Janssen Products, LP

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Important Update Regarding the Availability of DOXIL[®] (doxorubicin HCl liposome injection)

July 19, 2011

Dear Healthcare Provider:

In June, we notified you that we would be experiencing a potential shortage of DOXIL[®] 20 mg and 50 mg vials for injection. This letter is to provide an update to our <u>June 21, 2011</u> <u>letter</u>.

Due to the proprietary drug delivery method of this medicine, DOXIL[®] is produced by a specialty manufacturer. We recently experienced production delays at our third-party contract manufacturer and continue to experience a supply shortage of DOXIL[®] in the above dosages. We are deeply committed to ensuring that this treatment is readily available to physicians on an ongoing basis. We will continue to work diligently with the supplier to help expedite production as soon as possible. While exact timeframes are not yet confirmed, based on the latest estimates, initial replenishment supplies of DOXIL[®] should begin shipping in late August. Supplies may be intermittently available in the weeks thereafter. Until then, we advise that no new patients begin treatment with DOXIL[®].

We understand the impact this situation may cause with patients on DOXIL[®]. As an additional resource, please refer to national treatment guidelines, such as those of the National Comprehensive Cancer Network (NCCN). Although there are no generic alternatives to DOXIL[®] available in the US, and conventional doxorubicin is not bioequivalent to DOXIL[®], treatment decisions can be individualized after discussing options with your patients. As a reminder, you cannot substitute DOXIL[®] on mg-per-mg basis with doxorubicin HCl.

For more information about DOXIL[®], please see the accompanying <u>full Prescribing</u> <u>Information</u>. For updates on the supply situation, visit www.DOXIL.com.

DOXIL[®] continues to be a cornerstone of our product offering for the healthcare community. Patient well-being is our primary concern and we are working diligently to ensure delivery of product as soon as possible. If you have any questions about DOXIL[®], please contact our Medical Information Department at 800-526-7736 (800-JANSSEN).

Sincerely,

Peter Callegari, MD Vice President, Medical Affairs Janssen Products, LP