

****New release June 2011****

MarketVIEW: Melanoma vaccines (CAT: VAMV026)

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|--------------------------------|---|--|
| Proposal No/#PO | : | [Enter client specific #PO] |
| Product Name | : | MarketVIEW: Melanoma vaccines – Global market forecast |
| Project Initiation Date | : | n/a |
| Billable days | : | n/a |
| Initiator(s) | : | [Enter client name, function and address] |
| Therapeutic Area | : | <i>Novel therapeutic vaccines - oncology</i> |
| Product (if applicable) | : | CAT No: VAMV026, published June 2011 |

Background

Melanoma is a tumour arising from melanocytes of the basal layer of the epidermis. The major cause is considered overexposure to sunlight. Global incidence rates of melanoma are rising particularly in persons >65 yrs although the disease is not uncommon in younger persons. Early stage melanomas (Stage I and some Stage II) can be treated with surgery. However, for later stages (Stage III and Stage IV) most patients will not be cured with 5 year survival rates ranging from 50-70%. Newly approved treatments such as Bristol Myers Squibb's ipilimumab (Yervoy), a CTLA-4 monoclonal antibody improve overall survival in melanoma patients, although treatment is associated with a substantial risk of immune related reactions. Other advances include the BRAF kinase inhibitor vemurafenib.

This **MarketVIEW** analysis investigates the proposition of new therapeutic vaccines being used in the adjunctive treatment of melanoma. Potential indications, patient segmentation and vaccine target product profiles are discussed with a particular emphasis on GSK's GSK2132231A. The commercial potential of putative melanoma vaccine(s) is estimated with **HI** and **LO** scenarios postulated for the major Western markets to 2030. The product is comprised of a comprehensive value/volume MS Excel-based model + Summary executive presentation and is designed to aid early stage commercial decision making in the field of oncology therapeutic vaccines.

Methodology

VacZine Analytics has closely monitored all significant source material pertaining to melanoma disease epidemiology/dynamics, current treatments and novel immunotherapeutics (pipeline). Example, secondary source materials used are literature articles, government websites/databases, medical bodies and associations, conference proceedings and previously analyses (where publically available). Previously published research by **VacZine Analytics** in field of therapeutic vaccines has also been utilised. *****See Bibliography for exact sources.**

PRODUCT CONTENTS:

Published June 2011 (CAT No: VAMV026)

****This product is composed of a forecast model and summary presentation

Contents – Summary presentation (MS PowerPoint based)

- Contents
- Authors note
- Executive summary
- Commercial model: key outputs
- Total available market: melanoma vaccine (\$ 000s) to 2030
- Total predicted demand: melanoma vaccine (treated patients 000s) to 2030
- Total available US market (High scenario): melanoma vaccine (\$ 000s) to 2030
- Total available US market (Low scenario): melanoma vaccine (\$ 000s) to 2030
- Total available EU + other markets (High scenario): melanoma vaccine (\$ 000s) to 2030
- Total available EU + other markets (Low scenario): melanoma vaccine (\$ 000s) to 2030
- Melanoma: brief disease background
- Melanoma: global epidemiology
- Melanoma: age at diagnosis
- Melanoma: clinical staging
- Melanoma: treatment options
- Melanoma: cost of treatment
- Clinical staging
- Treatment options
- New treatments – focus on vemurafenib
- Cost of treatment
- The role of a melanoma vaccine
- Proposed vaccine indication
- Addressable vaccine populations by stage
- Addressable vaccine populations by stage: targeting GSK2132231A
- Melanoma epidemiology model: country/patient segmentation
- Melanoma vaccine: Target product profile (TPP)
- Major commercial model assumptions (Stage III/IV vaccine)
- Major commercial model assumptions (Stage II vaccine)
- Commercial model assumptions by country (Stage III/IV vaccine)
- Pipeline summary
- Bibliography
- About VacZine Analytics
- Disclaimer
- Back page

