May 19, 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. **Thermo Fisher Agrees to Buy Patheon for $7.2 Billion**

   Thermo Fisher Scientific has agreed to acquire Patheon, a CDMO of active pharmaceutical ingredients and drug products, for $7.2 billion, inclusive of $2.0 billion of net debt. The boards of director of both companies have approved the acquisition, which is expected to close by the end of 2017. **Read More**

2. **BI Opens Commercial-Scale Biomanufacturing Site in China**

   Boehringer Ingelheim has inaugurated its commercial biopharmaceutical production site in Shanghai, China. The facility, with first-phase investment of more than EUR 70 million ($78 million), will support the company's contract manufacturing business and add to the company's existing capabilities for clinical trial material supply in China. **Read More**

3. **Flamma Expands Small-Molecule Capabilities in China**

   Flamma SpA, a Italy-headquartered contract manufacturer of small-molecule active pharmaceutical ingredients, will formally open its new cGMP workshop and Research and Development (R&D) Center in Dalian, China on June 19, 2017. The investment of $20 million brings the total capacity of Flamma's Chinese operations in Dalian to 200 cubic meters and brings its R&D group to the same campus. **Read More**

4. **New FDA Commissioner Outlines Priorities**

   Scott Gottlieb, MD, the new FDA Commissioner, addressed his staff for the first time and outlined key priorities of the agency, including improving it through the program alignment by the Office of Regulatory Affairs, addressing drug pricing through increased competition, implementing the 21st Century Cures Act, improving the generic-drug review process, and addressing opioid abuse. **Read More**

5. **EMA Report Shows Higher GMP Non-Compliance in India**

   A report by the European Medicines Agency shows that in 2016 European inspectors issued non-GMP compliance statements to 11% of Indian sites visited in 2016 compared to 1% globally. **Read More**

6. **HHS, Congress Battle Over Funding and User Fees**

   Tom Price, the Secretary of Health and Human Services, advanced the Administration's budget blueprint in calling for increased user fees to fund the FDA rather than appropriated funding.

Congressional leaders have offered competing views and related legislative measures.. **Read More**

7. **Canada Proposes Changes to Drug-Pricing Regulations**

   For the first time in more than 20 years, Canada is proposing changes to its drug-pricing regulations, including a proposal to introduce new, economics-based price regulation factors. **Read More**

8. **Cambrex To Expand Small-Molecule Pilot Plant**

   Cambrex, a CMO of active pharmaceutical ingredients, plans to expand pilot-plant capabilities at its facility in High Point, North Carolina with the installation of a fourth reactor suite. The $2.4-million investment will increase the site's reactor capacity by around 30%. **Read More**

9. **Amgen Submits BLA for Migraine Drug**

   Amgen has submitted a biologics license application to the FDA for erenumab for preventing migraines. The drug is part of a pact, formed in 2015, between Amgen and Novartis for developing drugs to treat migraines and Alzheimer's disease. The news is part of *DCAT Value Chain Insights Pipeline News*. **Read More**

10. **Biogen Acquires Rare-Disease Drug for Strokes**

    Bioogen has completed an asset purchase from Remedy Pharmaceuticals for a Phase III candidate, Cirara (intravenous glyburide), for treating a severe form of ischemic stroke. Bioogen will make an upfront payment of $120 million to Remedy and may also pay additional milestone payments and royalties. **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.

DCAT
DRUG, CHEMICAL & ASSOCIATED TECHNOLOGIES ASSOCIATION

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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