Biosimilar	Reference Product	Marketing	Litigation
		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 Appeals
BLA: 125553	BLA: 103353  Indications/Uses: Treats neutropenia by increasing	launch by Sandoz/Novartis in September 2015.	for the Federal Circuit  en banc opinion  issued on  December 14, 2017.
	production of white blood cells. Often used for patients taking chemotherapy treatments or after bone marrow transplantation.		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,	Litigation initiated in the U.S. District Court
Manufacturer: Celltrion, Inc.	Manufacturer: Janssen Biotech, Inc.	2016. Commercial (at-	for the District of Massachusetts.
BLA: 125544	BLA: 103772	risk) launch by Pfizer/Celltrion in November	Grant of Celltrion's motion for summary judgment currently on
	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.	2016.	appeal to the U.S. Court of Appeals for the Federal Circuit.

<sup>\*</sup>Based on publicly available information as of the date of this publication. Last revised December 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
(*************************************	(**************************************	August 30,	District of New
Manufacturer: Sandoz	Manufacturer: Amgen	2016.	Jersey.
			, and the second
BLA: 761042	BLA: 103795	Received	Bench trial took place
		unanimous	from September 11,
	<i>Indications/Uses:</i> Inhibits	support (20-0) of	2018 to September 25,
	tumor necrosis factor-	approval by	2018.
	alpha to reduce	FDA's Arthritis	
	inflammation in patients	Advisory	
	with the following	Committee on	
	autoimmune diseases:	<u>July 13, 2016</u> .	
	rheumatoid arthritis,	Sandoz has	
	ankylosing spondylitis, psoriatic arthritis, and	agreed not to	
	plaque psoriasis.	launch its	
	prague psoriasis.	biosimilar	
		product Erelzi	
		until an	
		undisclosed date	
		or event occurs.	
Name: Amjevita <sup>TM</sup>	Name: Humira®	Approved by	Global settlement
(adalimumab-atto)	(adalimumab)	FDA on	1 / A11 T7' 1
_ `,	(adammumab)		between AbbVie and
		September 23,	Amgen for Amjevita
Manufacturer: Amgen	Manufacturer: AbbVie		Amgen for Amjevita announced in April
Manufacturer: Amgen	Manufacturer: AbbVie	September 23, 2016.	Amgen for Amjevita announced in April 2018 and provides for
		September 23, 2016. Received	Amgen for Amjevita announced in April 2018 and provides for a U.S. market entry
Manufacturer: Amgen	Manufacturer: AbbVie BLA: 125057	September 23, 2016.  Received unanimous	Amgen for Amjevita announced in April 2018 and provides for a U.S. market entry date of January 31,
Manufacturer: Amgen	Manufacturer: AbbVie  BLA: 125057  Indications/Uses: Inhibits	September 23, 2016.  Received unanimous support (26-0) of	Amgen for Amjevita announced in April 2018 and provides for a U.S. market entry
Manufacturer: Amgen	Manufacturer: AbbVie  BLA: 125057  Indications/Uses: Inhibits tumor necrosis factor-	September 23, 2016.  Received unanimous support (26-0) of approval by	Amgen for Amjevita announced in April 2018 and provides for a U.S. market entry date of January 31,
Manufacturer: Amgen	Manufacturer: AbbVie  BLA: 125057  Indications/Uses: Inhibits tumor necrosis factoralpha to reduce inflamm-	September 23, 2016.  Received unanimous support (26-0) of approval by FDA's Arthritis	Amgen for Amjevita announced in April 2018 and provides for a U.S. market entry date of January 31,
Manufacturer: Amgen	Manufacturer: AbbVie  BLA: 125057  Indications/Uses: Inhibits tumor necrosis factoralpha to reduce inflammation in patients with the	September 23, 2016.  Received unanimous support (26-0) of approval by FDA's Arthritis Advisory	Amgen for Amjevita announced in April 2018 and provides for a U.S. market entry date of January 31,
