

Global Pharmaceutical & Biotechnology Outlook 2012

https://marketpublishers.com/r/G5BBDA133AEEN.html Date: December 2011 Pages: 466 Price: US\$ 12,000.00 (Single User License) ID: G5BBDA133AEEN

Abstracts

Outlook-11' is an extensive, yet conclusive research work that encompasses a comprehensive, historical and forward looking analysis of ~80 small and large cap US, EU, Japan and ROW companies – formulated with an aim to facilitate strategic and long term investment decision making of senior management. Outlook-11' has been tailored to deliver more meaningfully in the current economic scenario.

MP Advisors integrated top-bottom and bottom-up research methodology spots business models which are valued to a lesser extent as compared to some of the 'popular' business models. The company capsules' of over 80 bio-pharmaceuticals elucidate the financial and strategic model they follow, the pros and cons about existing and new products, growth strategies for the future, and their key milestones.

The Global Pharmaceutical Model is changing. Major pharmaceutical companies continue to under-perform in a market constrained by patent expiry, generic competition and a lack of new blockbuster drugs. There are signs of improvement, with the outcome of new clinical trials and new launches expected to reshape market dynamics.

Our analysts have studied ~200 clinical and regulatory upcoming events, changing dynamics in generic players on back of dozens of Para IV, new found love by Large cap innovators in generics and emerging markets beyond BRIC, and dominance of Biologics in R&D pipeline etc. Some of the key findings from Outlook 2011 to share are: The pleasant shock of 2011 is that fresh peak sales generation from anticipated approvals; Outlook-2011 reveals how new product approvals will compensate for the next burst of patent expiries by a much larger magnitude than commonly perceived. Number of upcoming positive milestones in 2011 far exceed negative outcome milestones and ~ half a dozen of such events will bring moderate re-rating of companies which spend/invest ~ 15% of sales and ~ 40% of Operating profit in R&D and are trading at single digit PEx.



This new report makes sense of a rapidly changing pharmaceutical market and provides unparalleled insight and analysis that will enable you to seek out the capabilities that are needed for success and the companies that have those capabilities.

In the 454 page research report view at five market sections:

Rising Stars Mature Biotech Indian Generics Global Pharma Japan - Global and Emerging

For each market place the report provides a detailed sector overview and then recommends the companies that will succeed and explains why.

Each company analysis includes a detailed drug pipeline analysis with explanations of how a drug will perform in its therapy area and how the market will shape up due to competition.



Contents

CARDIOVASCULAR

NEXT GENERATION ORAL ANTICOAGULANTS

1. ANTICOAGULANTS MARKET

Market size and Segmentation – By Drugs and Indications Goals (Duration) of Current anticoagulant therapy in different indications New generation anticoagulants pipeline Major Upcoming Milestones Estimated launch timelines for new generation anticoagulants– Indication wise Characteristics of Ideal anticoagulants Factor Xa vs. Direct Thrombin inhibitor

2. STROKE PREVENTION IN ATRIAL FIBRILLATION

The Current Market Dynamics- Geography wise prevalence of SPAF and treatment paradigm of anticoagulation therapy in SPAF The need for new generation anticoagulants Does higher unmet need prevail in high risk (CHADS2 score) patients or low risk patients? Experts view on the hurdles to the adoption of new generation anticoagulants in SPAF Factors that will influence the choice of anticoagulation therapy in Atrial Fibrillation -Regulatory and Clinical Patient's history of stroke and bleeding risk factors impacting treatment decision Impact of dosing frequency on treatment practice in SPAF Warfarin discontinuers Concomitant Medicines- Donut hole and drug-drug interaction Regulatory Scenario – Medicare Shared Saving program to be implemented in 2012 Reimbursement status of PT/INR monitoring for warfarin in major countries Physician's Experience and cost effectiveness Warfarin Genotype testing, its regulatory approval and reimbursement Use of Device for Stroke Prevention in Atrial Fibrillation Warfarin continues to hold itself strong against Pradaxa – Will the entry of Xarelto / Eliquis / Edoxaban change the scenario? Clinical data comparison of ARISTOTLE, AVERROES, RELY and ROCKET AF Studies

and our analysis on each clinical data



Baseline and Clinical Trial Design comparisons – RELY, ROCKET AF AND ARISTOTLE

Overall Efficacy and Safety comparisons – ROCKET, RELY, ARISTOTLE AND AVERROES

Efficacy and safety comparison in high risk patient population

Clinical data analysis from ROCKET- AF detailed data

Clinical data analysis from ARISTOTLE detailed data

AVERROES trial rationale and results - No commercial implications

FDA approval of Xarelto in SPAF

Universal antidote for novel oral anticoagulants

The Future Mainstay Treatment In SPAF - Xarelto or Pradaxa or Eliquis or Edoxaban

3. ROLE OF NEW GENERATION ORAL ANTICOAGULANTS IN VTE PREVENTION IN ORTHOPEDIC SURGERY

Prevalence of VTE after Total Hip Replacement Surgery / Total Knee Replacement Surgery

The need and importance for extended prophylaxis and current limitations Clinical data comparison – Xarelto, Eliquis and Pradaxa

4. ROLE OF NEW GENERATION ORAL ANTICOAGULANTS IN VTE PREVENTION IN MEDICALLY-ILL PATIENTS

Market segmentation based on Illness

Risk/Incidence of DVT and Fatal PE in different categories of Medically ill Patients Incidence of DVT In Orthopedic Surgery vs. Acute Medically ill Patients VTE Prevention in Cancer Patients – VTE incidence rates in different types of cancer Ongoing clinical studies

