| Biosimilar | Reference Product | Marketing | Litigation |
|------------------------------------|---|--|---|
| Diosillilai | Reference Frounct | Marketing Status | (Active or Pending) |
| Name: Zarxio® (filgrastim-sndz) | Name: Neupogen® (filgrastim) | Approved by FDA on March 6, 2015. | U.S. Supreme Court opinion issued on June 12, 2017. |
| Manufacturer: Sandoz | Manufacturer: Amgen | Commercial | U.S. Court of |
| BLA: 125553 | 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. | launch by Sandoz/Novartis in September 2015. | 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) | Name: Remicade® (infliximab) | Approved by FDA on April 5, 2016. | Litigation in the U.S. District Court for the District of |
| Manufacturer: | Manufacturer: Janssen | | Massachusetts; |
| Celltrion, Inc. | Biotech, Inc. | Commercial (atrisk) launch by | summary judgment motions pending. |
| BLA: 125544 | 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. | Pfizer/Celltrion in November 2016. | U.S. Court of Appeals for the Federal Circuit affirmed patent invalidity on January 23, 2018. |

^{*}Based on publicly available information as of the date of this publication. Last revised June 13, 2018 – FOR INFORMATIONAL PURPOSES ONLY.



| Name: Erelzi® | Name: Enbrel® | Approved by | Litigation in the U.S. |
|---|--|--|---|
| (etanercept-szzs) | (etanercept) | FDA on | District Court for the |
| (Commercept SEES) | (0.00.10100) | August 30, | District of New |
| Manufacturer: Sandoz | Manufacturer: Amgen | 2016. | Jersey; summary |
| | 8 | | judgment motions |
| BLA: 761042 | BLA: 103795 | Received | pending. Trial is |
| | | unanimous | scheduled to begin on |
| | Indications/Uses: | support (20-0) | September 11, 2018. |
| | Inhibits tumor necrosis | of approval by | |
| | factor-alpha to reduce | FDA's Arthritis | |
| | inflammation in patients | Advisory | |
| | with the following | Committee on | |
| | autoimmune diseases: | <u>July 13, 2016</u> . | |
| | rheumatoid arthritis, | | |
| | ankylosing spondylitis, | Sandoz has | |
| | psoriatic arthritis, and | agreed not to | |
| | plaque psoriasis. | launch its | |
| | | biosimilar | |
| | | product Erelzi | |
| | | until an | |
| | | undisclosed date | |
| | | or event occurs. | |
| | | | |
| <i>Name:</i> Amievita TM | Name: Humira® | Approved by | Litigation settlement |
| <i>Name:</i> Amjevita TM (adalimumab-atto) | Name: Humira® (adalimumab) | Approved by FDA on | Litigation settlement reached between the |
| Name: Amjevita™ (adalimumab-atto) | Name: Humira® (adalimumab) | FDA on | reached between the |
| (adalimumab-atto) | | | |
| S S | (adalimumab) | FDA on September 23, | reached between the parties in September |
| (adalimumab-atto) | (adalimumab) | FDA on September 23, | reached between the parties in September |
| (adalimumab-atto) Manufacturer: Amgen | (adalimumab) Manufacturer: AbbVie | FDA on September 23, 2016. | reached between the parties in September 2017. |
| (adalimumab-atto) Manufacturer: Amgen | (adalimumab) Manufacturer: AbbVie | FDA on September 23, 2016. Received | reached between the parties in September 2017. Amgen's press |
| (adalimumab-atto) Manufacturer: Amgen | (adalimumab) Manufacturer: AbbVie BLA: 125057 Indications/Uses: Inhibits tumor necrosis | FDA on September 23, 2016. Received unanimous support (26-0) of approval by | reached between the parties in September 2017. Amgen's press release reported that AbbVie will grant patent licenses for the |
| (adalimumab-atto) Manufacturer: Amgen | (adalimumab) Manufacturer: AbbVie BLA: 125057 Indications/Uses: Inhibits tumor necrosis factor-alpha to reduce | FDA on September 23, 2016. Received unanimous support (26-0) of approval by FDA's Arthritis | reached between the parties in September 2017. Amgen's press release reported that AbbVie will grant patent licenses for the use and sale of the |
