Drug pipeline: 2Q15

Laura DeFrancesco

US Food and Drug Administration approvals seem to have waned from even the previous quarter when eight drugs with novel mechanisms were approved. Yet breakthrough therapy designation remains popular among drug developers and regulators as the designation moves into

less trafficked areas. Two monoclonal antibodies for lowering cholesterol were neck and neck with PDUFA dates mere months apart, with one gaining approval already in the US, the other in Europe as this page was being prepared. Biosimilars are starting to take root as well.

Historic US regulatory approvals by lead indication area

*2015 partial year from January 1 to June 30. Numbers in parentheses after legend are total approvals since 1995.

Notable clinical trial results (2Q15)

Drug/company	Indication	Summary
Glembatumumab vedotin/Celldex Therapeutics	Breast cancer	4/6/2015. Antibody against glycoprotein nonmetastatic melanoma protein B (NMB) showed efficacy in NMB over-expressors and triple-negative breast cancer in randomized phase 2 trial. <i>J. Clin. Oncol.</i> http://jco.ascopubs.org/content/early/2015/04/06/JCO.2014.56.2959.abstract (10 May 2015)
SB-010/Sterna Biologics	Asthma	5/17/2015. Inhaled DNzyme (34-bp synthetic DNA that inactivates GATA3 mRNA) in phase 3 randomized, placebo-controlled trial attenuated asthmatic response after allergen provocation. <i>N. Engl. J. Med.</i> 372 , 1987–1995 (2015)
DEZ-001/Dezima Pharma	Dyslipidemia/hypercholesterolemia	6/2/2015. Phase 2b trial of cholesteryl ester transfer protein (CETP) inhibitor showed 45% reduction in low-density lipoprotein, approaching proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors. <i>Lancet</i> http://dx.doi.org/10.1016/S0140-6736(15)60158-1 (2 June 2015)
T-Vec/Amgen	Melanoma	5/26/2015. Oncolytic virus demonstrated higher durable response rate and overall response rate in unresected melanoma in phase 3 trials. <i>J. Clin. Oncol.</i> http://jco.ascopubs.org/content/early/2015/05/22/JCO.2014.58.3377.abstract?sid=c731b9b7-7638-4197-8069-2caaeac16826 (26 May 2015)

Source: BioMedTracker, a service of Sagient Research (<http://www.biomedtracker.com/>).

Notable upcoming regulatory decisions (3Q15)

Drug/company	Indication	Summary
Praluent/Regeneron	Dyslipidemia/hypercholesterolemia	7/24/2015. FDA PDUFA for fully human mAb targeting proprotein convertase subtilisin/kexin type 9 (PCSK9)
Repatha/Amgen	Dyslipidemia/hypercholesterolemia	8/27/2015. FDA PDUFA for fully human mAb targeting PCSK9
Retacrit (recombinant human erythropoietin)/Hospira	Dialysis-dependent anemia	8/16/2015. FDA PDUFA for Epogen biosimilar
Kanuma (recombinant human lipase)/Alexion	Lysosomal acid lipase deficiency	9/8/2015. FDA PDUFA for this enzyme replacement therapy
Biosimilar pegfilgrastim/Apotex	Neutropenia/leukopenia	8/17/2015. FDA PDUFA for Neupogen biosimilar

FDA, US Food and Drug Administration; PDUFA, Prescription Drug User Fee Act; mAb, monoclonal antibody. Source: BioMedTracker, a service of Sagient Research (<http://www.biomedtracker.com/>).

Notable regulatory approvals (2Q15)

Drug/company	Indication	Drug information
Product registration		
Kybella (sodium deoxycholate)/Kythera Biopharmaceuticals	Fat removal	4/29/2015. FDA. Injectable adipolytic detergent (found in bile salt)
Zykadis (ceritinib)/Novartis	Non-small cell lung cancer	4/29/2015. FDA, accelerated approval, and 6/5/2015, EMA approval, for ALK inhibitor
Breakthrough therapy designation		
Rucaparib/Clovis Oncology	Ovarian cancer	4/6/2015. ADP-ribose polymerase inhibitor (PARP) inhibitor
Viaskin peanut/DBV Technologies	Food allergies	4/9/2015. Crude peanut protein extract bound electrostatically to skin patch for delivery to epidermis
SER-109/Seres Health	Clostridium difficile-associated diarrhea/infection	6/12/2015. Undisclosed mixture of Firmacure eubacterial spores that out-compete pathogen
Venetoclax/AbbVie	Chronic leukocytic leukemia with 17p deletion	5/6/2015. Bcl-2 selective antagonist
Olipudase Alfa-1/Sanofi	Niemann-Pick disease	6/4/2015. Recombinant acid sphingomyelinase

FDA, US Food and Drug Administration; EMA, European Medicines Agency. Source: BioMedTracker, a service of Sagient Research (<http://www.biomedtracker.com/>).

Notable regulatory setbacks (2Q14)

Drug/company	Indication	Drug information
BioVaxID/Accentia Biopharmaceuticals	Indolent non-Hodgkin's lymphoma	4/23/2015. Negative CHMP opinion of this vaccine comprising tumor-specific idiotypic conjugated to keyhole limpet hemocyanin plus GM-CSF (granulocyte-macrophage colony-stimulating factor) owing to inadequate trial design
Heparesc/Cytonet	Urea cycle disorder	6/25/2015. Negative CHMP opinion for primary heterogeneous human hepatocytes from non-transplantable donor liver cells due to multiple problems in trial
CERE-110 (Adeno-associated virus serotype 2 encoding nerve growth factor)/Sangamo	Alzheimer's disease	4/22/2015. Company suspended phase 2 trial owing to lack of statistical significance
Tasquinamod/Active Biotech	Prostate cancer	4/16/2015. Company suspended trial of small molecule targeting S100A9 due to unfavorable risk-benefit balance of this angiogenesis/metastasis inhibitor
NBI-77860/Neurocrine Biosciences	Congenital adrenal hyperplasia	6/8/2015. Company suspended trial, and FDA put trial on partial clinical hold owing to new preclinical data on corticotropin-releasing factor receptor antagonist

Source: BioMedTracker, a service of Sagient Research (<http://www.biomedtracker.com/>).

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Erratum: Drug pipeline: 2Q15

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In the version of this article initially published, in the “Notable clinical trial results (2Q 2015)” table, clinical trial data for the drug Glembatumumab vedotin was said to be phase 3. It was phase 2, not phase 3, data. The error has been corrected in the HTML and PDF versions of the article.