Approved and Pending Biosimilar Applications*

Biosimilar	Reference Product	Marketing Status	Litigation (Active or Pending)
Name: Zarxio® (filgrastim-sndz) *Manufacturer:* Sandoz *BLA:* 125553	*Name:* Neupogen® (filgrastim) *Manufacturer:* Amgen *BLA:* 103353 *Indications/Uses:* Treats neutropenia by increasing production of white blood cells. Often used for patients taking chemotherapy treatments or after bone marrow transplantation.	Approved by FDA on March 6, 2015. Commercial launch by Sandoz/Novartis in September 2015.	U.S. Supreme Court opinion issued on June 12, 2017. U.S. Court of Appeals for the Federal Circuit *en banc* opinion issued on December 14, 2017. Litigation in the U.S. District Court for the Northern District of California; summary judgment of non-infringement entered on January 1, 2018; on appeal to the U.S. Court of Appeals for the Federal Circuit.
Name: Inflectra® (infliximab-dyyb) *Manufacturer:* Celltrion, Inc. *BLA:* 125544	*Name:* Remicade® (infliximab) *Manufacturer:* Janssen Biotech, Inc. *BLA:* 103772 *Indications/Uses:* Inhibits tumor necrosis factor-alpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, Crohn's disease, and ankylosing spondylitis.	Approved by FDA on April 5, 2016. Commercial (at-risk) launch by Pfizer/Celltrion in November 2016.	Litigation initiated in the U.S. District Court for the District of Massachusetts. Grant of Celltrion's motion for summary judgment currently on appeal to the U.S. Court of Appeals for the Federal Circuit.

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Approved and Pending Biosimilar Applications*

Name: Erelzi® (etanercept-szzs) *Manufacturer:* Sandoz *BLA:* 761042	*Name:* Enbrel® (etanercept) Manufacturer: Amgen *BLA:* 103795 *Indications/Uses:* Inhibits tumor necrosis factor-alpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis.	Approved by FDA on August 30, 2016. Received unanimous support (20-0) of approval by FDA's Arthritis Advisory Committee on July 13, 2016. Sandoz has agreed not to launch its biosimilar product Erelzi until an undisclosed date or event occurs.	Litigation in the U.S. District Court for the District of New Jersey. Bench trial took place from September 11, 2018 to September 25, 2018.
Name: Amjevita™ (adalimumab-atto) *Manufacturer:* Amgen *BLA:* 761024	*Name:* Humira® (adalimumab) *Manufacturer:* AbbVie *BLA:* 125057 *Indications/Uses:* Inhibits tumor necrosis factor-alpha to reduce inflamm-ation in patients with the following autoimmune diseases: rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, moderate to severe chronic psoriasis, moderate to severe hidradenitis suppurativa, uveitis, and juvenile idiopathic arthritis.	Approved by FDA on September 23, 2016. Received unanimous support (26-0) of approval by FDA's Arthritis Advisory Committee on July 12, 2016. Amgen expects to launch its biosimilar product in Europe on Oct. 16, 2018, and in the United States on Jan. 31, 2023.	Global settlement between AbbVie and Amgen for Amjevita announced in April 2018 and provides for a U.S. market entry date of January 31, 2023.

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Name: Renflexis® (infliximab-abda) *Manufacturer:* Samsung Bioepis/Merck *BLA:* 761054	*Name:* Remicade® (infliximab) *Manufacturer:* Janssen Biotech, Inc. *BLA:* 103772 *Indications/Uses:* Inhibits tumor necrosis factor-alpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, Crohn's disease, and ankylosing spondylitis.	Approved by FDA on April 21, 2017. Commercial launch by Merck in late July 2017.	Litigation under the BPCIA settled in November 2017.
Name: Cyltezo® (adalimumab-adbm) *Manufacturer:* Boehringer Ingelheim *BLA:* Unknown	*Name:* Humira® (adalimumab) *Manufacturer:* AbbVie *BLA:* 125057 *Indications/Uses:* Inhibits tumor necrosis factor-alpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, moderate to severe chronic psoriasis, moderate to severe hidradenitis suppurativa, uveitis, and juvenile idiopathic arthritis.	Approved by FDA on August 25, 2017.	Litigation in the U.S. District Court for the District of Delaware. Expert discovery not scheduled to close until May 2020.