Manufacturer: Amgen	Manufacturer: AbbVie  BLA: 125057  Indications/Uses: Inhibits tumor necrosis factoralpha to reduce inflammation in patients with the following autoimmune	September 23, 2016.  Received unanimous support (26-0) of approval by FDA's Arthritis Advisory Committee on	Amgen for Amjevita announced in April 2018 and provides for a U.S. market entry date of January 31,
Manufacturer: Amgen	Manufacturer: AbbVie  BLA: 125057  Indications/Uses: Inhibits tumor necrosis factoralpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid	September 23, 2016.  Received unanimous support (26-0) of approval by FDA's Arthritis Advisory	Amgen for Amjevita announced in April 2018 and provides for a U.S. market entry date of January 31,
Manufacturer: Amgen	Manufacturer: AbbVie  BLA: 125057  Indications/Uses: Inhibits tumor necrosis factoralpha to reduce inflammation in patients with the following autoimmune	September 23, 2016.  Received unanimous support (26-0) of approval by FDA's Arthritis Advisory Committee on	Amgen for Amjevita announced in April 2018 and provides for a U.S. market entry date of January 31,
Manufacturer: Amgen	Manufacturer: AbbVie  BLA: 125057  Indications/Uses: Inhibits tumor necrosis factoralpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid arthritis, psoriatic	September 23, 2016.  Received unanimous support (26-0) of approval by FDA's Arthritis Advisory Committee on July 12, 2016.	Amgen for Amjevita announced in April 2018 and provides for a U.S. market entry date of January 31,
Manufacturer: Amgen	Manufacturer: AbbVie  BLA: 125057  Indications/Uses: Inhibits tumor necrosis factoralpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid arthritis, psoriatic arthritis, ankylosing	September 23, 2016.  Received unanimous support (26-0) of approval by FDA's Arthritis Advisory Committee on July 12, 2016.  Amgen expects	Amgen for Amjevita announced in April 2018 and provides for a U.S. market entry date of January 31,
Manufacturer: Amgen	Manufacturer: AbbVie  BLA: 125057  Indications/Uses: Inhibits tumor necrosis factoralpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, moderate to severe	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	Amgen for Amjevita announced in April 2018 and provides for a U.S. market entry date of January 31,
Manufacturer: Amgen	Manufacturer: AbbVie  BLA: 125057  Indications/Uses: Inhibits tumor necrosis factoralpha 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,	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	Amgen for Amjevita announced in April 2018 and provides for a U.S. market entry date of January 31,
Manufacturer: Amgen	Manufacturer: AbbVie  BLA: 125057  Indications/Uses: Inhibits tumor necrosis factoralpha 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	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,	Amgen for Amjevita announced in April 2018 and provides for a U.S. market entry date of January 31,
Manufacturer: Amgen	Manufacturer: AbbVie  BLA: 125057  Indications/Uses: Inhibits tumor necrosis factoralpha 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,	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	Amgen for Amjevita announced in April 2018 and provides for a U.S. market entry date of January 31,
Manufacturer: Amgen	Manufacturer: AbbVie  BLA: 125057  Indications/Uses: Inhibits tumor necrosis factoralpha 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	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,	Amgen for Amjevita announced in April 2018 and provides for a U.S. market entry date of January 31,