| (adalimumab-atto) Manufacturer: Amgen | (adalimumab) Manufacturer: AbbVie BLA: 125057 Indications/Uses: Inhibits tumor necrosis factor-alpha to reduce inflamm-ation in | FDA on September 23, 2016. Received unanimous support (26-0) of approval by FDA's Arthritis Advisory | reached between the parties in September 2017. Amgen's press release reported that AbbVie will grant patent licenses for the use and sale of the product worldwide, |
| (adalimumab-atto) Manufacturer: Amgen | (adalimumab) Manufacturer: AbbVie BLA: 125057 Indications/Uses: Inhibits tumor necrosis factor-alpha to reduce inflamm-ation in patients with the | FDA on September 23, 2016. Received unanimous support (26-0) of approval by FDA's Arthritis Advisory Committee on | reached between the parties in September 2017. Amgen's press release reported that AbbVie will grant patent licenses for the use and sale of the product worldwide, on a country-by- |
| (adalimumab-atto) Manufacturer: Amgen | (adalimumab) Manufacturer: AbbVie BLA: 125057 Indications/Uses: Inhibits tumor necrosis factor-alpha to reduce inflamm-ation in patients with the following autoimmune | FDA on September 23, 2016. Received unanimous support (26-0) of approval by FDA's Arthritis Advisory | reached between the parties in September 2017. Amgen's press release reported that AbbVie will grant patent licenses for the use and sale of the product worldwide, |
| (adalimumab-atto) Manufacturer: Amgen | (adalimumab) Manufacturer: AbbVie BLA: 125057 Indications/Uses: Inhibits tumor necrosis factor-alpha to reduce inflamm-ation in patients with the following autoimmune diseases: rheumatoid | FDA on September 23, 2016. Received unanimous support (26-0) of approval by FDA's Arthritis Advisory Committee on July 12, 2016. | reached between the parties in September 2017. Amgen's press release reported that AbbVie will grant patent licenses for the use and sale of the product worldwide, on a country-by- |
| (adalimumab-atto) Manufacturer: Amgen | (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 | FDA on September 23, 2016. Received unanimous support (26-0) of approval by FDA's Arthritis Advisory Committee on July 12, 2016. Amgen expects | reached between the parties in September 2017. Amgen's press release reported that AbbVie will grant patent licenses for the use and sale of the product worldwide, on a country-by- |
| (adalimumab-atto) Manufacturer: Amgen | (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 | 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 | reached between the parties in September 2017. Amgen's press release reported that AbbVie will grant patent licenses for the use and sale of the product worldwide, on a country-by- |
| (adalimumab-atto) Manufacturer: Amgen | (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 | 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 | reached between the parties in September 2017. Amgen's press release reported that AbbVie will grant patent licenses for the use and sale of the product worldwide, on a country-by- |
| (adalimumab-atto) Manufacturer: Amgen | (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 | 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 | reached between the parties in September 2017. Amgen's press release reported that AbbVie will grant patent licenses for the use and sale of the product worldwide, on a country-by- |
| (adalimumab-atto) Manufacturer: Amgen | (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 | 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 | reached between the parties in September 2017. Amgen's press release reported that AbbVie will grant patent licenses for the use and sale of the product worldwide, on a country-by- |
| (adalimumab-atto) Manufacturer: Amgen | (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, | 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, | reached between the parties in September 2017. Amgen's press release reported that AbbVie will grant patent licenses for the use and sale of the product worldwide, on a country-by- |