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Name: Mvasi™ (bevacizumab-awwb) *Manufacturer:* Amgen/Allergan *BLA:* 761028	*Name:* Avastin® (bevacizumab) *Manufacturer:* Genentech *BLA:* 125085 *Indications/Uses:* Vascular endothelial growth factor-specific angiogenesis inhibitor indicated for the treat-ment, either alone or as part of combination regimens, of: metastatic colorectal cancer; non-squamous non-small cell lung cancer;glioblastoma; metastatic renal cell carcinoma; cervical cancer; and recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.	Approved by FDA on September 14, 2017. Received unanimous support (17-0) of approval by FDA's Oncologic Drugs Advisory Committee on July 13, 2017.	Litigation in the U.S. District Court for the District of Delaware. Trial is scheduled to begin in July 2020.
Name: Ogivri™ (trastuzumab-dkst) *Manufacturer:* Mylan/Biocon *BLA:* 761074	*Name:* Herceptin® (trastuzumab) *Manufacturer:* Genentech *BLA:* 103792 *Indications/Uses:* HER2/neu receptor antagonist indicated for (1) the treatment of HER2 overexpressing breast cancer; and (2) the treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.	Approved by FDA on December 1, 2017. Received unanimous support (16-0) of approval by FDA's Oncologic Drugs Advisory Committee on July 13, 2017.	Mylan announced global licensing agreement for trastuzumab with Genentech on March 13, 2017.

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Name: Ixifi™ (infliximab-qbtx) *Manufacturer:* Pfizer *BLA:* 761072	*Name:* Remicade® (infliximab) *Manufacturer:* Janssen Biotech, Inc. *BLA:* 103772 *Indications/Uses:* Inhibits tumor necrosis factor-alpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, Crohn's disease, and ankylosing spondylitis.	Approved by FDA on December 13, 2017.	None under the BPCIA. Antitrust lawsuits are pending against Janssen/J&J in the U.S. District Court for the Eastern District of Pennsylvania, one filed by Pfizer in November 2017 and the second filed by Walgreen Co. and Kroger Co. in June 2018. District court denied Defendants' motion to dismiss the Pfizer complaint on August 8, 2018.
Name: Retacrit® (epoetin alfa-epbx) *Manufacturer:* Hospira/Pfizer *BLA:* 125545	*Name:* Epogen® or Procrit® (epoetin alfa) *Manufacturer:* Amgen (Epogen); Janssen Biotech (Procrit) *BLA:* 103234 *Indications/Uses:* Stimulates red blood cells to treat anemia. Often used for patients taking chemotherapy treatment or who have chronic renal failure.	Approved by FDA on May 15, 2018. Received support (14-1) for approval by FDA's Oncologic Drugs Advisory Committee on May 25, 2017.	Litigation initiated in the U.S. District Court for the District of Delaware. Currently on appeal by both parties to the U.S. Court of Appeals for the Federal Circuit.

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Approved and Pending Biosimilar Applications*

Name: Fulphila™ (pegfilgrastim-jmdb) *Manufacturer:* Mylan/Biocon *BLA:* 761075	*Name:* Neulasta® (pegfilgrastim) *Manufacturer:* Amgen *BLA:* 125031 *Indications/Uses:* Treats neutropenia by increasing production of white blood cells. Often used for patients in chemotherapy or after a bone marrow transplant. Neulasta® is the long-acting formulation of Neupogen®.	Approved by FDA on June 4, 2018. Commercial launch by Mylan in or around July 2018.	Litigation in the U.S. District Court for the Western District of Pennsylvania.
Name: Nivestym™ (filgrastim-aafi) *Manufacturer:* Hospira/Pfizer *BLA:* 761080	*Name:* Neupogen® (filgrastim) *Manufacturer:* Amgen *BLA:* 103353 *Indications/Uses:* Treats neutropenia by increasing production of white blood cells. Often used for patients taking chemotherapy treatments or after bone marrow transplantation.	Approved by FDA on July 20, 2018. Commercial launch by Pfizer on or around October 1, 2018.	Litigation in the U.S. District Court for the District of Delaware.

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Approved and Pending Biosimilar Applications*

