

From: [Francois Di Trapani](#)
To: [Submissions](#)
Subject: NCCN AML Dosing Erratum - Post-Remission Liposomal Daunorubicin and Cytarabine
Date: Thursday, March 7, 2019 4:17:57 PM
Attachments: [01. VYXEOS.en.US Prescribing Information.pdf](#)
[02. LancetJE-JClinOncol2018_phase3.pdf](#)

Dear Sir/Madam,

I am writing with regards to a dosing erratum in the NCCN AML Guideline for post-remission dual-drug liposomal encapsulation of daunorubicin and cytarabine (VYXEOS) based on the prescribing information (see section 2.1 "Recommended Dosage") and the phase 3 randomized study (Lancet JE, et al. J Clin Oncol. 2018;36(26):2684-2692):

AML-15 – Age ≥60 y, Post-Remission Therapy:

- Please revise the post-remission dual-drug liposomal dosing to "...daunorubicin **29** mg/m² and cytarabine **65** mg/m² IV over 90 min on days 1 and 3 x **1-2** cycle"

AML-11 – Age <60y, Post-Remission Therapy:

- Please revise the post-remission dual-drug liposomal dosing to "...daunorubicin 29 mg/m² and cytarabine 65 mg/m² IV over 90 min on days 1 and 3 x **1-2** cycle"

Thank you for your time and consideration.

Sincerely,

Francois Di Trapani
VP Global Scientific Affairs
Medical Affairs
Jazz Pharmaceuticals
Ph: 650-496-2759

Attachments for the message:

- VYXEOS[®] (daunorubicin and cytarabine) liposome for injection prescribing information. Jazz Pharmaceuticals, Inc.
- Lancet JE, et al. J Clin Oncol. 2018;36(26):2684-2692.

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