| (adalimumab-atto) Manufacturer: Amgen | (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 | 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 | reached between the parties in September 2017. Amgen's press release reported that AbbVie will grant patent licenses for the use and sale of the product worldwide, on a country-by- |
| (adalimumab-atto) Manufacturer: Amgen | (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, | 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, | reached between the parties in September 2017. Amgen's press release reported that AbbVie will grant patent licenses for the use and sale of the product worldwide, on a country-by- |

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| | uveitis, and juvenile | | |
|----------------------|---|-----------------------|------------------------|
| | idiopathic arthritis. | | |
| Name: Renflexis® | Name: Remicade® | Approved by | Litigation settled in |
| (infliximab-abda) | (infliximab) | FDA on | November 2017. |
| (IIIIIXIIIIao-aoda) | (IIIIIXIIIIab) | April 21, 2017. | TVOVCIIIOCI 2017. |
| Manufacturer: | Manufacturer: Janssen | <u>11pm 21, 2017.</u> | |
| Samsung | Biotech, Inc. | Commercial | |
| Bioepis/Merck | Biotech, me. | launch by | |
| Broopis, ivieren | BLA: 103772 | Merck in late | |
| BLA: 761054 | | July 2017. | |
| | Indications/Uses: | J | |
| | 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. | | |
| | | | |
| Name: Cyltezo® | Name: Humira® | Approved by | Litigation in the U.S. |
| (adalimumab-adbm) | (adalimumab) | FDA on | District Court for the |
| | | August 25, | District of Delaware. |
| Manufacturer: | Manufacturer: AbbVie | <u>2017.</u> | |
| Boehringer Ingelheim | DV 4 105055 | | Expert discovery not |
| | BLA: 125057 | | scheduled to close |
| BLA: Unknown | 7.1 /7.7 | | until May 2020. |
| | 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. | | |
| | Totoputile utilitis. | <u>l</u> | |

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| Name: Mvasi TM | Name: Avastin® | Approved by | Litigation in the U.S. |
|---|---|-----------------------------|-------------------------|
| (bevacizumab-awwb) | (bevacizumab) | FDA on | District Court for the |
| (************************************** | (6.1 | September 14, | District of Delaware. |
| Manufacturer: | Manufacturer: | 2017. | Trial is scheduled to |
| Amgen/Allergan | Genentech | | begin in July 2020. |
| | | Received | |
| BLA: 761028 | BLA: 125085 | unanimous | A separate action in |
| | | support (17-0) | the Central District of |
| | Indications/Uses: | of approval by | California was |
| | Vascular endothelial | FDA's | dismissed in |
| | growth factor-specific | Oncologic | February 2018. |
| | angiogenesis inhibitor | Drugs Advisory | |
| | indicated for the treat- | Committee on | |
| | ment, either alone or as | July 13, 2017. | |
| | 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. | | |
| | cancer. | | |
| Name: Ogivri TM | Name: Herceptin® | Approved by | N/A |
| (trastuzumab-dkst) | (trastuzumab) | FDA on | |
| | | December 1, | Mylan announced |
| Manufacturer: | Manufacturer: | <u>2017.</u> | global license |
| Mylan/Biocon | Genentech | | agreement for |
| | | Received | trastuzumab with |
| BLA: 761074 | BLA: 103792 | unanimous | Genentech on |
| | | support (16-0) | March 13, 2017. |
| | Indications/Uses: | of approval by | |
| | HER2/neu receptor | FDA's | |
| | antagonist indicated for | Oncologic | |
| | (1) the treatment of | Drugs Advisory Committee on | |
| | HER2 overexpressing | July 13, 2017. | |
| | breast cancer; and (2) | July 13, 2017. | |
| | the treatment of HER2- | | |
| | overexpressing | | |
| | metastatic gastric or | | |

