

Appendix C.

Table S1-1a. Analysis of Agreement of Immunogenicity testing between Anti-drug Antibody (ADA) CT-P13 tag and ADA INX tag assays

Actual treatment group: CT-P13 3 mg/kg

		ADA INX tag outcome					Cohen's Kappa		
Visit	ADA CT-P13 Tag outcome	Positive	Negative	Missing	PPA (%)	NPA (%)	Statistic	95% CI	p-value
Screening	Positive	9	3	0	100.00	98.97	0.85	(0.69, 1.00)	<0.001
	Negative	0	289	0					
	Missing	0	0	0					
Week 14	Positive	68	4	0	98.55	98.02	0.95	(0.91, 0.99)	<0.001
	Negative	1	198	0					
	Missing	0	1	0					
Week 30	Positive	120	6	0	98.36	95.38	0.94	(0.89, 0.98)	<0.001
	Negative	2	124	0					
	Missing	0	0	0					

Note: PPA = Positive Percent Agreement; NPA = Negative Percent Agreement. The p-value is significant at the 5% level.

Counts of missing values are for information purposes only and are not used in calculation of PPA, NPA or Cohen's Kappa. The ADA INX tag outcome is that outcome at the same visit which is displayed in the Visit column. Patients with a Quantity Not Sufficient (QNS) outcome are categorized as Missing for this analysis.

PPA = (Number of patients with positive outcome for both ADA CT-P13 and INX tags)/ (Number of patients with positive outcome for ADA INX tag) * 100.

NPA = (Number of patients with negative outcome for both ADA CT-P13 and INX tags)/ (Number of patients with negative outcome for ADA INX tag) * 100.

Table S1-1b. Analysis of Agreement of Immunogenicity testing between Anti-drug antibody (ADA) CT-P13 tag and ADA INX tag assays

Actual treatment group: INX 3 mg/kg

		ADA INX tag outcome					Cohen's Kappa		
Visit	ADA CT-P13 Tag outcome	Positive	Negative	Missing	PPA (%)	NPA (%)	Statistic	95% CI	p-value
Screening	Positive	6	1	0	100.00	99.66	0.92	(0.77, 1.00)	<0.001
	Negative	0	291	0					
	Missing	0	0	0					
Week 14	Positive	66	4	0	95.65	98.01	0.93	(0.88, 0.98)	<0.001
	Negative	3	197	0					
	Missing	1	0	0					
Week 30	Positive	118	2	0	96.72	98.47	0.95	(0.91, 0.99)	<0.001
	Negative	4	129	0					
	Missing	0	0	0					

Note: PPA = Positive Percent Agreement; NPA = Negative Percent Agreement. The p-value is significant at the 5% level.

Counts of missing values are for information purposes only and are not used in calculation of PPA, NPA or Cohen's Kappa. The ADA INX tag outcome is that outcome at the same visit which is displayed in the Visit column. Patients with a Quantity Not Sufficient (QNS) outcome are categorized as Missing for this analysis.

PPA = (Number of patients with positive outcome for both ADA CT-P13 and INX tags)/ (Number of patients with positive outcome for ADA INX tag) * 100.

NPA = (Number of patients with negative outcome for both ADA CT-P13 and INX tags)/ (Number of patients with negative outcome for ADA INX tag) * 100.

Table S1-1c. Analysis of Agreement of Immunogenicity testing between Anti-drug antibody (ADA) CT-P13 tag and ADA INX tag assays

Actual treatment group: Total

		ADA INX tag outcome					Cohen's Kappa		
Visit	ADA CT-P13 Tag outcome	Positive	Negative	Missing	PPA (%)	NPA (%)	Statistic	95% CI	p-value
Screening	Positive	15	4	0	100.00	99.32	0.88	(0.76, 1.00)	<0.001
	Negative	0	580	0					
	Missing	0	0	0					
Week 14	Positive	134	8	0	97.10	98.01	0.94	(0.91, 0.97)	<0.001
	Negative	4	395	0					
	Missing	1	1	0					
Week 30	Positive	238	8	0	97.54	96.93	0.94	(0.92, 0.97)	<0.001
	Negative	6	253	0					
	Missing	0	0	0					

Note: PPA = Positive Percent Agreement; NPA = Negative Percent Agreement. The p-value is significant at the 5% level.

