Biosimilares

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EULAR 2014

DISCUSIONES

Marco regulatorio, normativa, preguntas existenciales, etc.....

[SP0027] BIOSIMILARS: POTENTIAL CLINICAL DIFFERENCES AND EUROPEAN REGULATORY ASPECTS ***Authors:*** J. V. Esplugues Mota[1,2,3] ***Year:*** 2014 ***Session Info:*** Biosimilars: a SWOT analysis

[SP0062] ADVANTAGES AND DISADVANTAGES OF BIOSIMILARS – ARE THEY GENERIC BIOLOGIC AGENTS? ***Authors:*** V. Strand ***Year:*** 2014 ***Session Info:*** Biosimilars: friend or foe?

[SP0119] LATEST UPDATE ON BIOSIMILARS - CHANCES AND RISKS ***Authors:*** J. Braun ***Year:*** 2014 ***Session Info:*** What's new: latest advances in treatment and management of RMD

[2014] [SAT0256] ANALYTICAL AND FUNCTIONAL ASSESSMENTS WHEN DEVELOPING BIOSIMILAR CANDIDATES

T. Born[1], V. Fung[2]. [1]Biosimilars Development, Amgen, Seattle; [2]Biosimilars Development, Amgen, Thousand Oaks, United States

Se debe esperar diferencias analíticas, especialmente con respecto al perfil de glicano enlazado a N, entre un mAb biosimilar y el mAb innovador, así como entre diferentes mAb bioequivalentes. Para el desarrollo de biosimilares el enfoque debe ser “paso a paso” para que las diferencias entre el mAb biosimilar propuesto y el innovador sean cuidadosamente caracterizadas, demostrando una similitud funcional, antes de continuar con los estudios clínicos.

[2014] [AB1403] COMPREHENSIVE TARGET-DIRECTED APPROACH FOR THE DEVELOPMENT OF A HIGHLY-COMPARABLE RITUXIMAB BIOSIMILAR

A. da Silva[1], R. Grau[2], T. Stangler[1], H. Summer[1], I. Meyer[1], A. Rohde[1], A. Papandrikopoulou[1], J.M. Visser[1]. [1]Sandoz Biopharmaceuticals, Hexal Ag, Holzkirchen, Germany; [2]Novartis Pharma AG, Basel, Switzerland

En el desarrollo temprano de los biosimilares se pone un mayor énfasis en el aspecto técnico del producto en comparación con el desarrollo terapéutico biológico. Como tal, el desarrollo de un biosimilar está en la vanguardia innovadora de establecer y definir la "Calidad de Diseño“ y no al destino-dirigido. Este enfoque asegura un producto biosimilar muy comparable con el producto original, seguro y eficaz clinicamente.

Que opinan los médicos !!!

[2014] [SAT0094] RELATIONSHIP BETWEEN THE DURATION OF RHEUMATOLOGY PRACTICE EXPERIENCE AND LIKELIHOOD OF USE AND PERCEPTION TOWARDS BIOSIMILARS IN RHEUMATOID ARTHRITIS ARENA

S. Narayanan. Evidence Generation, Value & Access COE, Ipsos Healthcare, Columbia, United States

- 173 reumatologos de UE (Reino Unido / Alemania / España / Francia / Italia), Brasil, Japón y China
- Prescribir biosimilares: sin dudas 13%, muy probable 42%, puede ser/no estoy seguro 36%, improbable 10%
- Claves que impiden el uso:
  - Dudas en la similitud de la molécula.
  - Seguridad inadecuada/perfil de eficacia/datos.
  - Falta de datos a largo plazo.
  - Falta de directrices nacionales que recomienden el uso de biosimilares. Falta de datos locales.
  - Desconfianza en el fabricante

Que opinan los pacientes !!!