Name: Hyrimoz™ (adalimumab-adaz) *Manufacturer:* Sandoz *BLA:* 761071	*Name:* Humira® (adalimumab) *Manufacturer:* AbbVie *BLA:* 125057 *Indications/Uses:* Inhibits tumor necrosis factor-alpha to reduce inflamm-ation in patients with the following autoimmune diseases: rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, moderate to severe chronic psoriasis, moderate to severe hidradenitis suppurativa, uveitis, and juvenile idiopathic arthritis.	Approved by FDA on October 30, 2018.	Global settlement between AbbVie and Sandoz for Hyrimoz announced in October 2018 and provides for a U.S. market entry date of September 30, 2023.
Name: Udenyca™ (pegfilgrastim-cbqv) *Manufacturer:* Coherus BioSciences *BLA:* 761039	*Name:* Neulasta® (pegfilgrastim) *Manufacturer:* Amgen *BLA:* 125031 *Indications/Uses:* Treats neutropenia by increasing production of white blood cells. Often used for patients taking chemotherapy treatments.	Approved by FDA on November 2, 2018. Coherus expects to launch commercially in January 2019.	Complaint in the U.S. District Court for the District of Delaware dismissed on February 2, 2018, but currently on appeal to U.S. Court of Appeals for the Federal Circuit. Trade secret misappropriation and unfair competition lawsuit also pending in California Superior Court. Jury trial is scheduled to begin on January 22, 2019.

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Approved and Pending Biosimilar Applications*

Name: Truxima® (rituximab-abbs) *Manufacturer:* Celltrion, Inc. *BLA:* 761088	*Name:* Rituxan® (rituximab) *Manufacturer:* Genentech *BLA:* 103705 *Indications/Uses:* Targets CD-20 antigen on the surface of B-cells to treat (1) Non-Hodgkin's Lymphoma; (2) Chronic Lymphocytic Leukemia; (3) Rheumatoid Arthritis in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies; (4) Granulomatosis with Polyangiitis (Wegener's Granulomatosis) and Microscopic Polyangiitis in adult patients in combination with glucocorticoids.	Approved on November 28, 2018. Received unanimous support for approval from FDA's Oncologic Drugs Advisory Committee on October 10, 2018.	Complaint filed in the U.S. District Court for the District of New Jersey jointly and voluntarily dismissed on November 1, 2018.
Name: Lapelga™ *Manufacturer:* Apotex (Apobiologix) *BLA:* Unknown	*Name:* Neulasta® (pegfilgrastim) *Manufacturer:* Amgen *BLA:* 125031 *Indications/Uses:* Treats neutropenia by increasing production of white blood cells. Often used for patients taking chemotherapy treatments or after bone marrow transplantation.	Pending FDA approval.	Litigation in the U.S. District Court for the Southern District of Florida.

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Name: Grastofil® *Manufacturer:* Apotex (Apobiologix) *BLA:* Unknown	*Name:* Neupogen® (filgrastim) *Manufacturer:* Amgen *BLA:* 103353 *Indications/Uses:* Treats neutropenia by increasing production of white blood cells. Often used for patients taking chemotherapy treatments.	Pending FDA approval.	Complaint filed in the U.S. District Court for the Southern District of Florida consolidated into *Amgen v. Apotex* pegfilgrastim litigation (see above).
Name: LA-EP2006 *Manufacturer:* Sandoz *BLA:* Unknown	*Name:* Neulasta® (pegfilgrastim) *Manufacturer:* Amgen *BLA:* 125031 *Indications/Uses:* Treats neutropenia by increasing production of white blood cells. Often used for patients taking chemotherapy treatments. Neulasta® is the long-acting formulation of Neupogen®.	Pending FDA approval; delayed after being issued a Complete Response Letter ("CRL") by FDA in Q2 2016. Sandoz has stated that it is conducting an additional study per FDA's data request/expected to be completed in early 2019.	Litigation in the U.S. District Court for the Northern District of California (being coordinated for discovery and trial with the *Amgen v. Sandoz* filgrastim matter). Fully briefed oral arguments are expected to be scheduled for early 2019.

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Approved and Pending Biosimilar Applications*

Name: CT-P6/Herzuma *Manufacturer:* Celltrion/Teva *BLA:* Unknown	*Name:* Herceptin® (trastuzumab) *Manufacturer:* Genentech *BLA:* 103792 *Indications/Uses:* HER2/neu receptor antagonist indicated for (1) the treatment of HER2 overexpressing breast cancer; and (2) the treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.	Pending FDA approval; delayed after being issued a CRL by FDA in or prior to April 2018, relating to manufacturing problems.	Litigation in the U.S. District Court for the District of Delaware.
Name: ABP 980 *Manufacturer:* Amgen/Allergan *BLA:* Unknown	*Name:* Herceptin® (trastuzumab) *Manufacturer:* Genentech *BLA:* 103792 *Indications/Uses:* HER2/neu receptor antagonist indicated for (1) the treatment of HER2 overexpressing breast cancer; and (2) the treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.	Pending FDA approval; delayed after being issued a CRL by FDA on or around May 31, 2018.	Litigation in the U.S. District Court for the District of Delaware.