PAGES: ~45 MS PowerPoint slides, fully referenced/sourced. Available in .pdf form



Contents – Vaccine demand model (MS Excel-based)

Title sheet
TOTAL CHARTS
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Value (High)
Value (Low)
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Patient treated (Summary)
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Spain
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Australia
Source material
Global epidemiology
US (incidence)
US (incidence by age)
Staging
Clinical trials
Treatment costs
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WORKSHEETS: ~23

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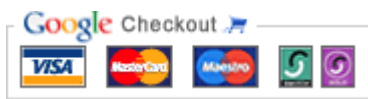
*A region is North America, Europe or ROW

For orders in the UK, VAT at 20% will be added to final invoice total

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BIBLIOGRAPHY:

1. Ferlay J et al. GLOBOCAN 2008, Cancer Incidence and Mortality Worldwide. Available at: <http://globocan.iarc.fr>. Accessed: May 2011.
2. Cancer Research UK. Skin cancer - UK incidence statistics. Available at: <http://info.cancerresearchuk.org/cancerstats/types/skin/incidence/#source12>. Accessed: May 2011.
3. Fast Stats. National Cancer Institute. Available at: <http://seer.cancer.gov/faststats>. Accessed: May 2011.
4. SEER Stat Fact Sheets: Melanoma of the Skin. National Cancer Institute. Available at: <http://seer.cancer.gov/statfacts/html/melan.html>. Accessed: May 2011.
5. British Association of Dermatologists (2010) UK guidelines for the management of cutaneous melanoma. Available from: www.bad.org.uk/healthcare/guidelines. Accessed: May 2011.
6. Balch CM et al. Final version of the American Joint Committee on Cancer staging system for cutaneous melanoma. *J Clin Oncol.* 2001;19:3635-3648
7. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. Melanoma Version April 2011. Available from: <http://www.nccn.org/>. Accessed: May 2011.
8. National Cancer Institute. Melanoma Treatment (PDQ), Treatment Option Overview. Available at: <http://www.cancer.gov/cancertopics/pdq/treatment/melanoma/HealthProfessional/page9>. Accessed: May 2011.
9. Yervoy, Bristol Myers Squibb's new treatment for advanced skin cancer has gained approval in the US. Available from: <http://www.inpharm.com/news/152647/new-melanoma-drug-approved-fda>. Accessed: May 2011.
10. Alexandrescu DT. Melanoma costs: A dynamic model comparing estimated overall costs of various clinical stages *Dermatology Online Journal* 15 (11): 1. Available at: http://dermatology.cdlib.org/1511/originals/melanoma_costs/alexandrescu.html. Accessed: May 2011
11. Eastern Cancer Registration and Information Centre. Stage distribution of cancers diagnosed in 2009 in the East of England by cancer site and area of residence. Available at: <http://www.ecric.org.uk/>. Accessed: May 2011.
12. Trefzer UA et al. FC13 DERMA Phase III trial of MAGE-A3 immunotherapy as adjuvant treatment in stage III melanoma: MAGE-A3 gene expression frequency and baseline demographics. *Melanoma Research*: June 2010 - Volume 20 - Issue - pp e34-e35
13. Velazquez EF et al. Expression of the cancer/testis antigen NY-ESO-1 in primary and metastatic malignant melanoma (MM)-correlation with prognostic factors. *Cancer Immun.* 2007 Jul 12;7:11.
14. Epping MT et al. A causal role for the human tumor antigen preferentially expressed antigen of melanoma in cancer. *Cancer Res.* 2006 Nov 15;66(22):10639-42.
15. MELACINE Vaccine – FDA. Available at: www.fda.gov/ohrms/dockets/ac/02/slides/3838s1_03_corixa.ppt. Accessed: May 2011.

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About VacZine Analytics:

VacZine Analytics is an established strategic research agency based in the United Kingdom. Its aim is to provide disease and commercial analysis for the vaccine industry and help build the case for developing new vaccines and biologics.

For more information please visit our website www.vacZine-analytics.com

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