



Update

### ❖ New Drug Information

- **Erwinaze™ (asparaginase *Erwinia chrysanthemi*):** The Food and Drug Administration (FDA) approved EUSA Pharma's injectable therapy for the treatment of acute lymphoblastic leukemia (ALL) in patients who have developed an allergy to *E. coli*-derived asparaginase and pegaspargase chemotherapy drugs.
- **Jakafi™ (ruxolitinib):** InCyte received FDA approval for their oral treatment for myelofibrosis. Myelofibrosis is a disease in where scar tissue replaces the bone marrow; therefore blood cells are made in other organs such as the liver and the spleen.
- **Eylea™ (aflibercept):** Regeneron Pharmaceuticals received FDA approval for their intravitreal injection for the treatment of neovascular (wet) age-related macular degeneration. Eylea will compete with products such as Macugen® and Lucentis® and will cost approximately \$16,000 annually.
- **Exparel™ (bupivacaine liposome injectable suspension):** The FDA approved Pacira Pharmaceuticals' Exparel to delay and shorten the need for pain relief from opioids. Exparel is given as a one-time post surgical injection at the surgical site.
- **Iluvien® (fluocinolone acetonide):** Alimera Sciences received a complete response letter from the FDA for their intravitreal insert for the treatment of diabetic macular edema associated with diabetic retinopathy. Additional safety and efficacy data is necessary prior to FDA approval.

### ❖ New Indications

- **Erbitux (cetuximab):** Bristol-Myers Squibb and Eli Lilly received FDA approval for an additional indication for their cancer drug. Erbitux is now approved to be used with chemotherapy in patients with metastatic head and neck cancer. The drug has indications for the treatment of certain types of colon cancer and nonmetastatic head and neck cancer alone or in combination with radiation therapy.



## ❖ November News

- “Drug regulators withdrew their approval of Roche’s Avastin® for breast cancer, saying the drug was not effective enough to justify its risks even if patients believe it has helped them live longer. Reversing course on a drug that was approved for the disease in 2008, U.S. Food and Drug Administration Commissioner Margaret Hamburg said subsequent research did not confirm hopes that Avastin would help patients with advanced breast cancer live longer or improve quality of life.”<sup>1</sup>
- “Momenta Pharmaceuticals Inc. won a federal court ruling that temporarily blocks other companies from selling a generic version of its anti-clotting drug [enoxaparin]. Momenta’s shares surged in after-hours trading. U.S. District Court Judge Nathaniel M. Gorton in Boston ordered other companies not to sell their generic version of anticoagulant Lovenox® until a patent lawsuit filed by Momenta is settled.”<sup>2</sup>
- “Pharmasset Inc. climbed 4.9 percent after the company said its experimental drug for treating hepatitis C cured all patients in a study. All 40 patients who received Pharmasset’s experimental PSI-7977 drug were responsive after 12 weeks, the Princeton, New Jersey-based company said at the annual meeting of the American Association for the Study of Liver Diseases in San Francisco. About half the patients had been followed up to 24 weeks, and they were all cured. There were no significant adverse events.”<sup>3</sup>

## References

- <sup>1</sup> <http://www.reuters.com/article/2011/11/18/us-fda-avastin-idUSTRE7AH1Q120111118>
- <sup>2</sup> <http://www.businessweek.com/ap/financialnews/D9QLJH9Oo.htm>
- <sup>3</sup> <http://www.businessweek.com/news/2011-11-08/pharmasset-rises-after-hepatitis-drug-shows-100-cure-rate.html>