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| | T . | T | |
|---------------------------|--|-----------------|-------------------------------------|
| | gastroesophageal | | |
| | junction | | |
| | adenocarcinoma. | | |
| Name: Ixifi TM | Name: Remicade® | Approved by | None under the |
| (infliximab-qbtx) | (infliximab) | FDA on | BPCIA. |
| M. C. A. D.C. | M. C. A. Janes | December 13, | A |
| Manufacturer: Pfizer | Manufacturer: Janssen | <u>2017.</u> | Antitrust lawsuits are |
| BLA: 761072 | Biotech, Inc. | | pending against Janssen/J&J in the |
| BLA. 701072 | BLA: 103772 | | U.S. District Court for the Eastern |
| | Indications/Uses: | | District of |
| | Inhibits tumor necrosis | | Pennsylvania, one |
| | factor-alpha to reduce | | filed by Pfizer in |
| | inflammation in patients | | November 2017 and |
| | with the following | | the second filed by |
| | autoimmune diseases: | | Walgreen Co. and |
| | rheumatoid arthritis, | | Kroger Co. in June |
| | psoriatic arthritis, | | 2018. |
| | ulcerative colitis, | | |
| | Crohn's disease, and | | |
| | ankylosing spondylitis. | | |
| Name: Retacrit® | Name: Epogen® or | Approved by | Litigation in the U.S. |
| (epoetin alfa-epbx) | Procrit® (epoetin alfa) | FDA on May | District Court for the |
| | , i | 15, 2018. | District of Delaware |
| Manufacturer: Hospira | Manufacturer: Amgen | | winding down. |
| | (Epogen); Janssen | Received | |
| BLA: 125545 | Biotech (Procrit) | support (14-1) | \$70 million jury |
| | | for approval by | verdict of patent |
| | BLA: 103234 | FDA's | infringement in |
| | | Oncologic | September 2017, |
| | Indications/Uses: | Drugs Advisory | pending post-trial |
| | Stimulates red blood | Committee on | motions for judgment |
| | cells to treat anemia. Often used for patients | May 25, 2017. | as a matter of law. |
| | taking chemotherapy | | |
| | treatment or who have | | |
| | chronic renal failure. | | |
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| Name: Fulphila TM | Name: Neulasta® | Approved by | Litigation in the U.C. |
|------------------------------|--------------------------|----------------|---|
| | | Approved by | Litigation in the U.S. District Court for the |
| (pegfilgrastim-jmbd) | (pegfilgrastim) | FDA on June 4, | |
| 1.6 | | <u>2018.</u> | Western District of |
| Manufacturer: | Manufacturer: Amgen | | Pennsylvania. |
| Mylan/Biocon | | | |
| | BLA: 125031 | | |
| BLA: 761075 | | | |
| | 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®. | | |
| | | | |
| Name: Lapelga TM | Name: Neulasta® | Pending FDA | None. |
| Name. Lapeiga | | • | Trone. |
| A. C. A. A. | (pegfilgrastim) | approval. | |
| Manufacturer: Apotex | | | |
| | Manufacturer: Amgen | | |
| BLA: Unknown | | | |
| | BLA: 125031 | | |
| | | | |
| | Indications/Uses: Treats | | |
| | neutropenia by | | |
| | increasing production of | | |
| | white blood cells. Often | | |
| | used for patients taking | | |
| | 1 | | |
| | chemotherapy | | |
| | treatments or after bone | | |
| | marrow transplantation. | | |
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| Name: Grastofil® Manufacturer: Apotex 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. | Litigation in the U.S. District Court for the Southern District of Florida (consolidated into Amgen v. Apotex pegfilgrastim litigation, 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 longacting 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). |



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|-----------------------|---------------------------------|-------------------|--------------------------------------|
| Name: CHS-1701 | Name: Neulasta® | Pending FDA | Action in the U.S. |
| | (pegfilgrastim) | approval; | District Court for the |
| Manufacturer: Coherus | | delayed after | District of Delaware |
| BioSciences | Manufacturer: Amgen | being issued a | dismissed on |
