

ICMJE DISCLOSURE FORM

Date: 11/7/2023

Your Name: Takeshi Masuda

Manuscript Title: Treatment rationale and protocol design: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

Manuscript Number (if known): [Click or tap here to enter text.](#)

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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Time frame: Since the initial planning of the work								
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Time frame: past 36 months								
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4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input type="checkbox"/> None	
		Chugai Pharmaceutical Co. Ltd.	MSD K.K.
		AstraZeneca K.K.	Bristol-Myers Squibb Co. Ltd.
		Eli Lilly Japan K.K.	Kyowa Kirin Co., Ltd.
		MSD K.K.	
		Taiho Pharmaceutical Co., Ltd.	
		Ono Pharmaceutical Co., Ltd.	
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None	
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> None	

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11	Stock or stock options	<input checked="" type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

Please place an "X" next to the following statement to indicate your agreement:

I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 11/24/2023

Your Name: Taizo Hirata

Manuscript Title: Treatment rationale and protocol design: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

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ICMJE DISCLOSURE FORM

Date: 11/6/2023

Your Name: Tomohiro Sakamoto

Manuscript Title: Treatment rationale and protocol design: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

Manuscript Number (if known): [Click or tap here to enter text.](#)

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ICMJE DISCLOSURE FORM

Date: 11/6/2023

Your Name: Yukari Tsubata

Manuscript Title: Treatment rationale and protocol design: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

Manuscript Number (if known): [Click or tap here to enter text.](#)

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		Kyowa Kirin Co., Ltd.	
		TAIHO PHARMACEUTICAL CO., LTD.	
		Bristol-Myers Squibb K.K	
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Date: 11/6/2023

Your Name: Eiki Ichihara

Manuscript Title: Treatment rationale and protocol design: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

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		Novartis	Honoraria
		Janssen Pharmaceutical K.K.	Honoraria
		Eli Lilly Japan K.K.	Honoraria
		Pfizer	Honoraria
		Ono Pharmaceutical Co. Ltd.	Honoraria
		Takeda Pharmaceutical Co. Ltd.	Honoraria
		Boehringer Ingelheim.	Honoraria
Bristol-Myers Squibb Co. Ltd.	Honoraria		
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Date: 11/6/2023

Your Name: TOSHIYUKI KOZUKI

Manuscript Title: Treatment rationale and protocol design: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

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		Sanofi Eisai Labcorp Development Japan IQVIA Services Japan Gilead Sciences Pfizer Bayer	Institution Institution Institution Institution Institution Institution Institution
3	Royalties or licenses	<input checked="" type="checkbox"/> None	
4	Consulting fees	<input type="checkbox"/> None	
		Chugai Pharmaceutical Co. AstraZeneca Ono Pharmaceutical Co. Pfizer Japan Daiichi-Sankyo Bayer Abbvie	Myself Myself Myself Myself Myself Myself Myself
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input type="checkbox"/> None	
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Please place an "X" next to the following statement to indicate your agreement:

I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 11/7/2023

Your Name: Hiroyasu Shoda

Manuscript Title: Treatment rationale and protocol design: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

Manuscript Number (if known): [Click or tap here to enter text.](#)

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4	Consulting fees	<input checked="" type="checkbox"/> None <table border="1" data-bbox="386 260 1516 394"> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> </table>									
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input type="checkbox"/> None <table border="1" data-bbox="386 483 1516 583"> <tr><td>Bristol-Myers Squibb K.K.</td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> </table>	Bristol-Myers Squibb K.K.								
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13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

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I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 11/7/2023

Your Name: Masanori Motonaga

Manuscript Title: Treatment rationale and protocol design: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

Manuscript Number (if known): [Click or tap here to enter text.](#)

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ICMJE DISCLOSURE FORM

Date: 11/6/2023

Your Name: Takako Yoshida

Manuscript Title: Treatment rationale and protocol design: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

Manuscript Number (if known): [Click or tap here to enter text.](#)

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ICMJE DISCLOSURE FORM

Date: 11/6/2023

Your Name: Miki Fukutani

Manuscript Title: Treatment rationale and protocol design: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

Manuscript Number (if known): [Click or tap here to enter text.](#)

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12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

Please place an "X" next to the following statement to indicate your agreement:

I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 11/24/2023

Your Name: Kazue Takayama

Manuscript Title: Treatment rationale and protocol design: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

Manuscript Number (if known): [Click or tap here to enter text.]

