Submitted by
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Date of request: March 14th 2019

NCCN Acute Myeloid Leukemia Panel

Re: Request for clarification of VYXEOS® (dual-drug liposomal encapsulation of daunorubicin and cytarabine) use after induction in AML

On behalf of Jazz Pharmaceuticals, I am writing with regards to the new language “if given in induction” added to VYXEOS in V1.2019 of the NCCN AML Guideline for re-induction, post-remission, and consolidation. We respectfully ask that the language be revised to “preferred if given in induction” to avoid potential clinical misinterpretation as outlined below.

Background:

- On 11/5/2018, Jazz sent a letter to the NCCN AML Panel requesting clarification to recommend VYXEOS be used consistently through all treatment phrases.
- The NCCN Panel voted unanimously in favor (19 yes, 0 no) for this request. On V1.2019 of the NCCN Clinical Practice Guidelines in Oncology for Acute Myeloid Leukemia, the phrase “if given in induction” was added to VYXEOS in guideline pages AML-9, AML-11, AML-14, AML-15.

We are concerned that the added language (“if given in induction”) may be misinterpreted to enable use of other regimens for re-induction and consolidation after VYXEOS induction, while restricting the clinical use of VYXEOS. The misinterpretation will be inconsistent with category 1, phase 3 randomized study data that demonstrated superior clinical outcome when VYXEOS is used consistently through all treatment phases (Lancet JE, et al. J Clin Oncol. 2018;36(26):2684-2692; Kolitz JE, et al. SOHO Annual Meeting. 2018. Abstract AML-275).

Suggested revision:

- We respectfully request revision of the current language to “preferred if given in induction” for the use of VYXEOS for re-induction, post-remission, and consolidation (AML-9, AML-11, AML-14, AML-15).
An NCCN recommendation for consistent usage of the regimen is important to ensure best patient outcome based on clinical evidence. We appreciated your consideration of our request.

Sincerely,

[Signature]

Francois di Trapani
Vice President Global Scientific Affairs, Medical Affairs

References (enclosed):