



Biosimilar Humira® (adalimumab) and Enbrel® (etanercept) – FDA Advisory Committee Recommendations

- On July 12-13, 2016, the [FDA held Advisory Committee Meetings](#) to discuss Amgen's [ABP 501](#), a proposed biosimilar to AbbVie's [Humira \(adalimumab\)](#) and Sandoz's [GP2015](#), a proposed biosimilar to Amgen's [Enbrel \(etanercept\)](#).
- Humira is indicated for the treatment of rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult and pediatric Crohn's disease (CD), ulcerative colitis (UC), plaque psoriasis (PsO), hidradenitis suppurativa (HS), and uveitis (UV).
- Enbrel is indicated for the treatment of RA, JIA, PsA, AS, and PsO.
- The FDA advisory panel recommendations for ABP 501:
 - The [panel voted](#) 26 – 0 that ABP 501 was similar in safety and effectiveness to Humira for 7 indications, including RA, PsA, JIA, AS, PsO, CD and UC.
 - The panel voiced concerns over the CD and UC indications and requested that the FDA ask Amgen for post-market surveillance studies to ensure that ABP 501 works as expected for CD and UC.
- The FDA advisory panel recommendations for GP2015:
 - The [panel voted](#) 20 – 0 in support of GP2015 for all 5 indications of Enbrel.
- The final decision about the approval for ABP 501 and GP2015 will be determined by the FDA.
 - A Biosimilar User Fee Act (BsUFA) target action date of September 25, 2016 has been set for ABP 501.
 - The BsUFA date for GP2015 has not been disclosed but is estimated to be sometime in September 2016.
- Although approvals for both agents are likely to occur by September 2016, ABP 501 and GP2015 will likely not launch for at least 180 days after approval based on recent [court rulings](#).
- Additionally, patent disputes filed by both brand manufacturers against the biosimilar manufacturers of ABP 501 and GP2015 may further delay the launch of these agents.
 - AbbVie claims it has patents protecting Humira until at least 2022.
 - Amgen claims it has patents protecting Enbrel until 2029.
- U.S. annual sales in 2015 for Humira were \$8.4 billion and \$5.1 billion for Enbrel.



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