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Please place an "X" next to the following statement to indicate your agreement:

I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 11/10/2023

Your Name: Atsushi Tamura

Manuscript Title: Treatment rationale and protocol design: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

Manuscript Number (if known): [Click or tap here to enter text.](#)

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I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 11/8/2023

Your Name: Harunobu Amagase

Manuscript Title: Treatment rationale: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

Manuscript Number (if known): [Click or tap here to enter text.](#)

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I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 11/6/2023

Your Name: Hideki Fujihara

Manuscript Title: Treatment rationale and protocol design: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

Manuscript Number (if known): [Click or tap here to enter text.](#)

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ICMJE DISCLOSURE FORM

Date: 11/24/2023

Your Name: Gaku Aoki

Manuscript Title: Treatment rationale and protocol design: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

Manuscript Number (if known): [Click or tap here to enter text.]

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2	Grants or contracts from any entity (if not indicated in item #1 above).	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr><td style="width: 60%; height: 20px;"></td><td style="width: 40%;"></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> </table>						
3	Royalties or licenses	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr><td style="width: 60%; height: 20px;"></td><td style="width: 40%;"></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> </table>						

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)						
4	Consulting fees	<input checked="" type="checkbox"/> None <table border="1"> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> </table>							
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None <table border="1"> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> </table>							
6	Payment for expert testimony	<input checked="" type="checkbox"/> None <table border="1"> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> </table>							
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None <table border="1"> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> </table>							
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None <table border="1"> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> </table>							
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None <table border="1"> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> </table>							
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> None <table border="1"> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> </table>							

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	<input checked="" type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

Please place an "X" next to the following statement to indicate your agreement:

I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 11/11/2023

Your Name: Tomoyuki Akita

Manuscript Title: Treatment rationale and protocol design: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

Manuscript Number (if known): [Click or tap here to enter text.](#)

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

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2	Grants or contracts from any entity (if not indicated in item #1 above).	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; height: 40px; margin-top: 5px;"> <tr><td style="width: 60%;"></td><td style="width: 40%;"></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>						
3	Royalties or licenses	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; height: 40px; margin-top: 5px;"> <tr><td style="width: 60%;"></td><td style="width: 40%;"></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>						

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4	Consulting fees	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>									
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>									
6	Payment for expert testimony	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>									
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9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>									
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11	Stock or stock options	<input checked="" type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

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I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 11/6/2023

Your Name: Yasushi Orihashi

Manuscript Title: Treatment rationale and protocol design: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

Manuscript Number (if known): [Click or tap here to enter text.](#)

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		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	<input checked="" type="checkbox"/>	
		Kitasato University Hospital	Payments for statistical consulting to me
		Association of Medical Education and Ethics	Payments for statistical consulting to me
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/>	
		Tokai University, Graduate School of Medicine	Lectures of biostatistics, payments to me
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None	
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/>	
		EVA-001-02 study sponsored by Evastem Co., Ltd.	Data Monitoring Committee member, payments to me
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/>	
		Certified Committee for Regenerative Medicine, Tokai University	Committee member, payments to me

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
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12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
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I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 11/6/2023

Your Name: Toshio Miyata

Manuscript Title: Treatment rationale: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

Manuscript Number (if known): [Click or tap here to enter text.](#)

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6	Payment for expert testimony	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 20px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> </table>									
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11	Stock or stock options	<input type="checkbox"/> None	
		Renascience	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input type="checkbox"/> None	

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I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 11/7/2023

Your Name: Noboru Hattori

Manuscript Title: Treatment rationale: an investigator-initiated phase II study of combination treatment of nivolumab and TM5614, a PAI-1 inhibitor for previously treated patients with non-small cell lung cancer

Manuscript Number (if known): [Click or tap here to enter text.](#)

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Renascience Inc.	The payments were made to my institution.							
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3	Royalties or licenses	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> </table>						

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4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input type="checkbox"/> None	
		Chugai Pharmaceutical Co., Ltd.	The payments were made to myself.
		Ono Pharmaceutical Co., Ltd	The payments were made to myself.
		AstraZeneca K.K.	The payments were made to myself.
		Bristol Myers Squibb	The payments were made to myself.
		MSD	The payments were made to myself.
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None	
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> None	

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