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Multiple Myeloma: Update Bulletin #3 [March 2018]

https://marketpublishers.com/r/M4395A7C8D2EN.html
Date: February 2018
Pages: 0
Price: US$ 1,095.00 (Single User License)
ID: M4395A7C8D2EN

Abstracts

This edition presents key opinion leader (KOL) views on recent developments in the treatment of multiple myeloma (MM). Topics covered include KOL views on; Celgene and bluebird bio's presentation of updated findings from a Phase I trial of their anti-BCMA CAR-T cell therapy bb2121 at ASH 2017;Genmab/Janssen Biotech's publication of preliminary data from the Phase II CENTAURUS trial, evaluating the safety and efficacy of Darzalex (daratumumab) as a monotherapy in the treatment of intermediate to high-risk smoldering MM, a condition that is currently rarely treated with therapeutic intervention; and PharmaMar/Chugai's ASH conference presentation of data from the Phase III ADMYRE trial, evaluating Aplidin (plitidepsin) in combination with dexamethasone for the treatment of relapsed/refractory MM is also discussed.

Business Questions:

> In December 2017, Celgene and bluebird bio presented findings from a Phase I trial of their anti-BCMA (B-cell maturation antigen) Chimeric-Antigen Receptor-T (CAR-T) therapy, bb2121, for multiple myeloma, but do KOLs view the data as suggestive of sufficient clinical responsiveness?
>
> What concerns, if any, do KOLs have with regard to bb2121's toxicity profile given that over 70 percent of patients in the Phase I study experienced cytokine release syndrome?
>
> If approved, where in the treatment paradigm will bb2121 sit and what proportion of patients can this immunotherapy hope to attract?
>
> With the emergence of new therapies for the treatment of multiple myeloma there is increasing interest in exploring treatment intervention in smoldering multiple myeloma, but how do KOLs view the potential for therapy in this

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currently predominantly untreated condition?

Genmab and Janssen Biotech are currently investigating the CD38 targeting monoclonal antibody Darzalex (daratumumab) for the indication of intermediate to high-risk smoldering multiple myeloma, but how convincing are the data from the CENTAURUS Phase II clinical study, presented at ASH 2017?

PharmaMar and Chugai presented data from the Phase III ADMYRE trial investigating Aplidin (plitidepsin) in combination with dexamethasone for the indication of relapsed/refractory multiple myeloma, but how robust is the study design?

In January 2018, PharmaMar requested that the EMA's CHMP re-evaluate its decision not to recommend Aplidin for the treatment of relapsed/refractory multiple myeloma, but how likely is it that the committee's former decision will be overturned, based on the strength of the ADMYRE Phase III data?

If approved, where in the current treatment paradigm will Aplidin sit and what future will this product have in the treatment of multiple myeloma?

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