[2014] [AB1052] BIOSIMILARS USE IN RHEUMATOLOGY - THE PATIENT PERSPECTIVE

F. Berghea[1], C. Popescu[2], R. Ionescu[1], N. Damjanov[3], G. Singh[4], On behalf of RCRD. [1]Rheumatology, Carol Davila University of Medicine And Pharmacy; [2]Rheumatology, Sf. Maria Hospital, Bucharest, Romania; [3]Rheumatology, Institute of Rheumatology, Belgrade, Serbia; [4]Division of Gastroenterology and Hepatology, Stanford University School of Medicine, Woodside, United States

- Los medicamentos originales son mejores que las copias.
- Un precio más alto significa mayor calidad.
- Las características de una droga dependen de la calidad de la producción y de los excipientes que llevan.
- Una vez que se comienza con una medicación uno debe tener el derecho de permanecer en él, sin importar que su médico certifique similar eficacia y perfil de seguridad de un biosimilar.
- Los pacientes en lista de espera no tienen preferencia por original o biosimilar. Confían en la elección del médico.
- Cuando el co-pago es mayor en el caso del original, el biosimilar se convierte en aceptable.

Conclusión: En algunas áreas (pero no en todas partes) el conocimiento del paciente sobre los medicamentos (copias) podría ser más profunda de lo que esperamos; las ventajas socio-económicas de los biosimilares parece ser plenamente comprendido; aunque el médico tratante debe tomar la decisión y asumir las responsabilidades de la prescripción.

Que hay de nuevo !!!

Fase I

[2014] [FRI0301] A PHASE I PHARMACOKINETICS TRIAL COMPARING PF-06438179 (A POTENTIAL BIOSIMILAR) AND INFLIXIMAB IN HEALTHY VOLUNTEERS (REFLECTIONS B537-01)

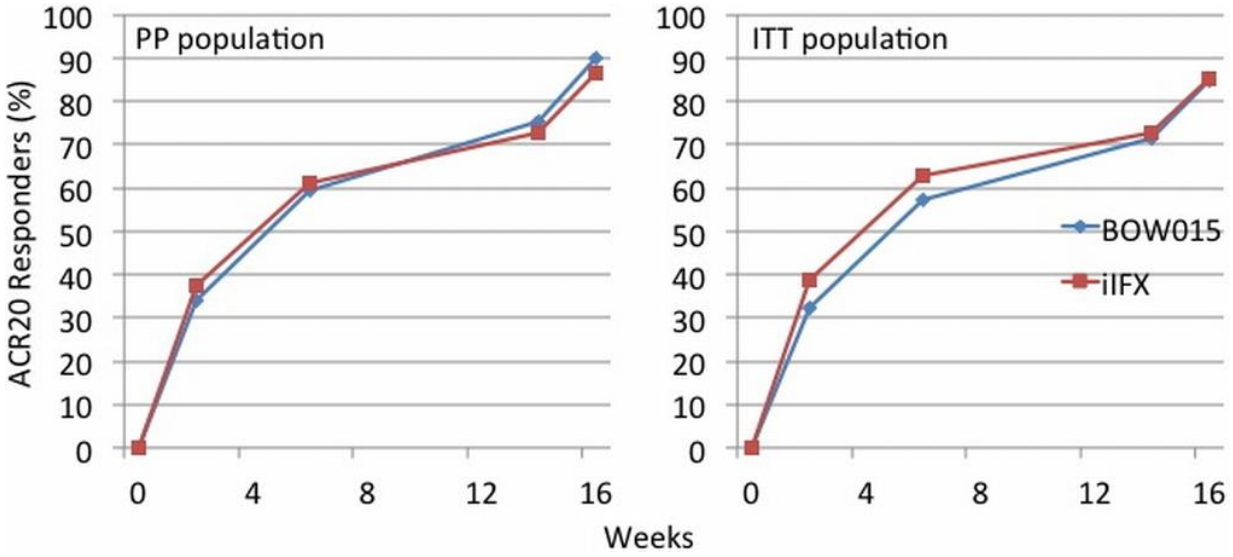
C. Udata[1], S. Y. Hua[1], D. Yin[1], S. Salts[1], X. Meng[2], M. I. Rehman[3]. [1]Pfizer Inc. San Diego, CA; [2]Pfizer Inc., San Diego; [3]Pfizer Inc., Cambridge, MA, United States

[2014] [AB0412] PRECLINICAL PK AND SAFETY ASSESSMENT OF THE PROPOSED ADALIMUMAB BIOSIMILAR GP2017, COMPARED TO HUMIRA®

U. Kronthaler[1], M. Baron[2], J. Poetzl[2], A. Da Silva[1]. [1]Clinical Department, Sandoz Biopharmaceuticals, Hexal AG, Holzkirchen; [2]Bioanalytics, Sandoz Biopharmaceuticals, Hexal AG, Oberhaching, Germany

