Direct Healthcare Professional Communication

17 January 2014

Re: ABRAXANE® (paclitaxel formulated as albumin bound nanoparticles, EU/1/07/428/001-002) Visible strands in the intravenous infusion bag

Dear Healthcare Professional:

Celgene Europe Ltd. would like to inform you of the following:

Summary

- Celgene has received reports of thin, translucent or white to yellow proteinaceous strands (1-2 mm in length) being observed during visual inspection of reconstituted ABRAXANE® suspension in an intravenous (IV) infusion bag.
- The root cause for formation of these strands has been determined to be an interaction of albumin, a major component of ABRAXANE suspension, with silicone oil lubricant within a medical device, causing the generation of strands which are comprised of human albumin, paclitaxel and silicone. A similar phenomenon has also been observed with other protein-based injectable products.
- Based on currently available data, including clinical trials and post-marketing experience, there is no indication of an increased risk of embolic events should these strands inadvertently be administered to patients.
- However, as a precaution, ABRAXANE suspension should be inspected visually using standard procedure for particulate matter or discoloration in the infusion bag prior to administration. ABRAXANE suspension should appear milky and homogenous without visible precipitates.
- If strands are visible in the IV bag, administer ABRAXANE through an infusion set incorporating a 15 µm filter. Use of a 15 µm filter removes strands and does not change the physical or chemical properties of the reconstituted product.
- If strands are present and a 15 µm filter is not available, discard the product.
- Should you have any difficulty obtaining infusion sets incorporating a 15 µm filter, please contact your local Celgene Medical Information department for further information.
- This letter is being sent in agreement with the European Medicines Agency and Irish Medicines Board (IMB).

Further information
Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

In the European Economic Area, ABRAXANE monotherapy is indicated for the treatment of metastatic breast cancer in adult patients who have failed first-line treatment for metastatic disease and for whom standard, anthracycline containing therapy is not indicated. Abraxane is also indicated in combination with gemcitabine for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas.

Company contact point
If you have questions or concerns about reconstituting, dispensing or prescribing ABRAXANE please contact your local Celgene Medical Information department at:

Telephone: 1800 333 111
Fax: 1800 333 112
E-mail: medinfo.uk.ire@celgene.com

Alternatively you may contact Celgene Global Medical Affairs on +1 908 673 9800 or via email at medinfo@celgene.com

Suspected adverse reactions should be reported to the IMB using a Yellow Card obtained either from the IMB, or electronically via the website at www.imb.ie. Adverse reactions can also be reported to the IMB by calling (01) 676 4971.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Adverse reactions associated with the use of ABRAXANE may also be reported to Celgene:

Celgene Drug Safety
Celgene Ltd
1 Longwalk Road
Stockley Park
Uxbridge
UB11 1DB

Telephone: 1800 936 217
Fax: 1800 936 477
Email: drugsafetyuk@celgene.com

Yours faithfully,

Dr Adrian Kilcoyne
Medical Director, UK and Ireland
Celgene Limited