view ImmunoPulse IL-12/Keytruda's safety and efficacy?

What are the challenges facing the successful commercialisation of ImmunoPulse IL-12/Keytruda and what direction should development go in?

What other recent developments are of interest?

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