

Supplementary Appendix

Title: Switching from one biosimilar to another biosimilar of the same reference biologic:

A systematic review of studies

Target journal: BioDrugs

Running heading: A Systematic Review of Biosimilar-to-Biosimilar Switch Studies

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Conflict of Interest

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HPC is an employee of Sandoz Inc., a division of the Novartis Corporation. He may own stock in Novartis. Sandoz manufactures and markets multiple biosimilars worldwide, including several discussed in this publication.

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SH and WB are employees of Sandoz Biopharmaceuticals GmbH, a division of Novartis. They may own stock in Novartis. Sandoz manufactures and markets multiple biosimilars worldwide, including several discussed in this publication.

Table S1 Published observational studies

Author, year [reference]	Biosimilars	Treatment indication and number of patients (biosimilar-to-biosimilar ^a)	Study design	Follow-up	Efficacy, safety, and other outcomes	Author conclusion/switch suggestion
Trystram, 2021 [1]	Infliximab biosimilars: CT-P13 and SB2	IBD; 115 (infliximab to CT-P13 to SB2) and 43 in single-switch group (CT-P13 to SB2)	Prospective, multicenter cohort study	52 weeks	<p>Drug persistence was high in 94.9% of patients and the loss of response rate was low in 10.8%</p> <p>140/153 (91.5%) patients remained in sustained steroid-free clinical remission; 104/113 (92.0%) in the double-switch group and 36/40 (90.0%) in the single-switch group</p> <p>AEs occurred in 63 (39.9%) patients, including 50 (41.1%) in the double-switch group and 13 (31.6%) in the single-switch group ($p=0.15$)</p> <p>No difference was found in the overall AE (0.54 ± 0.72 vs. 0.35 ± 0.61, $p=0.13$) and serious AE (0.05 ± 0.22 vs. 0.09 ± 0.29, $p=0.41$) rates between patients in the double- and single-switch groups</p> <p>A higher rate of infectious AEs (0.40 ± 0.60 vs. 0.16 ± 0.43, $p=0.02$) in the double-switch group</p> <p>The rate of ADAs did not increase after the switch (3.9% vs. 2.8%, $p=0.75$)</p>	<p>Double-switching from reference infliximab to CT-P13 and then to SB2 did not impair the effectiveness, immunogenicity, or safety of anti-TNF therapy after 54 weeks of follow-up</p> <p>Double-switching was not associated with an impairment of patient beliefs regarding the necessity of, and concerns about, biosimilars</p>

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Mazza, 2022 [2]	Infliximab biosimilars: CT-P13 and SB2	IBD; 52 (originator infliximab to CT-P13 to SB2)	Retrospective data analysis	52 weeks	<p>Clinical remission: 24 week, 49/52 (94%); end of follow-up: 46/52 (88%)</p> <p>From Kaplan-Meier survival curve, the proportions of patients maintaining a clinical response over time were 98% (95% CI 94–100) at Week 24 and 91% (95% CI 83–99) at Week 52</p> <p>Four patients experienced a total of 5 AEs, all graded 1–3 according to CTCAE</p> <p>No infusion reactions were observed</p> <p>No differences were observed in the safety and efficacy outcomes when comparing the double-switch group with a single-switch group of 66 patients with IBD</p>	Non-medical double-switching of biosimilars is effective and safe in patients with IBD
Khan, 2021 [3]	Infliximab biosimilars: CT-P13 and SB2	IBD; 101 (infliximab to SB2), 170 (infliximab to CT-P13 to SB2)	Retrospective cohort study	1 year	<p>In the single-switch group, 12.9% of patients discontinued SB2 within 1 year and 11.9% continued SB2, but were not in IBD remission after 1 year</p> <p>In the double-switch group, 17.6% of patients discontinued SB2 within 1 year and 9.4% continued SB2, but were not in IBD remission after 1 year</p>	May reassure gastroenterologists who have concerns about the safety and efficacy of switching between multiple biosimilars when treating IBD
Luber, 2021 [4]	Infliximab biosimilars: CT-P13 and SB2	IBD; 186 (99 second switch)	Single-center, prospective observational cohort study	1 year	<p>No significant change (vs. baseline) in CRP, clinical disease activity scores, or median trough infliximab level at the early time point among first-switch (baseline vs. early: 5.7 vs. 6.6 µg/mL, $p=0.05$) and second-switch (4.3 vs. 4.9 µg/mL, $p=0.07$) patients nor at 1 year (median infliximab trough levels, baseline vs. 1 year, in first-switch [5.7 vs. 5.7 µg/mL, $p=0.37$] and</p>	Switching from one infliximab biosimilar to another had no adverse impact on infliximab trough levels, and clinical and biochemical disease activity, regardless of whether switching for the first or second time