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Name: Renflexis®	Name: Remicade®	Approved by	Litigation under the
(infliximab-abda)	(infliximab)	FDA on	BPCIA settled in November 2017.
Manufacturer:	Manufacturer: Janssen	April 21, 2017.	November 2017.
Samsung Bioepis/Merck	Biotech, Inc.	Commercial	
		launch by Merck	
BLA: 761054	BLA: 103772	in late July 2017.	
	<i>Indications/Uses:</i> Inhibits	2017.	
	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
(www.iii.w.ii.w.c wwe.iii.)	(waariii waa iyaa aa	August 25,	District of Delaware.
Manufacturer:	Manufacturer: AbbVie	<u>2017.</u>	
Boehringer Ingelheim	771 18707		Expert discovery not
BLA: Unknown	BLA: 125057		scheduled to close
bla. Ulikilowii	<i>Indications/Uses:</i> Inhibits		until May 2020.
	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.		

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Name: Mvasi <sup>TM</sup>	Name: Avastin®	Approved by	Litigation in the U.S.
(bevacizumab-awwb)	(bevacizumab)	FDA on	District Court for the
(**************************************	(0.0.0000000000000000000000000000000000	September 14,	District of Delaware.
Manufacturer:	Manufacturer:	<del>2017.</del>	Trial is scheduled to
Amgen/Allergan	Genentech		begin in July 2020.
		Received	
BLA: 761028	BLA: 125085	unanimous	
		support (17-0) of	
	Indications/Uses:	approval by	
	Vascular endothelial	FDA's	
	growth factor-specific	Oncologic	
	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.		
	peritoliear cancer.		
Name: Ogivri <sup>TM</sup>	Name: Herceptin®	Approved by	Mylan announced
(trastuzumab-dkst)	(trastuzumab)	FDA on	global licensing
	,	December 1,	agreement for
Manufacturer:	Manufacturer:	2017.	trastuzumab with
Mylan/Biocon	Genentech		Genentech on
		Received	March 13, 2017.
BLA: 761074	BLA: 103792	unanimous	
		support (16-0) of	
	Indications/Uses:	approval by	
	HER2/neu receptor	FDA's	
	antagonist indicated for	Oncologic	
	(1) the treatment of	Drugs Advisory	
	HER2 overexpressing	Committee on	
	breast cancer; and (2) the	July 13, 2017.	
	treatment of HER2-		
	overexpressing metastatic		
	gastric or		
	gastroesophageal		
	junction adenocarcinoma.		
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<sup>\*</sup>Based on publicly available information as of the date of this publication. Last revised December 13, 2018 – FOR INFORMATIONAL PURPOSES ONLY.



Name: Ixifi <sup>TM</sup>	Name: Remicade®	A namovo d by	None under the
		Approved by	
(infliximab-qbtx)	(infliximab)	FDA on	BPCIA.
Manufacturer: Pfizer BLA: 761072	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.	December 13, 2017.	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
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.	Currently on appeal by both parties to the U.S. Court of Appeals for the Federal Circuit.

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Name: Fulphila <sup>TM</sup> (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 longacting 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 <sup>TM</sup> (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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M H TM	Name: Humira®	A mmnorra 1 1	Clabal asult
Name: Hyrimoz <sup>TM</sup> (adalimumab-adaz)	(adalimumab)	Approved by FDA on	Global settlement between AbbVie and
(adammumao-adaz)	(adammumab)	October 30,	Sandoz for Hyrimoz
Manufacturer: Sondoz	Manufacturer: AbbVie	2018.	announced in October
Manufacturer: Sandoz	Manajaciurer: Abb vie	<u>2016.</u>	
BLA: 761071	BLA: 125057		2018 and provides for
BLA: /010/1	BLA: 123037		a U.S. market entry
	I I I a di a a /II a a a I a la ilaita		date of September 30,
	Indications/Uses: Inhibits		2023.
	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.		
77.1 TM	N. N. I.		
Name: Udenyca <sup>TM</sup>	Name: Neulasta®	Approved by	Complaint in the U.S.
(pegfilgrastim-cbqv)	(pegfilgrastim)	FDA on	District Court for the
		November 2,	District of Delaware
Manufacturer: Coherus	Manufacturer: Amgen	<u>2018.</u>	dismissed on
BioSciences	D. 1. 105001		February 2, 2018, but
	BLA: 125031	Coherus expects	currently on appeal to
BLA: 761039		to launch	U.S. Court of Appeals
	Indications/Uses: Treats	commercially in	for the Federal
	neutropenia by increasing	January 2019.	Circuit.
	production of white		
	blood cells. Often used		Trade secret
	for patients taking		misappropriation and
	chemotherapy treatments.		unfair competition
			lawsuit also pending
			in California Superior
			Court. Jury trial is
			scheduled to begin on
			January 22, 2019.

<sup>\*</sup>Based on publicly available information as of the date of this publication. Last revised December 13, 2018 – FOR INFORMATIONAL PURPOSES ONLY.



Name: Truxima®	Name: Rituxan®	Approved on	Complaint filed in the
(rituximab-abbs)	(rituximab)	November 28,	U.S. District Court for
		2018.	the District of New
Manufacturer:	Manufacturer:		Jersey jointly and
Celltrion, Inc.	Genentech	Received	voluntarily dismissed
BLA: 761088	BLA: 103705	unanimous support for	on November 1, 2018.
	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.	approval from FDA's Oncologic Drugs Advisory Committee on October 10, 2018.	
Name: Lapelga <sup>TM</sup>	Name: Neulasta®	Pending FDA	Litigation in the U.S.
Manufacturary Anotar	(pegfilgrastim)	approval.	District Court for the Southern District of
Manufacturer: Apotex	Manufacturen Amaon		Florida.
(Apobiologix)	Manufacturer: Amgen		Florida.
BLA: Unknown	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.		
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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 <i>Amgen v. Apotex</i> 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 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).  Fully briefed oral arguments are expected to be scheduled for early 2019.