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Approved and Pending Biosimilar Applications*

Name: TBD *Manufacturer:* Adello Biologics *BLA:* Unknown	*Name:* Neupogen® (filgrastim) *Manufacturer:* Amgen *BLA:* 103353 *Indications/Uses:* Treats neutropenia by increasing production of white blood cells. Often used for patients taking chemotherapy treatments or after bone marrow transplantation.	Pending FDA approval; aBLA accepted for filing in September 2017.	Litigation in the U.S. District Court for the District of New Jersey.
Name: SB3 *Manufacturer:* Samsung Bioepis/Merck *BLA:* Unknown	*Name:* Herceptin® (trastuzumab) *Manufacturer:* Genentech *BLA:* 103792 *Indications/Uses:* HER2/neu receptor antagonist indicated for (1) the treatment of HER2 overexpressing breast cancer; and (2) the treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.	Pending FDA approval; aBLA accepted for filing in late December 2017.	Litigation in the U.S. District Court for the District of Delaware.

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Approved and Pending Biosimilar Applications*

Name: Rixathon/GP2013 *Manufacturer:* Sandoz *BLA:* Unknown	*Name:* Rituxan® (rituximab) *Manufacturer:* Genentech *BLA:* 103705 *Indications/Uses:* Targets CD-20 antigen on the surface of B-cells to treat (1) Non-Hodgkin's Lymphoma; (2) Chronic Lymphocytic Leukemia; (3) Rheumatoid Arthritis in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies; (4) Granulomatosis with Polyangiitis (Wegener's Granulomatosis) and Microscopic Polyangiitis in adult patients in combination with glucocorticoids.	Pending FDA approval; delayed after being issued a CRL by FDA in May 2018.	Litigation in the U.S. District Court for the District of New Jersey.
Name: TBD *Manufacturer:* Hospira/Pfizer *BLA:* Unknown	*Name:* Herceptin® (trastuzumab) *Manufacturer:* Genentech *BLA:* 103792 *Indications/Uses:* HER2/neu receptor antagonist indicated for the treatment of HER2-overexpressing breast and metastatic gastric/ gastroesophageal adenocarcinoma.	Pending FDA approval.	Complaint filed under the BPCIA in the U.S. District Court for the District of Delaware has been dismissed.

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Approved and Pending Biosimilar Applications*

Name: SB5 *Manufacturer:* Samsung Bioepis/Merck *BLA:* Unknown	*Name:* Humira® (adalimumab) *Manufacturer:* AbbVie *BLA:* 125057 *Indications/Uses:* Inhibits tumor necrosis factor-alpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, moderate to severe chronic psoriasis, moderate to severe hidradenitis suppurativa, uveitis, and juvenile idiopathic arthritis.	Pending FDA approval; aBLA accepted for filing in late September 2018.	Global resolution of all IP-related litigation related to SB5 (adalimumab) announced by Abbvie and Samsung in April 2018 and provides for a U.S. market entry date of June 30, 2023.
Name: TX-01 *Manufacturer:* Tanvex BioPharma *BLA:* Unknown	*Name:* Neupogen® (filgrastim) *Manufacturer:* Amgen *BLA:* 103353 *Indications/Uses:* Treats neutropenia by increasing production of white blood cells. Often used for patients taking chemotherapy treatments or after bone marrow transplantation.	Pending FDA approval; aBLA submitted on or around October 1, 2018.	N/A

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Name: TBD *Manufacturer:* Mylan *BLA:* Unknown	*Name:* Humira® (adalimumab) *Manufacturer:* AbbVie *BLA:* 125057 *Indications/Uses:* Inhibits tumor necrosis factor-alpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, moderate to severe chronic psoriasis, moderate to severe hidradenitis suppurativa, uveitis, and juvenile idiopathic arthritis.	Pending FDA approval.	Global settlement between AbbVie and Mylan for a follow-on adalimumab product announced in July 2018 and provides for a U.S. market entry date of July 31, 2023.
Name: TBD *Manufacturer:* Fresenius Kabi *BLA:* Unknown	*Name:* Humira® (adalimumab) *Manufacturer:* AbbVie *BLA:* 125057 *Indications/Uses:* Inhibits tumor necrosis factor-alpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, moderate to severe chronic psoriasis, moderate to severe	Pending FDA approval.	Global settlement between AbbVie and Fresenius Kabi for a follow-on adalimumab product provides for a U.S. market entry date of September 30, 2023.

	hidradenitis suppurativa, uveitis, and juvenile idiopathic arthritis.		