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					second-switch [4.3 vs. 4.7 µg/mL, $p=0.06$ patients)	
					The proportion of patients in clinical remission did not significantly change at the early (92% vs. 91% at baseline, $p=0.75$) or 1 year (95% vs. 91% at baseline, $p=0.16$) time points	
					There was no significant difference in time to loss of response between patients switching for the first or second time ($p=0.69$)	
Hanzel, 2022 [5]	Infliximab biosimilars: CT-P13 and SB2	IBD; 149 (69 underwent double-switch; infliximab to CT-P13 to SB2)	Prospective multicenter cohort study	12 months	At 12 months after the most recent switch, 76.9% (40/52, double-switch group), 65.7% (46/70, single-switch), and 76.9% (20/26, reference biologic to CT-P13) of patients were in clinical remission; treatment persistence at 12 months was 85.0%, 87.0%, and 70.1%, respectively	Multiple successive switching and switching between biosimilars of infliximab seemed to be effective and safe
					<i>De novo</i> ADAs were not detected in any of the patients switching successively from reference biologic to CT-P13 and SB2, in 3.8% (3/80) switching from CT-P13 and SB2, and in 3.7% (1/27) switching from reference biologic to CT-P13, and 3.8% (3/80) switching from CT-P13 to SB2	
Bouhnik, 2020 [6]	Infliximab biosimilars: CT-P13 and SB2	IBD; 109 patients transitioned from another infliximab	Prospective/retrospective non-interventional cohort	12 months	No loss of disease control and no safety concerns Over 92% of patients who transitioned from reference or another biosimilar	No loss of efficacy or safety concerns upon switching from one biosimilar to another biosimilar.

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		biosimilar to SB2			infliximab continued SB2 treatment at 12 months post-initiation	
Lovero, 2021 [7]	Infliximab biosimilars: CT-P13 and SB2	CD and UC; 36 (12 involving double-switch infliximab to CT-P13 to SB2)	Retrospective analysis of a cohort	>6 months	Prior to 6 months and 3 months after switch to SB2: clinical remission rate was the same (58.3%); the rate of mild activity varied from 27.8–33.3% ($p=0.68$); proportion of patients with normal CRP values of 94.4% and 91.7% 2 patients (5.5%) had AE and 11 (30.5%) had loss of response	Switching from CT-P13 to SB2 seems to be safe and effective either in patients with a single-switch than in those with multiple switches for the various (reference biologic or biosimilar) infliximab compounds
Macaluso, 2021 [8]	Infliximab biosimilars: CT-P13 and SB2	IBD; 43 (15.6%; group D) CT-P13 to SB2, and 24 (8.7%; group E) infliximab to CT-P13 to SB2	Prospective observational study	Median: 8 months (IQR 4–12 months)	Nine patients from group D (20.9%) and 4 patients from group E (16.7%) interrupted SB2 treatment Cox survival analysis showed no significant difference in the probability of treatment discontinuation between the 5 groups (log-rank $p=0.15$) Dose optimization was performed in 92 patients (group D 53.5%; group E 37.5%). 67 SAEs occurred in 57 patients (20.7%), with an incidence of 36.7 per 100 PY 11 SAEs in 11 patients from group D (25.6%; incidence per 100 PY = 39.3), and 4 SAEs in 4 patients from group E (16.7%; incidence per 100 PY = 24.7)	Switching from the reference biologic or CT-P13, including multiple switches, should not be dangerous for patients with IBD
Siakavella, 2021 [9]	Infliximab biosimilars: CT-P13 and GP1111	IBD; 246 CT-P13 to GP1111 (57/246, double-switch)	Single center study	6 months	No significant differences were observed between the Harvey-Bradshaw Index ($p = 0.11$), Mayo Score ($p = 0.18$), CRP ($p = 0.44$), fecal calprotectin ($p = 0.29$) nor trough infliximab levels ($p = 0.27$)	Single and multiple biosimilar infliximab switching appears to be safe and have no negative effects in clinical outcomes at 6 months