| | | CRL by FDA in | February 2, 2018, but |
| BLA: Unknown | BLA: 125031 | June 2017. | currently on appeal to |
| | | | U.S. Court of |
| | <i>Indications/Uses:</i> Treats | Coherus | Appeals for the |
| | neutropenia by | announced that | Federal Circuit. |
| | increasing production of | this resubmitted | |
| | white blood cells. Often | aBLA was | Trade secret |
| | used for patients taking | accepted by | misappropriation and |
| | chemotherapy | FDA for review | unfair competition |
| | treatments. | on May 14, | lawsuit also pending |
| | treatments. | 2018. | in California Superior |
| | | 2016. | Court. |
| | | | Court. |
| Name: CT-P6/Herzuma | Name: Herceptin® | Pending FDA | Litigation in the U.S. |
| | (trastuzumab) | approval; | District Court for the |
| Manufacturer: | (trustuzumus) | delayed after | District of Delaware. |
| Celltrion/Teva | Manufacturer: | being issued a | District of Bolaware. |
| Centrion/Teva | Genentech | CRL by FDA in | Separate complaint |
| BLA: Unknown | Genenteen | or prior to April | filed in the U.S. |
| BL1. Chknown | BLA: 103792 | 2018, related to | District Court for the |
| | BLA. 103/92 | | Northern District of |
| | 1 1 /17 | manufacturing | |
| | Indications/Uses: | problems. | California, dismissed on Genentech's |
| | HER2/neu receptor | | |
| | antagonist indicated for | | motion on May 9, |
| | (1) the treatment of | | 2018. |
| | HER2 overexpressing | | |
| | breast cancer; and (2) | | |
| | the treatment of HER2- | | |
| | overexpressing | | |
| | 1 0 | | |
| | metastatic gastric or | | |
| | gastroesophageal | | |
| | junction | | |
| | adenocarcinoma. | | |
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|----------------------|---------------------------------|----------------|--|
| Name: ABP 980 | Name: Herceptin® | Pending FDA | N/A |
| | (trastuzumab) | approval; | |
| Manufacturer: | | delayed after | |
| Amgen/Allergan | Manufacturer: | being issued a | |
| | Genentech | CRL by FDA on | |
| BLA: Unknown | | or around | |
| | BLA: 103792 | May 31, 2018. | |
| | | , | |
| | 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. | | |
| | | | |
| Name: TBD | Name: Neupogen® | Pending FDA | Litigation in the U.S. |
| | (filgrastim) | approval; aBLA | District Court for the |
| Manufacturer: Adello | | accepted for | District of New |
| Biologics | Manufacturer: Amgen | filing in | Jersey. |
| | | September | , and the second |
| BLA: Unknown | BLA: 103353 | 2017. | |
| | | | |
| | <i>Indications/Uses:</i> Treats | | |
| | neutropenia by | | |
| | increasing production of | | |
| | white blood cells. Often | | |
| | used for patients taking | | |
| | chemotherapy | | |
| | treatments or after bone | | |
| | | | |
| | marrow transplantation. | | |
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| Name: SB3 Manufacturer: Samsung Bioepis/Merck | Name: Herceptin® (trastuzumab) Manufacturer: Genentech | Pending FDA approval; aBLA accepted for filing in late December 2017. | N/A |
|--|--|---|---|
| BLA: Unknown | 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. | | |
| Name: Truxima Manufacturer: Celltrion, Inc. 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) | Pending FDA approval; delayed after being issued a CRL by FDA in or prior to April 2018, related to manufacturing problems. | Litigation in the U.S. District Court for the District of New Jersey. Separate complaint filed in the U.S. District Court for the Northern District of California, dismissed on Genentech's motion on May 9, 2018. |

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| | Granulomatosis with Polyangiitis (Wegener's Granulomatosis) and Microscopic Polyangiitis in adult patients in combination with glucocorticoids. | | |
|---|--|--|---|
| 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 | 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. |
| | combination with glucocorticoids. | | |

