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Treating Refractory Hematological Malignancies - Multiple Myeloma (MM): New Treatment Options Driving In-Licensing and M&A

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Abstracts

Summary:

The report (ToC) provides an overview of the therapies for Multiple Myeloma (Newly diagnosed - NDMM and relapsed/ refractory - RRMM), unmet need, and limitations of the current standard of care (SoC) for relapsed and refractory MM pts. The report highlights the competition and commercial opportunity in pursuing this therapy area – Comprehensive list of the early and late stage drugs in the clinic, their MoA and the companies developing them.

Detailed financial and competitive analysis of the companies leading in this field for this indication – Celgene, Amgen (post-acquisition of Onyx pharma), and MorphoSys are available within this full report. Key M&A activities that have taken place in this area in the last 5 years and a list of products in early /late-stages of development available for in-licensing are highlighted in the report. This report is built using primary and secondary research data and in-house proprietary database.

Reasons to buy the report:

Useful for investors, Scientists, Business development managers of Pharma companies with focus in oncology to address the following-

What are the opportunities or new approaches to be deployed in the R&D of the company?

List of validated and new targets

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In-licensing opportunities – Is the way to go forward and be in the race?

Commercial opportunity and companies' valuation.

Key Points Discussed in the Report:

Overview of the Disease and Unmet need

Drugs in the pipeline: NDMM & RRMM – Mechanism of Action (MoA) and Clinical Stage of development

Comparative Clinical data of Late-stage Pipeline in RRMM and NDDM

Ongoing Clinical trial Details of Key Drugs in Pipeline

Key milestones

MPA view on the Future of the drugs in the late-stage pipeline

Launch Timeline and Commercial Opportunity of Late-stage pipeline

M&A and Licensing deals in the last 5 years

In-licensing and/or M&A Opportunity

Detailed Company analysis includes Clinical data of drugs, Milestones, and Valuation – Amgen (AMGN), Celgene (CELG), and MorphoSys (MOR)

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About

Targeting unmet needs in the treatment of cancer/ hematological malignancies through innovative drug development strategies have witnessed favorable outcomes recently. Over the past decade, Proteasome inhibitor, Velcade (bortezomib) and the immunomodulatory drugs – Thalomid (thalidomide) and Revlimid (lenalidomide) have become the cornerstone of treatment for patients with Multiple Myeloma (MM) resulting in improved survival. However, eventually all patients relapse and new treatment options for Relapsed/ Refractory Multiple Myeloma (RRMM) are required to further improve survival and quality of life of this group of pts. Two new drugs have successfully fulfilled this need – POMALYST/ IMNOVID (pomalidomide – POM, Celgene, approved in Aug. 2013 in the EU and approved in Feb. 2013 in US) and Kyprolis (carfilzomib-CFZ, Onyx pharma – now Amgen/ Ono pharma – JP, received accelerated approval in July 2012 in US) but Is there room for more? While novel targets address new MOA the pertinent Question remains – is there a need for further improvement? What would the market dynamics be like by the time some of these drugs are approved?

Data from novel therapies in the pipeline for RRMM presented at meetings (ASCO '13/ EHA '13/IMW '13) emphasize the role of new targets whose mode of action (MOA) is beyond IMiDs and Proteasome inhibitors. In this report, we highlight the competition in RRMM /Newly Diagnosed Multiple Myeloma (NDMM) and new treatment emerging which includes combination of small molecules and biologics. While most of the small molecules in pipeline are already partnered, there are several mAbs targeting MM which are unpartnered and present licensing/ M&A opportunities!

Innovations have contributed to a range of new treatments resulting in improvements in the length and quality of life and reduced disease burden for individuals and society. The need for innovative new therapies for unmet needs /challenging diseases continues to grow accelerating the pace of drug development directly or through partnership/ inlicensing. Approval of new drugs, successful launches, maturing pipeline sustain the growth trajectory of the biotech companies, and as a result the stock performance has been very rewarding and the enthusiasm remains unabated! Acquisition of Onyx by Amgen (at a premium of ~45%, Aug. 26, 2013) should strengthen AMGN's presence in Hematology/ Oncology while partnering of CELG-MOR adds a monoclonal antibody (mAb) to CELG's portfolio of drugs for RRMM.

Multiple myeloma (MM) is a cancer that affects plasma cells within the bone marrow. The number of myeloma cells is elevated, potentially causing kidney problems, skeletal

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issues, immune suppression, and anemia. The American Cancer Society estimates there are 14,600 new cases of MM each year in the US, with 45,000 patients actively living with the disease, making it the second most prevalent blood cancer after non-Hodgkin's lymphoma. Survival varies with stage of diagnosis, from 62 months for patients in stage 1 to 29 months for stage 3. Younger pts are usually treated aggressively with reinduction therapy / high-dose chemotherapy combined with autologous or allogenic stemcell transplant. However, progression and recurrences should be anticipated, even for pts who show an excellent response to initial therapy.

Approval of Thalidomide, Revlimid and Velcade revolutionized the treatment of multiple myeloma within the last decade, where Revlimid and Velcade brought a paradigm shift in the treatment of MM by offering significant survival improvement and quality of life. However, relapse is inevitable and with the growing MM population demand for drugs for Relapsed and Refractory MM (RRMM) is likely to increase. RRMM may be defined as a disease that achieved at least a minimal response to prior therapy but is nonresponsive to salvage therapy or progresses within 60 days of the last treatment. The National Comprehensive Cancer Network (NCCN) recommends salvage therapy for pts with evidence of either biochemical or clinical parameters for disease progression.

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