Counts of missing values are for information purposes only and are not used in calculation of PPA, NPA or Cohen's Kappa. The ADA INX tag outcome is that outcome at the same visit which is displayed in the Visit column. Patients with a Quantity Not Sufficient (QNS) outcome are categorized as Missing for this analysis.

PPA = (Number of patients with positive outcome for both ADA CT-P13 and INX tags)/ (Number of patients with positive outcome for ADA INX tag) * 100.

NPA = (Number of patients with negative outcome for both ADA CT-P13 and INX tags)/ (Number of patients with negative outcome for ADA INX tag) * 100.

Table S1-2a. Analysis of Agreement of Immunogenicity testing between Neutralising Antibody (NAb) CT-P13 tag and NAb INX tag assay

Actual treatment group: CT-P13 3 mg/kg

Visit	CT-P13 Tag outcome	INX tag outcome					PPA (%)	NPA (%)	Cohen's Kappa		
		Positive	Negative ^[1]	QNS	NR	Missing			Statistic	95% CI	p-value
Screening	Positive	1	1	0	0	0	33.33	99.66	0.40	(-0.15, 0.94)	<0.001
	Negative	2	297	0	0	0					
	QNS	0	0	0	0	0					
	NR	0	0	0	0	0					
	Missing	0	0	0	0	0					
Week 14	Positive	67	4	0	0	0	97.10	98.02	0.94	(0.90, 0.99)	<0.001
	Negative	2	198	0	0	0					
	QNS	0	0	0	0	0					
	NR	0	0	0	0	0					
	Missing	0	1	0	0	0					

[1]The NAb negative population constitutes both (1) patients who were originally tested for ADA using tagged CT-P13 or tagged INX assay and who were found to be negative (therefore these patients were not further tested for NAb using either assay NAb-A or NAb-B, but are included in the NAb negative data group), and (2) patients who were originally tested for ADA using tagged CT-P13 or tagged INX assay and who were found to be positive; these patients were then tested for NAb using tagged CT-P13 and found to be negative.

Note: PPA = Positive Percent Agreement; NPA = Negative Percent Agreement. QNS = Quantity Not Sufficient, NR = No Result. The p-value is significant at the 5% level. Counts of Missing, QNS, and NR values are for information purposes only and are not used in calculation of PPA, NPA or Cohen's Kappa. The INX tag outcome is that outcome at the same visit which is displayed in the Visit column. N.E. = Non-estimable.

PPA = (Number of patients with positive outcome for both CT-P13 and INX tags)/ (Number of patients with positive outcome for INX tag) * 100.

NPA = (Number of patients with negative outcome for both CT-P13 and INX tags)/ (Number of patients with negative outcome for INX tag) * 100.

Table S1-2a. Analysis of Agreement of Immunogenicity testing between Neutralising Antibody (NAb) CT-P13 tag and NAb INX tag assay

Actual treatment group: CT-P13 3 mg/kg

		INX tag outcome					Cohen's Kappa				
Visit	CT-P13 Tag outcome	Positive	Negative ^[1]	QNS	NR	Missing	PPA (%)	NPA (%)	Statistic	95% CI	p-value
Week 30	Positive	117	6	0	0	0	96.69	95.42	0.92	(0.87, 0.97)	<0.001
	Negative	4	125	0	0	0					
	QNS	0	0	0	0	0					
	NR	0	0	0	0	0					
	Missing	0	0	0	0	0					

[1]The NAb negative population constitutes both (1) patients who were originally tested for ADA using tagged CT-P13 or tagged INX assay and who were found to be negative (therefore these patients were not further tested for NAb using either assay NAb-A or NAb-B, but are included in the NAb negative data group), and (2) patients who were originally tested for ADA using tagged CT-P13 or tagged INX assay and who were found to be positive; these patients were then tested for NAb using tagged CT-P13 and found to be negative.