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					<p>comparing before and 6 months post GP1111 switch in either single-switch or double-switch groups</p> <p>Five patients (2%) developed new infliximab antibodies after switching from CT-P13 to GP1111</p> <p>236/246 (96.3%) patients remain on GP1111 at 6 months post switch</p>	
O'Neill, 2020 [10]	Infliximab biosimilars: CT-P13 and SB2	IBD; 227 patients switched from CT-P13 to SB2	Study in a teaching hospital	Not specified	<p>99.2% of patients did not report any adverse events</p> <p>Two reports of adverse effects were attributable to changes in the rate of administration rather than the drug</p>	No negative clinical impact of multiple switches
Harris, 2019 [11]	Infliximab biosimilars: CT-P13 and SB2	IBD; 133 patients switched from CT-P13 to SB2	Real-world study	18 Weeks	<p>The mean mHBI and partial Mayo scores at week 0 vs. week 16/18 were 3.13 +/- 3.31 vs. 3.15 +/- 3.17 (p=0.32) and 1.53 +/- 1.75 vs. 0.91 +/- 1.64 (p=0.15) respectively</p> <p>The overall disease control component of the IBD control PROM at week 0 and week 16/18 for CD and UC were 74.99 +/- 23.4 vs. 78.09 +/- 19.27 (p=0.66) and 76.22 +/- 23.80 vs. 81.57 +/- 21.21 (p=0.49) respectively</p> <p>The treatment specific components of the IBD-Control PROM showed no significant differences between Week 0 and Week 16/18</p>	This data suggests that there does not appear to be a detrimental effect of switching from one biosimilar to another biosimilar on patient outcomes and drug persistence for at least 4 months

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					7 patients stopped treatment due to therapeutic failure, 6 due to adverse drug reactions.	
Mott 2021 [12]	Infliximab biosimilars: CT-P13 and GP1111	IBD; 289 patients switched from CT-P13 to SB2	Real-world study	6 months	One infusion reaction was reported (0.3%) which was successfully treated following standard infusion reaction procedure, and subsequent doses of infliximab were not given. One patient (0.3%) switched back to the previous biosimilar infliximab due to loss of efficacy and 17 (6%) stopped treatment due to LOR. 'Best value' infliximab accounted for over 90% of total infliximab use after 6 months.	Larger than previously published evaluations, this short-term evaluation adds to the literature that switching between biosimilar infliximab is safe and appears effective
Gisondi, 2020 [13]	Infliximab biosimilars: CT-P13 and SB2	Psoriasis; 96 (infliximab to CT-P13 to SB2)	Observational study	6 months	PASI remained stable during the 6-month period of observation PASI at the time of the switch and after 2, 4, and 6 months was 0.9 ± 2 ; 0.9 ± 1.6 ; 1.1 ± 2.2 ; 0.7 ± 1.1 , respectively Treatment withdrawal in 10/96 (10%) patients because of loss of response ($n=7$) or acute infusion reactions ($n=3$)	No conclusive statement on switching, although the authors highlight healthcare cost reductions with biosimilars and the need for controlled studies
Lauret, 2020 [14]	Infliximab biosimilars: CT-P13 and SB2	Chronic inflammatory diseases; 140 (infliximab to CT-P13 to SB2); 29 (CT-P13 to SB2)	Prospective observational study	3 years	The rate of ADA seroconversion was 8.5% in patients receiving infliximab biosimilars who were previously receiving the original molecule ADA seroconversion rate was 25% in infliximab-naïve patients who received infliximab biosimilars during the observation period	No increase in immunogenicity was observed after biosimilar-to-biosimilar switches.

