

Hematological Malignancies: Multiple Myeloma (MM) – Early and Robust Diagnosis along with New Treatment Options can have Considerable Impact on Management of the Disease

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Abstracts

While targeting unmet needs in the treatment of hematological malignancies/ cancer through innovative drug development strategies have witnessed favorable outcomes, the specific choice of the therapies is dependent on the identification of important genomic alterations in cancerous cells that allow for the tumor's sub classification. Over the past decade, Proteasome inhibitor and the immunomodulatory drugs have become the cornerstone of treatment for pts with Multiple Myeloma (MM) resulting in improved survival. However, eventually all pts relapse and use of modern diagnosis will enable risk stratification to help distinguish pts along the spectrum of the condition. This can aid in the selection of new treatment options for Relapsed/ Refractory Multiple Myeloma (RRMM) to further improve survival and quality of life of each patient. Two new drugs have successfully fulfilled this need – POMALYST/ IMNOVID (pomalidomide – POM, Celgene, approved) and Kyprolis (carfilzomib-CFZ, Amgen/ Ono Pharma – JP, approved). While novel targets address unmet need, the pertinent Question remains – is there a need for further improvement? What should be the diagnosis criteria and/or novel imaging / diagnostic tools that can further stratify a pts' risk profile?

Precision medicine approaches in myeloma require fast, robust, and practicable molecular diagnostic tools, and the current diagnostic standard iFISH (interphase fluorescence in situ hybridization) is unable to fulfill any of these criteria. Integration of Diagnostics into therapeutic products/ industry has potential to improve trial design, enhance safety profile, enhance therapeutic efficacy, accelerate trial outcome, and increase commercial success. However, there are few hurdles which are also associated with new model, such as understanding the diagnostic industry, complex trial



execution, seeking a 'right' diagnostic partner, managing the co-development process, regulatory uncertainty around companion diagnostics and intellectual property issues.



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