June 2, 2017

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. **Merck & Co. Plans to Invest $310 Million in Irish Manufacturing Facilities**

   Merck & Co. plans to invest EUR 280 million ($313 million) over the next three years at its manufacturing sites in Carlow and Cork Counties, Ireland. **Read More**

2. **FDA Advisory Committee Recommends Pfizer's Biosimilar of Amgen's Epogen**

   A FDA advisory committee has recommended for approval Pfizer's proposed epoetin alfa biosimilar across all indications to its reference products, Amgen's Epogen and Johnson & Johnson's Procrit. The news is part of *DCAT Value Chain Insights Pipeline News*. **Read More**

3. **EMA Accepts Novartis' Filings for Biosimilars of AbbVie's Humira and J&J's Remicade**

   The European Medicines Agency has accepted for review applications by Sandoz, the generics arm of Novartis, for proposed biosimilars of adalimumab (reference product, AbbVie's Humira) and infliximab (reference product, Johnson & Johnson's Remicade). Humira is AbbVie's top-selling drug with 2016 sales of $16 billion, and Remicade is Johnson & Johnson's top-selling pharmaceutical with 2016 sales of $6.97 billion. The news is part of *DCAT Value Chain Insights Pipeline News*. **Read More**

4. **FDA Commissioner Discusses Drug Pricing at House Budget Hearing**

   FDA Commissioner Scott Gottlieb outlined at a US House of Representatives hearing some actions the FDA is considering to increase competition and mitigate high drug pricing. **Read More**

5. **Cambrex Expands Small-Molecule Manufacturing**

   Cambrex, a contract manufacturer of small-molecule active pharmaceutical ingredients, has expanded large-scale manufacturing capacity at its cGMP facility in Karlskoga, Sweden and has introduced additional continuous flow manufacturing for the production of high-purity intermediates. **Read More**

6. **Roquette Agrees to Acquire Brazilian Excipient Manufacturer**

   Roquette, an excipient manufacturer, has agreed to acquire the excipient business of Itacel, headquartered in Itapevi, Brazil, near São Paulo, which includes a range of products (binders, fillers, disintegrants), a manufacturing plant, and research and development laboratories. **Read More**

7. **Roche Recalls Valium Products in Australia Due to Tampering**

Roche, in consultation with the Therapeutic Goods Administration, the national regulatory authority in Australia, is recalling all batches of Valium 5-mg tablets supplied in blister packs of 50 tablets due to the discovery of evidence of medicine tampering. **Read More**

8. **EMA, EC Issue Guidance for Pharma Companies Post Brexit**

   The European Medicines Agency and the European Commission have published guidance to help pharmaceutical companies prepare for the UK's withdrawal from the European Union. **Read More**

9. **Otsuka, Proteus Digital Health Refile for Digital Medicine**

   The FDA has acknowledged receipt of a new drug application resubmission by Otsuka Pharmaceutical and Proteus Digital Health for the drug-device combination product of Abilify (aripiprazole) embedded with a Proteus ingestible sensor in the tablet. The NDA resubmission will now be reviewed by the FDA, with an anticipated action date by the agency in the fourth quarter of 2017. **Read More**

10. **Janssen, Protagonist Therapeutics Form Pact Worth Up to $990 Million**

    Protagonist Therapeutics, a Newark, California-based clinical-stage biopharmaceutical company, has formed a worldwide license and collaboration agreement, worth up to $990 million ($50 million upfront, $940 in milestones), with Janssen Biotech, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, for the co-development and commercialization of Protagonist's oral peptide IL-23 receptor antagonist for all indications, including inflammatory bowel disease. **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.

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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