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Cunningham, 2019 [15]	Infliximab biosimilars	Not specified; 607 patients switched from one biosimilar to another biosimilar	Descriptive analysis of outpatients	Not specified	A total of 138 patients had at least one adverse drug event, and 22 patients had at least one hospitalization	Multiple switches do not correlate to increased adverse events or hospitalizations
Nabi, 2020 [16]	Infliximab biosimilars	RA, PsA or axSpA; 780 patients (multiple switches from infliximab to CTP-13 to GP1111)	Observational cohort study	1-year	A total of 780 patients completed the first switch; patients with treated with reference biologic for median 7 years. At 1-year, 83% maintained CT-P13 treatment. In 2019, 52% of CT-P13 treated patients were still on treatment and performed a second biosimilar switch to GP1111. At 1-year, 91% maintained GP1111 treatment.	For both rounds of switching, withdrawals were associated with higher baseline patient reported outcomes (PROs), higher HAQ and less frequent acceptable symptom state (PASS=yes) whereas objective markers (CRP, Physician global) were similar. Withdrawal was associated with higher PROs at baseline, suggesting outcomes to be more affected by patient-related than drug-related factors
Fautrel et al 2021 [17]	Infliximab biosimilars	RA, PsA or axSpA; 210 patients (switching from prior infliximab biosimilar to SB2)	Prospective/retrospective non-interventional cohort	12 months	No loss of disease control and with no dose penalty over 12 months post-transition. At least 75% of patients transitioned from prior infliximab remained on SB2 at 12 months post-initiation. Seroconversion post-initiation of SB2 was low, and no immunogenicity or other safety signal was detected.	No loss of efficacy or safety concerns upon initiation on SB2 as first infliximab or after transition from reference or infliximab biosimilar to SB2.
Ribaldone, 2021 [18]	Adalimumab biosimilars: ABP 501 and SB5	CD; 61 (43 involving multiple switches); adalimumab to ABP 501 to SB5	Prospective, single-center observational study	6 months	Success of the switch was defined as: no systemic corticosteroids within 6 months, no discontinuation of SB5, and no dose escalation Success rate was 82.0% (50/61 patients)	Switching (including multiple switches) from adalimumab biosimilar-to-biosimilar in patients with CD is safe and effective

					<p>Dose escalation rate of 6.6% (4/61); no difference vs. prior to switch (3.3%: 2/61; $p=0.44$)</p> <p>Use of systemic corticosteroids (before and after the switch: rate of 3.3% for both, $p=1.0$).</p> <p>Thiopurine use before switch (8.2%; 5/61) and after switch (4.9%; 3/61; $p=0.48$)</p> <p>In the 6 months following the switch to SB5, AEs occurred in 7 patients (11.5%)</p> <p>CRP and fecal calprotectin values at the end of follow-up did not increase significantly ($p=0.6$ and $p=0.4$, respectively) vs. at time of switching</p> <p>No significant increase in Harvey–Bradshaw Index value ($p=0.5$)</p>	
Derikx 2021 [19]	Adalimumab biosimilars: SB5 to ABP 501	IBD; 35 patients (double-switch from the ADA reference biologic to SB5 to ABP 501)	Observational cohort study in a tertiary IBD	52 Weeks	<p>During ABP 501 treatment, none of the patients developed new detectable antibodies</p> <p>None of the 35 patients who had a second switch discontinued treatment, and trough levels remained stable throughout time</p>	Findings advocates allowance of a double biosimilar switch
Gall, 2021 [20]	Adalimumab biosimilars (not specified)	Chronic inflammatory rheumatic diseases; 42 mono-switch, 48 multi-switch	Chronic inflammatory rheumatic diseases (e.g, rheumatoid arthritis, axial	Not specified	<p>Patients were satisfied with care irrespective of the switching scenario.</p> <p>The knowledge about biosimilar was generally rather low.</p>	The study showed that multi-switching did not result in decreased patient satisfaction in patients receiving biosimilar therapy