Xarelto - Review of MAGELLAN study

Semuloparin - Clinical data comparison of VTE prophylaxis in cancer Patients

5. ROLE OF NEW GENERATION ORAL ANTICOAGULANTS -VTE TREATMENT

New Generation anticoagulants will expand the DVT treatment opportunity manifold Pradaxa - RECOVER study

Eliquis - BOTTICELLI Study and AMPLIFY study

Xarelto – EINSTEIN DVT study

Xarelto – EINSTEIN EXT study

Xarelto - Other ongoing studies



Edoxaban – HOKUSAI study Clinical data comparison from DVT treatment studies

6. FACTOR XA INHIBITORS - DO THEY HAVE POTENTIAL TO BE AN IDEAL ANTICOAGULANT FOR SECONDARY PREVENTION OF ACS?

Historically, Anticoagulants have failed to show a positive risk-reward profile in ACS – Xarelto succeeded in ATLAS TMI 58 Clinical data comparison of Anticoagulant as add on to current ACS treatment vs. Newer Antiplatelet agent Upcoming clinical data news flow which has potential to change market dynamics

7. IS ANYONE COMPETENT ENOUGH IN THE EARLY STAGE FACTOR XA INHIBITORS? – LY517717

Eribaxaban Betrixaban TAK-442 YM150

8. HOW WILL THE NEXT GENERATION ORAL ANTICOAGULANTS STACK UP?

METASTATIC MELANOMA

1. PREVALENCE, MARKET SIZE IN DIFFERENT GEOGRAPHY

Current Market and Potential

2. TARGET PRODUCT PROFILE VS. CURRENT LEVEL OF ATTAINMENT

3. WORLDWIDE MELANOMA MARKET FORECAST

US and Ex-US Melanoma

4. RECENTLY APPROVED THERAPIES:

Yervoy And Zelboraf - How Will the Ongoing Trials Impact Their Potential USFDA is unlikely to approve 10mg/kg ipilimumab dose as toxicity is likely to play



spoilsport Durability of Response vs. Overall response Rate Ongoing Ipilimumab Clinical Study In Metastatic Melanoma Zelboraf (Vemurafenib, Roche) – Spectacular benefits, managing resistance is the key

5. B-RAF RESISTANCE: HOW TO OVERCOME?

Combination Therapy to reduce B-RAF resistance!! GSK 436 +GSK 212 ahead in the race than Vemurafenib Safety data –GSK 436+ GSK 212 Vemurafenib + MEK inhibitor Vemurafenib with PI3K/AKT/mTOR inhibitors and Immunotherapy Early research for reducing Resistance to BRAF inhibitors Ongoing clinical studies with Vemurafenib

6. MELANOMA PIPELINE – NEW APPROACHES UNDERWAY

Targeted Chemotherapy Targeted Immunotherapy Targeted MAP Kinase therapy Vaccines Anti-angiogenesis Therapy

7. KEY PATHWAYS AND BIOMARKERS FOR METASTATIC MELANOMA

8. EXTENSIVE REVIEW OF METASTATIC MELANOMA PIPELINE CANDIDATES

9. B-RAF INHIBITORS – SPECIFICITY TO B-RAF IS THE KEY FOR EFFICACY

B-RAF inhibitors: Late stage and Early stage pipeline compounds PhI/II clinical data of GSK 436 in the treatment of metastatic melanoma

10. MEK INHIBITORS

GSK 212 AZD 6244 MEK 162 GDC 0973 PD0325901



TAK-733 BAY 86-9766 RO 5126766

11. C-KIT MUTATION AND C-KIT INHIBITORS IN THE PIPELINE

12. PIPELINE ASSESSMENT OF IMMUNOTHERAPEUTICS: IPILIMUMAB

13. EARLY STAGE IMMUNOTHERAPY APPROACHES TO TREAT MELANOMA

PD1 blocking agents CD-40 activation

14. CHEMO OR CHEMO+TARGETED THERAPY

Nab-Paclitaxel Abraxane + Avastin Abraxane + carboplatin Avastin + Dacarbazine Vaccine pipeline assessment Allovectin – 7 Talimogene laherparepvec (formerly OncoVEXGM-CSF) MAGE-A3 ASCI

15. OTHERS

PV 10 (Rose Bengal) Genasense

16. TRIAL DESIGN AND CLINICAL DATA COMPARISON OF LAUNCHED AND PIPELINE CANDIDATES IN FIRST LINE,

Second line settings of Metastatic Melanoma Clinical trial data comparison for metastatic melanoma- first line setting Clinical trial data comparison for metastatic melanoma- second line setting Clinical trial data comparison for metastatic melanoma- unresectable stage IV & adjuvant setting

17. UPCOMING MILESTONES AND LAUNCH TIMELINES OF LATE STAGE



PIPELINE CANDIDATES

18. KEY MILESTONES IN METASTATIC MELANOMA THERAPY CLASS

19. ANNEXURE

Etiology and Survival of Melanoma Stages of Melanoma and Treatment Options Overview Survival of Melanoma Patients FDA requirement for new drug approval in Melanoma (Oncology) RESIST evaluation criteria for the assessment of drugs' efficacy in cancer



I would like to order

Product name: Global Pharmaceutical & Biotechnology Outlook 2012

Product link: https://marketpublishers.com/r/G5BBDA133AEEN.html

Price: US\$ 12,000.00 (Single User License / Electronic Delivery) If you want to order Corporate License or Hard Copy, please, contact our Customer Service: <u>info@marketpublishers.com</u>

Payment

To pay by Credit Card (Visa, MasterCard, American Express, PayPal), please, click button on product page <u>https://marketpublishers.com/r/G5BBDA133AEEN.html</u>