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September 25, 2013

Notice of CAELYX[®] Supply Shortage

Dear Health Care Provider:

Due to issues at our external contract manufacturer, Ben Venue Laboratories, Inc., we are writing to inform you about an interruption of supply of CAELYX[®] (pegylated liposomal doxorubicin) that will likely result in patient level shortages in the coming months.

This supply shortage does not reflect a safety or quality issue with the product in the marketplace.

Timing and Next Steps

An exact timeframe for stock out is not yet confirmed. **Until then, to optimize supply for patients currently on drug, we advise that no new patients begin treatment with CAELYX[®].**

Treatment Alternatives

Please refer to regional or international treatment guidelines for guidance in identifying alternative treatment options as necessary. Please also note that non-liposomal and non-pegylated forms of doxorubicin are not considered bioequivalent to CAELYX[®], and thus may be associated with a different risk:benefit ratio.

Patient well-being remains our primary concern and we are working diligently to ensure availability of product as soon as possible. We are working closely with our global partners and Health Canada on alternative sources of CAELYX[®] supply for Canadian patients.

We will continue to provide updates on the status of CAELYX[®] supply. In addition information about this shortage can be found on the drug shortages website www.drugshortages.ca. If you have any questions about CAELYX[®], please contact our Medical Information Department at 1-800-567-3331 or 1-800-387-8771.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul Kershaw".

Paul Kershaw, MD
VP, Medical Affairs
Janssen Inc.