August 26, 2016

DCAT

TOP Industry NEWS

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

1. **Pfizer to Acquire Medivation for $14 Billion**

   Pfizer has agreed to acquire Medivation, a pharmaceutical company based in San Francisco, California that is developing and commercializing small molecules for oncology, for $14 billion. Medivation's key product is Xtandi (enzalutamide), a prostate cancer drug that generated approximately $2.2 billion in worldwide net sales over the past four quarters. **Read More**

2. **Pfizer To Acquire AstraZeneca's Small-Molecule Antibiotics Business**

   In yet another deal, Pfizer has agreed to acquire the development and commercialization rights to AstraZeneca's late-stage small-molecule anti-infectives business, primarily outside the US, in a deal valued up to $1.575 billion. The deal is expected to close in the fourth quarter of 2016. **Read More**

3. **Teva Has Setback in Copaxone Patent Ruling**

   Teva Pharmaceutical Industries has experienced a setback when a US agency invalidated two patents for the company's multiple sclerosis drug, Copaxone (glatiramer acetate injection). Copaxone accounted for $4.0 billion (including $3.2 billion in the US), or 20% of Teva's revenues in 2015. Teva plans to appeal. **Read More**

4. **Mallinckrodt To Build Out New Campus in New Jersey for Specialty Brands**

   Mallinckrodt will invest more than $80 million for building out a new campus in Bedminster, New Jersey that will consolidate operations for its specialty brands groups, co-locating more than 400 commercial and science employees.The investment is intended to help consolidate operations after a series of acquisitions over the last 18 months that resulted in Mallinckrodt having commercial and development operations spread across more than a dozen US sites. **Read More**

5. **Mylan Comments On EpiPen**

   Mylan has responded to comments from several US senators calling for lower pricing for Mylan's EpiPen (epinephrine injection) Auto-Injector, which is used for the emergency treatment of life-threatening allergic reactions (anaphylaxis). Mylan's EpiPen leads the company's specialty product portfolio, accounting for $1 billion of the total $1.2 billion global 2015 sales in specialty revenues. **Read**

More

6. **Sanofi To Supply FDA with Additional Info For Combo Diabetes Therapy**

Sanofi has amended its new drug application for the diabetes therapy combination of basal insulin glargine and lixisenatide by submitting updated information about the therapy's pen delivery device. The additional information, submitted at the request of the FDA, extends the FDA's review goal date by three months to November 2016. The combination therapy is an important piece of Sanofi's strategy for its diabetes franchise, the company's highest revenue therapeutic area. **Read More**

7. **Pfizer Gets FDA Approval for Abuse-Deterrent Opioid**

Pfizer has received FDA approval for an abuse-deterrent version of oxycodone, Troxyca ER (oxycodone hydrochloride and naltrexone hydrochloride) extended-release capsules. Troxyca ER has properties that are expected to reduce abuse when crushed and administered by oral and intranasal routes. **Read More**

8. **Portola Receives FDA Complete Response Letter For Manufacturing Issues**

Portola Pharmaceuticals, a South San Francisco-based biopharmaceutical company, has received a Complete Response Letter from the FDA requesting additional information primarily related to manufacturing in the company's biologics license application for AndexXa (andexanet alfa), an anticoagulant antidote. Earlier this year, Pfizer and Bristol-Myers Squibb formed a collaboration with Portola to develop and commercialize andexanet alfa in Japan and had formed two earlier separate non-exclusive clinical collaboration agreements to support Phase II and Phase III development in the US and the European Union. **Read More**

9. **AstraZeneca, Lilly Receive Fast Track Designation For Alzheimer's Drug**

AstraZeneca and Eli Lilly and Company have received FDA fast-track designation for AZD3293, an oral beta secretase cleaving enzyme inhibitor in Phase III clinical trial for Alzheimer's disease. AstraZeneca and Lilly formed an alliance in 2014 for the drugs' development and commercialization. Lilly leads clinical development, AstraZeneca is responsible for manufacturing, and the companies are jointly responsible for commercialization. **Read More**

10. **FDA Issues Draft Guidance of Pharmaceutical Co-Crystals**

The FDA has issued draft guidance on regulatory classification of pharmaceutical co-crystal solid-state forms. Pharmaceutical co-crystals have opened up opportunities beyond conventional solid-state forms of an active pharmaceutical ingredient (API), such as salts and polymorphs, and can be tailored to enhance bioavailability, stability and processability of APIs during drug product manufacture. **Read More**

Upcoming DCAT Event

DCAT After the Show

Don't miss DCAT's inaugural networking event following CPhI Worldwide in Barcelona on Wednesday, October 5th from 6:00 PM to 8:30 PM at the beautiful Casa Llotja de Mar. Located just steps away from the Gothic Quarter and Port of Barcelona, this event offers the perfect opportunity to utilize that time between the tradeshow and your late-night dinner plans to catch up with colleagues and establish valuable industry connections.

Registration for this event is now open. The reception is $79.00 USD per person, and includes food and beverage, and transportation from the show to Casa Llotja de Mar, compliments of ACIC Fine Chemicals, Inc. Further event information and available branding opportunities may be found **here.**

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.

The Drug, Chemical & Associated Technologies Association (DCAT) is a not-for-profit, global business development association whose unique membership model integrates both innovator and generic drug manufacturers and suppliers of ingredients, development and manufacturing services, and related technologies. We are committed to provide programs, events and services that help our members meet their business objectives, expand their network of customers and suppliers, and gain insight into industry trends, markets, and those issues impacting pharmaceutical development and manufacturing.

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