**New approvals**

- None

**New indications**

- **Daklinza™ (daclatasvir):** Bristol-Myers Squibb’s Daklinza was approved for use in combination with Sovaldi® (sofosbuvir) for the treatment of chronic hepatitis C virus (HCV) in patients co-infected with HIV. Additionally, it was approved in HCV patients with advanced cirrhosis, including decompensated cirrhosis and patients with post-liver transplant recurrence of HCV genotype 1 infection.

- **Harvoni® (ledipasvir/sofosbuvir):** The Food and Drug Administration (FDA) approved two additional indications for Gilead's Harvoni. The drug is now indicated for the treatment of liver transplant recipients with genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis, and for genotype 1-infected patients with decompensated cirrhosis.
February news

- “Sarepta Therapeutics, Inc., a developer of innovative RNA-targeted therapeutics, announced that the U.S. Food and Drug Administration (FDA) will require additional time to complete its review of the New Drug Application (NDA) for eteplirsen, for the treatment of Duchenne muscular dystrophy (DMD) amenable to exon 51 skipping. In a notice received from the FDA, the Prescription Drug User Fee Act (PDUFA) date for eteplirsen has been extended to May 26, 2016. The rescheduled date for the Peripheral and Central Nervous System Advisory Committee meeting has not yet been determined.”

- “The agency’s arthritis panel voted 21-3 in support of approval for Inflectra, a biosimilar developed by South Korea’s Celltrion and co-marketed with Pfizer. In clinical development, the treatment proved itself similar to J&J’s Remicade® in rheumatoid arthritis and ankylosing spondylitis, and the panel signed off on approving it for psoriatic arthritis, Crohn’s disease, ulcerative colitis and psoriasis, as well.”

- “CTI BioPharma Corp. provided an update regarding the clinical studies being conducted under the Company’s Investigational New Drug (“IND”) application for pacritinib. Following the issuance of the Company’s February 8, 2016, press release describing the partial clinical hold issued by the U.S. Food and Drug Administration (FDA) regarding those clinical studies, the Company received an oral communication from the FDA followed by a letter notifying the Company that the Company’s IND for pacritinib has been placed on full clinical hold. The Company has withdrawn its New Drug Application (NDA) until the Company has had a chance to review the safety and efficacy data from the PERSIST-2 Phase 3 clinical trial and decide next steps.”

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