

November 18, 2016



*BUSY WEEK? Here are the
TOP INDUSTRY NEWS stories
you might have missed, as
selected by DCAT Editorial
Director Patricia Van Arnum.*

1. Mylan Forms Pact for Biosimilar to Roche's Rituxan

Mylan has signed an agreement with Mabion, a Poland-based biopharmaceutical company, for exclusive rights to sell Mabion's biosimilar referencing MabThera/Rituxan (rituximab), Roche's non-Hodgkin's lymphoma drug, in all EU countries and non-EU Balkan states. MabThera/Rituxan is a top-selling Roche drug with 2015 sales of CHF 7 billion (\$7.1 billion). [Read More](#)

2. FDA Launches New Pharma Learning Site Visit Program

FDA plans to launch in 2017 the Staff Experiential Learning Site Visit Program through its Office of Pharmaceutical Quality. The program is intended to provide FDA staff with a better understanding of drug-development and manufacturing processes through site visits of pharmaceutical companies. [Read More](#)

3. Biogen Appoints Executives to Spin-Off Company

Biogen has appointed two new members to the executive management team of Bioverativ Inc., Biogen's planned spin-off company focused on treating hemophilia and other blood disorders. The spin-off of Bioverativ is expected to be completed in early 2017. [Read More](#)

4. Roche Launches Cancer-Study Network, Invests \$100 Million

Roche has launched the Centers of Research Excellence Network, a global cancer immunotherapy network of scientific and clinical experts in cancer immunotherapy and will invest up to CHF 100 million (\$100 million) to support basic and clinical research collaborations related to cancer immunotherapy. [Read More](#)

5. Mylan Recalls Over 100,000 Units of Generic Anti-Seizure Drug

Mylan has issued a voluntarily Class III recall for more than 100,000 units of clonazepam, a generic version of Roche's anti-seizure drug, Klonopin (clonazepam), due to an out-of-specification result for clonazepam-related compound A, a known impurity. [Read More](#)

6. Eagle to Acquire Arsia, Boosts Formulation Capabilities for Biologics, Biobetters

Eagle Pharmaceuticals has agreed to acquire Arsia Therapeutics, an early-stage biotechnology firm with proprietary viscosity-reducing technology and formulation expertise, in a deal worth up to \$78 million to boost Eagle's drug-formulation technology for biologics, including for biobetters. [Read More](#)

7. Sanofi Ends Insulin Pact, Forgives \$72 Million Debt

Sanofi has completed the remaining terms of a previously announced termination of its pact with MannKind Corporation for Afrezza, an inhaled insulin product, and has forgiven a full outstanding loan balance of nearly \$72 million. The companies formed the pact in 2014, worth up to \$925 million, to

commercialize the product and terminated it in January 2016. [Read More](#)

8. [Janssen in Deal with Artificial Intelligence Firm](#)

Reflecting pharmaceutical companies' efforts to use new technology in drug development, Janssen Pharmaceuticals signed an agreement with BenevolentAI, a London-based artificial intelligence company, for a series of clinical-stage small-molecule drug candidates. [Read More](#)

9. [Sanofi Genzyme Opts-In on Hemophilia Drug](#)

Sanofi Genzyme has opted to co-develop and co-commercialize fitusiran, an investigational RNAi therapeutic for treating hemophilia and rare bleeding disorders, with Alnylam Pharmaceuticals in the US, Canada, and Western Europe. The companies formed an alliance in January 2014. [Read More](#)

10. [EMA OKs Nine Drugs, Including Three Biosimilars](#)

The European Medicines Agency has recommended the approval of nine drugs, including three biosimilars. Among them are Gilead Sciences' Vemlidy for chronic hepatitis B, Novo Nordisk's Fiasp for diabetes, and Sanofi's Sulfiqua, also for diabetes. The news is part of *DCAT Value Chain Insights Pipeline News*. [Read More](#)

*The DCAT organization is happy to provide this service to its members each Friday.
Have a great weekend!*

About Top Industry News

The DCAT organization recognizes its members have minimal time to keep up with the continuous flow of news covering this dynamic industry. To help ensure our members never miss the most important stories impacting the global pharmaceutical manufacturing industry, we will deliver each Friday, the week's Top Industry News, as selected by DCAT Editorial Director Patricia Van Arnum.



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