REVISTA ESPAÑOLA DE
ENFERMEDADES DIGESTIVAS
The Spanish Journal of Gastroenterology

Title:
ABP 501 (adalimumab-atto) in the treatment of inflammatory bowel disease: an example of evidence-based extrapolation

Authors:
Fernando Muñoz Núñez, Carlos Taxonera, Jordi Marrón

DOI: 10.17235/reed.2021.7921/2021
Link: PubMed (Epub ahead of print)

Please cite this article as:
Muñoz Núñez Fernando , Taxonera Carlos , Marrón Jordi. ABP 501 (adalimumab-atto) in the treatment of inflammatory bowel disease: an example of evidence-based extrapolation. Rev Esp Enferm Dig 2021. doi: 10.17235/reed.2021.7921/2021.

REVISTA ESPAÑOLA DE
ENFERMEDADES DIGESTIVAS
The Spanish Journal of Gastroenterology

SCIENTIFIC LETTER

Title: ABP 501 (adalimumab-atto) in the treatment of inflammatory bowel disease: an example of evidence-based extrapolation

Authors' names and affiliations:

Fernando Muñoz Núñez[a], Carlos Taxonera[b], Jordi Marrón[c]

[a] *Gastrointestinal Department, Complejo Asistencial Universitario de Salamanca, P.º de San Vicente 58-182, 37007 Salamanca, Spain. Email: jmunozn@gmail.com*

[b] *Gastrointestinal Department, Hospital Clínico San Carlos and Instituto de Investigación del Hospital Clínico San Carlos (IdISSC), C. del Profesor Martín Lagos s/n, 28040 Madrid, Spain. Email: carlos.taxonera@salud.madrid.org*

[c] *Amgen S.A., World Trade Center, Moll de Barcelona s/n, Edifici Sud, 7ª planta, 08039 Barcelona, Spain. E-mail: jmarron@amgen.com*

Corresponding author:

Fernando Muñoz Núñez

Gastrointestinal Department, Complejo Asistencial Universitario de Salamanca, P.º de San Vicente 58-182, 37007 Salamanca, Spain. Email: jmunozn@gmail.com

Keywords: Adalimumab; Biosimilar; Inflammatory bowel disease; Extrapolation; Amgevita.

Dear Editor,

We report the available evidence demonstrating the biosimilarity of ABP 501 (AMGEVITA®, adalimumab-atto) to its reference product (RP) (Humira®, adalimumab), and the rationale for the extrapolation of the results obtained with the RP in inflammatory bowel disease (IBD) to ABP 501.

Based on its preclinical and clinical data, ABP 501 has been authorised for use in Europe in all the indications approved for the RP, including Crohn's disease and ulcerative colitis[1].

Once similarity to the RP has been proven through preclinical and clinical studies, the efficacy and safety data obtained for the RP in its approved indications may be extrapolated to the biosimilar, without requiring efficacy equivalence studies for each indication. However, for this extrapolation to be acceptable, three conditions must be met: 1-It must be proven that the biosimilar and RP have the same mechanism of action in each of the indications for which data extrapolation is intended; 2-The populations and primary endpoints chosen for phase III trials must be sensitive enough to detect differences between the biosimilar and its RP, if existent; 3-The biosimilar should demonstrate at least equivalent immunogenicity to the RP in clinical studies. All these three conditions were demonstrated in different studies[1,2].

All the available evidence demonstrates the similarity between ABP 501 and its RP in terms of quality, efficacy, and safety, justifying the extrapolation of data on RP to ABP 501 in patients with IBD and aligned with the latest positioning statements of medical societies in the gastroenterology field[3,4]. This scientific evidence is supported by recent data on real-world evidence that also show a good interchangeability with its RP[5].

In the current environment of healthcare resources optimization, this evidence supports the use of ABP 501.

References

1 European Medicines Agency (EMA). AMGEVITA product information, https://www.ema.europa.eu/en/medicines/human/EPAR/amgevita; 2019

2 Halder S, Khan W, Wang X, et al. P071 Supporting extrapolation of indications for ABP 501, the first adalimumab biosimilar: focus on Crohn's disease. *J Crohns Colitis*.

2019;13:S121. Doi: 10.1093/ecco-jcc/jjy222.195

3 Danese S, Fiorino G, Raine T, et al. ECCO position statement on the use of biosimilars for inflammatory bowel disease-an update. *J Crohns Colitis*. 2017;11:26–34. Doi: 0.1093/ecco-jcc/jjw198

4 Argüelles Arias F, Hinojosa Del Val J, Vera Mendoza I. Update of the SEPD position statement on the use of biosimilars for inflammatory bowel disease. *Rev Esp Enferm Dig*. 2018;110:407. Doi: 10.4321/s1130-01082013000100006

5 Ribaldone DG, Caviglia GP, Pellicano R, et al. Effectiveness and safety of adalimumab biosimilar ABP 501 in Crohn's disease: an observational study. *Rev Esp Enferm Dig*. 2020;112 (3):195-200. Doi: 10.17235/reed.2020.6693/2019