[2014] [OP0012] A PHASE 3, RANDOMIZED, DOUBLE-BLIND, ACTIVE COMPARATOR STUDY OF THE EFFICACY AND SAFETY OF BOW015, A BIOSIMILAR INFLIXIMAB, IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS ON STABLE METHOTREXATE DOSES

J. Kay[1], A. Chopra[2], S. Chandrashekara[3], D. J. Olakkengil[4], K. S. Bhojani[5], G. Bhatia[6], G. Rathi[7], M. Thomas[8], S. Maroli[9], E. S. Thomson[10], L. Shneyer[11], M. S. Wyand[12]. [1]Division of Rheumatology, Department of Medicine, University of Massachusetts Medical School, Worcester, MA, United States;[2]Center for Rheumatic Diseases, Pune; [3]ChanRe Rheumatology & Immunology Center & Research; [4]St. John's Medical College Hospital, Bengaluru;[5]Department of Rheumatology, Fortis Hospital, Mumbai; [6]Pentagon Multispeciality Clinic and Research Centre, Pune; [7]Rathi Hospital, Ahmedabad;[8]Health and Research Center, Trivandrum; [9]Reliance Life Sciences, Mumbai, India; [10]Epirus Biopharmaceuticals, Surrey, United Kingdom; [11]Shneyer Statistics LLC, Denville, NJ; [12]Epirus Biopharmaceuticals, Boston, MA, United States



Conclusión: La proporción similar de respondedores a la semana 16 provee una evidente equivalencia terapéutica.

[2014] [OP0011] A RANDOMIZED, DOUBLE-BLIND, PHASE 3 EQUIVALENCE TRIAL COMPARING THE ETANERCEPT BIOSIMILAR, HD203, WITH ENBREL®, IN COMBINATION WITH METHOTREXATE (MTX) IN PATIENTS WITH RHEUMATOID ARTHRITIS (RA)

S. C. Bae[1], J. S. Kim[2], J. Y. Choe[3], W. Park[4], S. R. Lee[5], Y. Ahn[6], Y. Seo[5], On behalf of Hera Study Investigators. [1]Hanyang University Hospital for Rheumatic Diseases, Seoul; [2]Jeju National University Hospital, Jeju; [3]Catholic University of Daegu, Daegu; [4]IN-HA University Hospital, Incheon;[5]Hanwha Chemical, Seoul; [6]Hanwha Chemical, Daejeon, Korea, Republic of

Table 1. Proportion of patients achieving ACR20 at week 24 and week 48

	HD203	Enbrel®	Difference (95% CI)	P-value
24-week PPS	83.48% (96/115)	81.36% (96/118)	2.12 (−7.65, 11.89)	0.6706†
FAS	79.10% (106/134)	75.56% (102/135)	3.55 (−6.45, 13.55)	0.4870†
48-week PPS	86.27% (88/102)	81.90% (86/105)	4.37 (−5.57, 14.31)	0.3905†

Conclusions: The study met the primary endpoint of demonstrating equivalence in efficacy of HD203 compared with Enbrel®. HD203 was well tolerated, with a safety profile comparable to that of Enbrel® in this population of Korean patients with RA.

[2014] [SAT0214] STATISTICAL EVALUTION OF JOINT DAMAGE PRGRESSION IN PATIENTS WITH RHEUMATOID ARTHRITIS TREATED WITH INFLIXIMAB OR BIOSIMILAR INFLIXIMAB (CT-P13) ANTI-TNF THERAPY: A ROLE OF SENSITIVITY ANALYSIS FOR MISSING DATA EVALUATING SIMILARITY

S. J. Lee[1], D. H. Yoo[2], W. Park[3], U. Müller-Ladner[4], T. N. Pyo[1]. [1]CELLTRION Inc., Incheon; [2]Hanyang Univ. Hospital; [3]Inha Univ. Hospital, Seoul, Korea, Republic of; [4]Justus-Liebig-University of Giessen, Kerckhoff-Klinik, Bad Nauheim, Germany

- Los cambios del score radiográfico desde el comienzo a la semana 54 fueron 1.3±9.3 and 0.7±7.0 para CT-P13 e INX, respectivamente.
- No hubieron diferencias estadisticamente significatvas entre CT-P13 e INX (p=0.3171).