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Name: CT-P6/Herzuma	Name: Herceptin®	Pending FDA	Litigation in the U.S.
	(trastuzumab)	approval;	District Court for the
Manufacturer:	_	delayed after	District of Delaware.
Celltrion/Teva	Manufacturer:	being issued a	
	Genentech	CRL by FDA in	
BLA: Unknown	BLA: 103792	or prior to April 2018, relating to manufacturing	
	Indications/Uses:	problems.	
	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: ABP 980	Name: Herceptin®	Pending FDA	Litigation in the U.S.
_	(trastuzumab)	approval;	District Court for the
Manufacturer:		delayed after	District of Delaware.
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		
	1 0		
	breast cancer; and (2) the		
	treatment of HER2-		
	overexpressing metastatic		
	gastric or		
	gastroesophageal		
	junction adenocarcinoma.		

<sup>\*</sup>Based on publicly available information as of the date of this publication. Last revised December 13, 2018 – FOR INFORMATIONAL PURPOSES ONLY.



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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Name:	Name: Rituxan®	Pending FDA	Litigation in the U.S.
Rixathon/GP2013	(rituximab)	approval; delayed after	District Court for the District of New
Manufacturer: Sandoz	Manufacturer: Genentech	being issued a CRL by FDA in	Jersey.
BLA: Unknown	BLA: 103705	May 2018.	
	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.		
Name: TBD	Name: Herceptin® (trastuzumab)	Pending FDA approval.	Complaint filed under the BPCIA in the U.S.
Manufacturer:	Manufacturer:		District Court for the
Hospira/Pfizer	Genentech		District of Delaware
BLA: Unknown	BLA: 103792		has been dismissed.
	Indications/Uses:		
	HER2/neu receptor		
	antagonist indicated for		
	the treatment of HER2-		
	overexpressing breast		
	and metastatic gastric/		
	gastroesophageal		
	adenocarcinoma.		

<sup>\*</sup>Based on publicly available information as of the date of this publication. Last revised December 13, 2018 – FOR INFORMATIONAL PURPOSES ONLY.



M CD C	M II ' ®	D 1. ED 4	C1-1-1 1 C
Name: SB5	Name: Humira®	Pending FDA	Global resolution of
	(adalimumab)	approval; aBLA	all IP-related litigation
Manufacturer:		accepted for	related to SB5
Samsung Bioepis/Merck	<i>Manufacturer</i> : AbbVie	filing in late	(adalimumab)
		September 2018.	announced by Abbvie
BLA: Unknown	BLA: 125057		and Samsung in April
			2018 and provides for
	<i>Indications/Uses:</i> Inhibits		a U.S. market entry
	tumor necrosis factor-		date of June 30, 2023.
	alpha to reduce		,
	inflammation in patients		
	with the following		
	autoimmune diseases:		
	rheumatoid arthritis,		
	psoriatic arthritis,		
	ankylosing spondylitis,		
	Crohn's disease,		
	1		
	ulcerative colitis,		
	moderate to severe		
	chronic psoriasis,		
	moderate to severe		
	hidradenitis suppurativa,		
	uveitis, and juvenile		
	idiopathic arthritis.		
Name: TX-01	Name: Neupogen®	Pending FDA	N/A
	(filgrastim)	approval; aBLA	
Manufacturer: Tanvex		submitted on or	
BioPharma	Manufacturer: Amgen	around	
		October 1, 2018.	
BLA: Unknown	BLA: 103353		
	<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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<sup>\*</sup>Based on publicly available information as of the date of this publication. Last revised December 13, 2018 – FOR INFORMATIONAL PURPOSES ONLY.



Name: TBD	Name: Humira® (adalimumab)	Pending FDA approval.	Global settlement between AbbVie and
Manufacturer: Mylan	Manufacturer: AbbVie	арргочаг.	Mylan for a follow-on adalimumab product announced in July
BLA: Unknown	Indications/Uses: Inhibits tumor necrosis factoralpha 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		announced in July 2018 and provides for a U.S. market entry date of July 31, 2023.
	idiopathic arthritis.		
Name: TBD  Manufacturer: Fresenius Kabi	Name: Humira® (adalimumab)  Manufacturer: AbbVie	Pending FDA approval.	Global settlement between AbbVie and Fresenius Kabi for a follow-on
BLA: Unknown	BLA: 125057		adalimumab product provides for a U.S. market entry date of
	Indications/Uses: Inhibits tumor necrosis factoralpha 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		September 30, 2023.

<sup>\*</sup>Based on publicly available information as of the date of this publication. Last revised December 13, 2018 – FOR INFORMATIONAL PURPOSES ONLY.



hidradenitis suppurativa, uveitis, and juvenile idiopathic arthritis.	