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			spondylarthritis, psoriatic arthritis).		Less than one third of patients was able to identify correct answers about manufacturing, efficacy/safety issues, approval status and costs of biosimilars	
Piaserico, 2021 [21]	Etanercept biosimilars: SB4 and GP2015	Psoriasis; 76 (etanercept to SB4 to GP2015)	Multicenter, prospective, observational cohort study	12 months	Stable median PASI; 1 (0–2) after 3 months to 0.5 (0–1) after 12 months. 2 patients developed a flare-up No treatment-emergent serious AEs were reported. 1 patient interrupted the treatment after 9 months because of a pregnancy, whose outcome was positive	Efficacy and safety were maintained after cross-switching between etanercept biosimilars
Kiltz, 2020 [22]	Etanercept biosimilars: SB4 and GP2015	RA, PsA, or axSpA; 100 (etanercept to SB4 to GP2015)	Retrospective study	Mean 21.1 ± 7.4 months	Retention rate after the second etanercept biosimilar switch was 89% about 6 months after the second switch While 2 patients were lost to follow-up and 1 died (cardiac arrest), 7 discontinued due to inefficacy or AE, including 1 case of pancreatic cancer. 1 patient was withdrawn because of pregnancy Overall, 14 AEs were reported in 8 patients	Retention rate after multiple switches from innovator etanercept to two etanercept biosimilars was close to 90% No major changes in disease activity and function were observed in all three indications
Urru, 2021 [23]	Rituximab biosimilars: Truxima and Rixathon	NHL and CLL; 83 (26 switched during the study period)	Prospective observational study	Median: 10.5 months (IQR 7–14 months)	AEs were reported in 71 patients (85.5%); treatment-related grade 3–4 events were reported in 5 patients (6.0 %), whereas grade 1 rituximab-related infusion events were observed in 6 patients (7.1%) AEs were similar in patients who had received one or two biosimilar formulations (32/33 patients in the no-switch group vs. 25/26 with a switch during the study period, $p=0.86$) and for	Support the position of switching between rituximab biosimilars No safety signal emerged in association with the use of a specific biosimilar nor with the practice of switching

events of grade 3–4 (2/33 vs. 1/26;
 $p=0.70$)

^aof the study population we had only included number of patients who underwent biosimilar-to-biosimilar switch.

ADA antidrug antibody, *AE* adverse event, *axSpA* axial spondyloarthritis, *CD* Crohn's disease, *CI* confidence interval, *CLL* chronic lymphocytic leukemia, *CRP* C-reactive protein, *CTCAE* Common Terminology Criteria for Adverse Events, *HAQ* Health Assessment Questionnaire, *HR* hazard ratio, *IBD* inflammatory bowel disease, *IQR* interquartile range, *NHL* non-Hodgkin's lymphoma, *OR* odds ratio, *PASI* Psoriasis Area and Severity Index, *PsA* psoriatic arthritis, *PY* patient/person-years, *RA* rheumatoid arthritis, *SAE* serious adverse event, *UC* ulcerative colitis

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