#### Introducing Fitzpatrick's BIOLOGICS DIOLOGICS DIOLOG



# **BiologicsHQ Company Pages**

provide information about

biologic drug licensors

# **CELLTRION**

### FDA-Approved Biologics and Pending Applications

Inflectra® Infliximab-dyyb aBL 125544

### Approved Foreign Follow-On Biologics / Biosimilars

**Biosimilars Approved In Canada** Remsima (Celltrion) (January-2014)

Biosimilars Approved In The E.U. Remsima (Celltrion) (September-2013) Truxima (Celltrion) (February-2017)

**Biosimilars Approved In Japan** Infliximab BS (Remsima) (Celltrion / Nippon Kayaku) (July-2014)

**Biosimilars Approved In South Korea** Herzuma (CT-P6) (Celltrion) (January-2014) Remsima (Celltrion) (July-2012) Truxima (CT P10) (Celltrion) (November-2016)

### 🗐 Inter Partes Review Proceedings

Approved Foreign Follow-On Biologics / Biosimilars Herceptin® IPR2017-00959 IPR2017-01121 Biosimilars Approved In The E.U. IPB2017-01122 Amgevita / Solymbic (Amgen) (March-2017) IPR2017-01139 IPB2017-01140 Inter Partes Review Proceedings **Rituxan®** IPR2015-01733 PTAB Portal Click to view IPR2015-01744 IPR2016-01614 information IPR2016-01667 IPR Case No(s): concerning IPR2017-01093 IPR2017-00827 / IPR2017-01009 IPR2017-01094 **IPRs** IPR2017-01095 IPR2017-00826 / IPR2017-01008 IPR2017-01227 IPR2017-01229 IPR2017-00823 IPR2017-01230 🗇 U.S. BPCIA / Biosimilar Litigation U.S. BPCIA / Biologics Litigation Click to view PACER information **Remicade®** 1:14-cv-02256 (S.D.N.Y.) concerning 1:14-cv-11613 (D. Mass.) Case No(s): 1:14-cv-07049 (S.D.N.Y.) patent 1:16-cv-00666 (D. Del.) 1:15-cv-10698 (D. Mass.) litigations 1:16-cv-00071 (N.D. Utah) 2:16-cv-00322 (E.D. Va.) 1:16-cv-11117 (D. Mass.) Related News Articles Related News Articles Click to view The U.S. Biosimilars Market is "Spotlight On" Spotlight On Humira® (adalimumab) Heating Up: Guidance from the report for Federal Circuit is Expected Late Spotlight On Corinne E. Atton; April M. Breyer; Whitney L. Meier Spring April 10, 2017 this drug Adalimumab Robert S. Schwartz, Ph.D.; Corinne E. Atton April 6, 2015 For More Information On:

www.BiologicsHQ.com

**April M. Breyer** (212) 218-2561

**Corinne E. Atton** (212) 218-2212

Fitzpatrick's Biotechnology/ **Biologics Group:** 

Robert S. Schwartz, Ph.D. (212) 218-2298

Brendan M. O'Malley, Ph.D. (212) 218-2249

# **BiologicsHQ Product Pages**

provide information for CDER-listed / 505(2)(b) biologic drugs

### Humira® (adalimumab)

BL	125057	
	120001	

U.S. License Holder:	Date of License:	Last Update:
AbbVie Inc.	December-31-2002	April-28-2017

### FDA-Approved Indications

HUMIRA (adalimumab) is a tumor necrosis factor (TNF) blocker indicated for treatment of:

Rheumatoid Arthritis (RA): Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA:

Juvenile Idiopathic Arthritis (JIA): Reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older:

### All aBLA / 505(b)(2) Activity

aBLA / 505(b)(2) Approved by FDA Amjevita: Amgen (September-2016)

aBLA / 505(b)(2) Accepted by FDA BI 695501 Boehringer Ingelheim (January-2017)

**Business Development** 

# & Marketing:

Linda Ficano (212) 218-2284