[2014] [OP0157] CLINICAL RESPONSE OF DISEASE ACTIVITY, DISABILITY AND MOBILITY INDICES IN RELATION TO ANTI-DRUG ANTIBODY IN THE PLANETAS

W. Park[1], D. H. Yoo[2], S. Szánto[3], F. Berghea[4], M. Brzosko[5], P. Wiland[6], S. Smiyan[7], R. Araiza-Casillas[8], F. Díaz-González[9], J. H. Suh[10]. [1]Inha University Hospital, Incheon; [2]Hanyang University Hospital, Seoul, Korea, Republic of; [3]Medical and Health Science Center of the University of Debrecen, Debrecen, Hungary; [4]Carol Davila University of Medicine General Secretary of Romanian Society of Rheumatology, Bucharest, Romania; [5]Pomeranian Medical University, Szczecin; [6]Medical University of Wroclaw, Wroclaw, Poland; [7]Municipal Institution of Ternopil Regional Council Ternopil University Hospital, Ternopil, Ukraine; [8]Consultorio Medico Privado de Reumatologia, Mexicali, Mexico; [9]University of La Laguna, Hospital Universitario de Canarias, Canarias, Spain; [10]Celltrion Inc., Incheon, Korea, Republic of

Indices de actividad, discapacidad y morbilidad en pacientes con AR entre CT-P13 e infliximab son similares

[2014] [THU0158] INHIBITION OF RADIOGRAPHIC PROGRESSION AND ITS ASSOCIATION WITH CLINICAL PARAMETERS IN RA PATIENTS TREATED WITH CT-P13 AND INNOVATOR INFLIXIMAB IN PLANETRA STUDY