Note: PPA = Positive Percent Agreement; NPA = Negative Percent Agreement. QNS = Quantity Not Sufficient, NR = No Result. The p-value is significant at the 5% level. Counts of Missing, QNS, and NR values are for information purposes only and are not used in calculation of PPA, NPA or Cohen's Kappa. The INX tag outcome is that outcome at the same visit which is displayed in the Visit column. N.E. = Non-estimable.

PPA = (Number of patients with positive outcome for both CT-P13 and INX tags)/ (Number of patients with positive outcome for INX tag) * 100.

NPA = (Number of patients with negative outcome for both CT-P13 and INX tags)/ (Number of patients with negative outcome for INX tag) * 100.

Table S1-2b. Analysis of Agreement of Immunogenicity testing between Neutralising Antibody (NAb) CT-P13 tag and NAb INX tag assay

Actual treatment group: INX 3 mg/kg

Visit	CT-P13 Tag outcome	INX tag outcome					PPA (%)	NPA (%)	Cohen's Kappa		
		Positive	Negative ^[1]	QNS	NR	Missing			Statistic	95% CI	p-value
Screening	Positive	2	1	0	0	0	100.00	99.66	0.80	(0.41, 1.00)	<0.001
	Negative	0	295	0	0	0					
	QNS	0	0	0	0	0					
	NR	0	0	0	0	0					
	Missing	0	0	0	0	0					
Week 14	Positive	63	4	2	0	0	95.45	98.02	0.93	(0.88, 0.98)	<0.001
	Negative	3	198	0	0	0					
	QNS	1	0	0	0	0					
	NR	0	0	0	0	0					
	Missing	0	0	0	0	0					

[1]The NAb negative population constitutes both (1) patients who were originally tested for ADA using tagged CT-P13 or tagged INX assay and who were found to be negative (therefore these patients were not further tested for NAb using either assay NAb-A or NAb-B, but are included in the NAb negative data group), and (2) patients who were originally tested for ADA using tagged CT-P13 or tagged INX assay and who were found to be positive; these patients were then tested for NAb using tagged CT-P13 and found to be negative.

Note: PPA = Positive Percent Agreement; NPA = Negative Percent Agreement. QNS = Quantity Not Sufficient, NR = No Result. The p-value is significant at the 5% level. Counts of Missing, QNS, and NR values are for information purposes only and are not used in calculation of PPA, NPA or Cohen's Kappa. The INX tag outcome is that outcome at the same visit which is displayed in the Visit column. N.E. = Non-estimable.

PPA = (Number of patients with positive outcome for both CT-P13 and INX tags)/ (Number of patients with positive outcome for INX tag) * 100.

NPA = (Number of patients with negative outcome for both CT-P13 and INX tags)/ (Number of patients with negative outcome for INX tag) * 100.

Table S1-2b. Analysis of Agreement of Immunogenicity testing between Neutralising Antibody (NAb) CT-P13 tag and NAb INX tag assay

Actual treatment group: INX 3 mg/kg

		INX tag outcome							Cohen's Kappa		
Visit	CT-P13 Tag outcome	Positive	Negative ^[1]	QNS	NR	Missing	PPA (%)	NPA (%)	Statistic	95% CI	p-value
Week 30	Positive	117	2	0	0	0	95.90	98.47	0.94	(0.90, 0.99)	<0.001
	Negative	5	129	0	0	0					
	QNS	0	0	0	0	0					
	NR	0	0	0	0	0					
	Missing	0	0	0	0	0					

[1]The NAb negative population constitutes both (1) patients who were originally tested for ADA using tagged CT-P13 or tagged INX assay and who were found to be negative (therefore these patients were not further tested for NAb using either assay NAb-A or NAb-B, but are included in the NAb negative data group), and (2) patients who were originally tested for ADA using tagged CT-P13 or tagged INX assay and who were found to be positive; these patients were then tested for NAb using tagged CT-P13 and found to be negative.

Note: PPA = Positive Percent Agreement; NPA = Negative Percent Agreement. QNS = Quantity Not Sufficient, NR = No Result. The p-value is significant at the 5% level. Counts of Missing, QNS, and NR values are for information purposes only and are not used in calculation of PPA, NPA or Cohen's Kappa. The INX tag outcome is that outcome at the same visit which is displayed in the Visit column. N.E. = Non-estimable.

PPA = (Number of patients with positive outcome for both CT-P13 and INX tags) / (Number of patients with positive outcome for INX tag) * 100.

NPA = (Number of patients with negative outcome for both CT-P13 and INX tags) / (Number of patients with negative outcome for INX tag) * 100.

Table S1-2c. Analysis of Agreement of Immunogenicity testing between Neutralising Antibody (NAb) CT-P13 tag and NAb INX tag assay

Actual treatment group: Total

		INX tag outcome							Cohen's Kappa		
Visit	CT-P13 Tag outcome	Positive	Negative ^[1]	QNS	NR	Missing	PPA (%)	NPA (%)	Statistic	95% CI	p-value
Screening	Positive	3	2	0	0	0	60.00	99.66	0.60	(0.24, 0.96)	<0.001
	Negative	2	592	0	0	0					
	QNS	0	0	0	0	0					
	NR	0	0	0	0	0					
	Missing	0	0	0	0	0					
Week 14	Positive	130	8	2	0	0	96.30	98.02	0.94	(0.90, 0.97)	<0.001
	Negative	5	396	0	0	0					
	QNS	1	0	0	0	0					
	NR	0	0	0	0	0					
	Missing	0	1	0	0	0					

[1]The NAb negative population constitutes both (1) patients who were originally tested for ADA using tagged CT-P13 or tagged INX assay and who were found to be negative (therefore these patients were not further tested for NAb using either assay NAb-A or NAb-B, but are included in the NAb negative data group), and (2) patients who were originally tested for ADA using tagged CT-P13 or tagged INX assay and who were found to be positive; these patients were then tested for NAb using tagged CT-P13 and found to be negative.

Note: PPA = Positive Percent Agreement; NPA = Negative Percent Agreement. QNS = Quantity Not Sufficient, NR = No Result. The p-value is significant at the 5% level. Counts of Missing, QNS, and NR values are for information purposes only and are not used in calculation of PPA, NPA or Cohen's Kappa. The INX tag outcome is that outcome at the same visit which is displayed in the Visit column. N.E. = Non-estimable.

PPA = (Number of patients with positive outcome for both CT-P13 and INX tags)/ (Number of patients with positive outcome for INX tag) * 100.

NPA = (Number of patients with negative outcome for both CT-P13 and INX tags)/ (Number of patients with negative outcome for INX tag) * 100.

Table S1-2c. Analysis of Agreement of Immunogenicity testing between Neutralising Antibody (NAb) CT-P13 tag and NAb INX tag assay

Actual treatment group: Total

		INX tag outcome							Cohen's Kappa		
Visit	CT-P13 Tag outcome	Positive	Negative ^[1]	QNS	NR	Missing	PPA (%)	NPA (%)	Statistic	95% CI	p-value
Week 30	Positive	234	8	0	0	0	96.30	96.95	0.93	(0.90, 0.96)	<0.001
	Negative	9	254	0	0	0					
	QNS	0	0	0	0	0					
	NR	0	0	0	0	0					
	Missing	0	0	0	0	0					

[1]The NAb negative population constitutes both (1) patients who were originally tested for ADA using tagged CT-P13 or tagged INX assay and who were found to be negative (therefore these patients were not further tested for NAb using either assay NAb-A or NAb-B, but are included in the NAb negative data group), and (2) patients who were originally tested for ADA using tagged CT-P13 or tagged INX assay and who were found to be positive; these patients were then tested for NAb using tagged CT-P13 and found to be negative.

Note: PPA = Positive Percent Agreement; NPA = Negative Percent Agreement. QNS = Quantity Not Sufficient, NR = No Result. The p-value is significant at the 5% level. Counts of Missing, QNS, and NR values are for information purposes only and are not used in calculation of PPA, NPA or Cohen's Kappa. The INX tag outcome is that outcome at the same visit which is displayed in the Visit column. N.E. = Non-estimable.

PPA = (Number of patients with positive outcome for both CT-P13 and INX tags) / (Number of patients with positive outcome for INX tag) * 100.

NPA = (Number of patients with negative outcome for both CT-P13 and INX tags) / (Number of patients with negative outcome for INX tag) * 100.