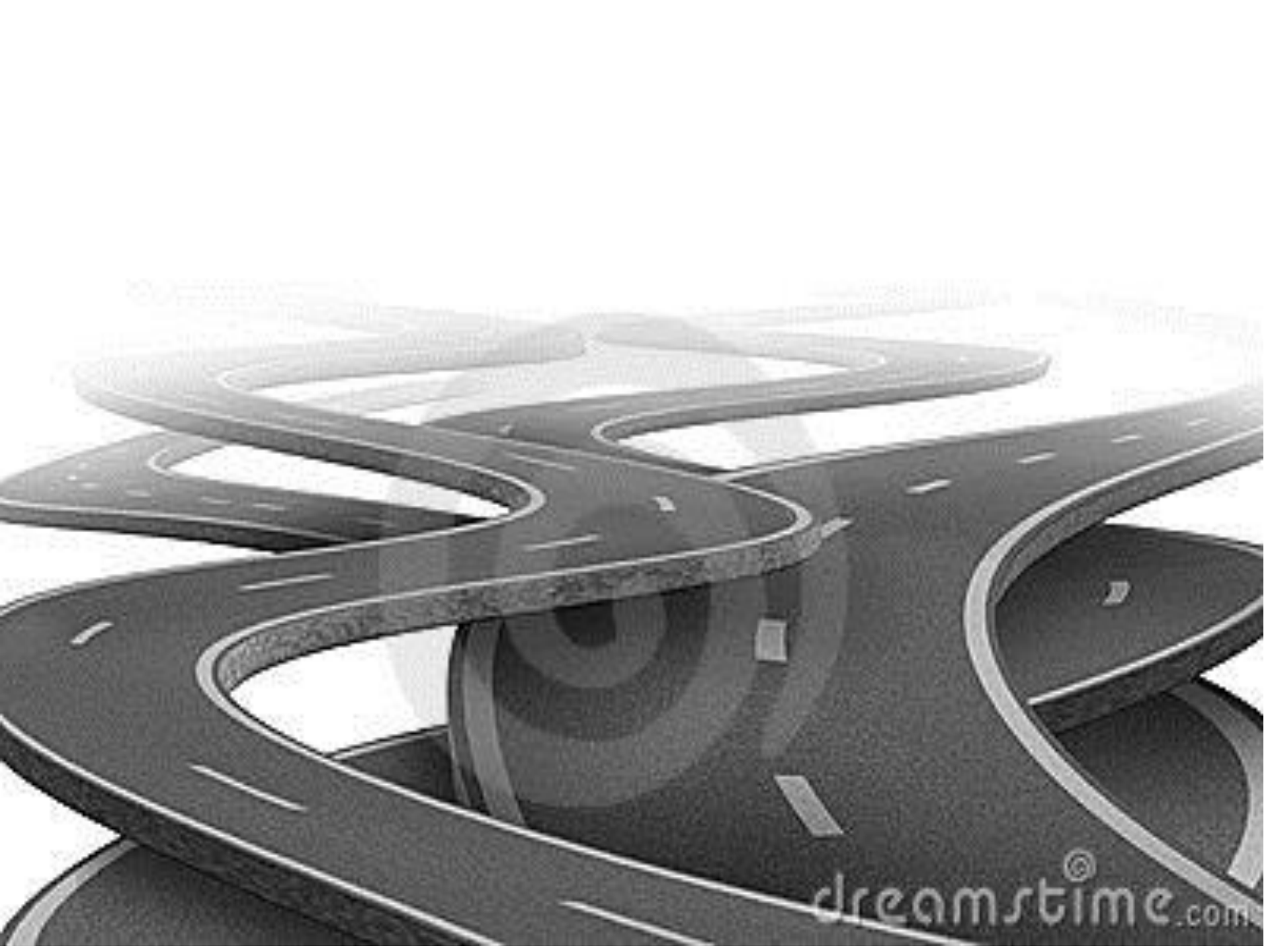
D. Yoo[1], W. Park[2], P. Miranda[3], M. Piotrowski[4], E. Ramiterre[5], S. Shevchuk[6], A. Baranauskaite[7], S. Lee[8], U. Müller-Ladner[9]. [1]Hanyang Univ. Medical Center, Seoul; [2]Inha Univ. Hospital, Incheon, Republic of Korea; [3]Centro de Estudios Reumatologicos, Santiago, Chile; [4]Dept. of Rheumatology, Medical University of Lublin, Lublin, Poland; [5]Brokenshire Memorial Hospital, Davao City, Philippines; [6]The Ministry of Health, Vinnytsya, Ukraine;[7]Hospital of Lithuanian University of Health Sciences, Kaunas, Lithuania; [8]Celltrion, Inc., Incheon, Republic of Korea; [9]Justus-Liebig Univ. Giessen, Bad Nauheim, Germany

Conclusions: Patients treated with CT-P13 showed a comparable radiographic progression as compared to those treated with INX at week 54. The ADA and clinical parameters such as ACR20, IgM RF, and anti-CCP showed tendency of association with radiographic progression.

[2014] [THU0159] DISEASE ACTIVITY ASSESSMENT USING THE DAS28, CDAI AND SDAI AND EFFECT OF ANTI-DRUG ANTIBODY ON CLINICAL RESPONSE IN A RANDOMIZED, DOUBLE-BLIND, COMPARATIVE TRIAL OF CT-P13 AND INNOVATOR INFLIXIMAB: PLANETRA STUDY

D. H. Yoo[1], W. Park[2], M. Brzosko[3], P. Géher[4], D. Andersone[5], J. Jaworski[6], D. Rekalov[7], B. Oparanov[8], R. Kausiene[9], C. Pacheco-Tena[10], S. Lee[11].[1]Hanyang University Hospital for Rheumatic Diseases, Seoul; [2]Inha University Hospital, Incheon, Republic of Korea; [3]Pomeranian Medical University, Szczecin, Poland; [4]Budai Irgalmasrendi Korház, Budapest, Hungary; [5]Pauls Stradins Clinical University Hospital, Riga, Latvia; [6]Reumatika Centrum Reumatologi, Warszawa, Poland; [7]Municipal Institution Zaporizhzhia Regional

Conclusions: These results demonstrate the efficacy of CT-P13 which is comparable to that of INX, based on various clinical outcome measures. The ADA development could diminish the clinical response achieved by infliximab, and the magnitude of influence was similar in both CT-P13 and INX treatment groups throughout the study.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