

ICMJE DISCLOSURE FORM

Date: 22.07.2021 _____
 Your Name: Dimitra Kiritsi _____
 Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa _____
 Manuscript number (if known): _____

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 following questions apply to the author’s relationships/activities/interests as they relate to the current manuscript only.

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.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

		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)
Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	DK’s work is funded by the Berta-Ottenstein-Programme for Advanced Clinician Scientists, Faculty of Medicine, University of Freiburg, by the German Research Foundation (DFG) through SFB1160 project B03, SFB-1479 – Project ID: 441891347 and KI1795/2-1 and the Fritz Thyssen Foundation. All funding organizations provided funding covering the conduct of the study and the preparation of the manuscript, but were not	Payments made to the institution.

		involved in the design of the study.	
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	Has received funding from Rheacell GmbH for the conduct of scientific studies with ABCB5+ cells in a mouse model with DEB.	Payments made to the institution.
3	Royalties or licenses	___ None	
4	Consulting fees	___ None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	Has received honoraria from Rheacell GmbH for consulting on the design of the trial protocol. Honoraria for consulting of Amryt Pharmaceuticals, FIBRX Derm Inc, Colzyk AB.	Payments to DK.
6	Payment for expert testimony	___ None	
7	Support for attending meetings and/or travel	___ None	
8	Patents planned, issued or pending	___ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	Is participating in the Data Safety Monitoring Board of the trial, as Principal Investigator of the Trial.	

10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input type="checkbox"/> None	
11	Stock or stock options	<input type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input type="checkbox"/> None	
13	Other financial or non-financial interests	<input 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: 27.07.2021
Your Name: Kathrin Dieter
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

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: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	X None	
3	Royalties or licenses	X None	

4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
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	
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	RHEACELL GmbH & Co.KG	Employee

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: 27.07.2021
Your Name: Elke Niebergall-Roth
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

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Time frame: past 36 months			
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3	Royalties or licenses	X None	

4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
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	
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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	TICEBA GmbH	Employee

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ICMJE DISCLOSURE FORM

Date: 27.07.2021
Your Name: Silvia Fluhr
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

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Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	X None	
3	Royalties or licenses	X None	

4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
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	
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	RHEACELL GmbH & Co.KG	Employee

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ICMJE DISCLOSURE FORM

Date: 27.07.2021
Your Name: Cristina Daniele
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

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Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	X None	
3	Royalties or licenses	X None	

4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
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	
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	RHEACELL GmbH & Co.KG	Employee

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ICMJE DISCLOSURE FORM

Date: 27.07.2021
Your Name: Jasmina Esterlechner
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

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3	Royalties or licenses	X None	

4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
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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	
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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	TICEBA GmbH	Employee

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ICMJE DISCLOSURE FORM

Date: 27.07.2021
Your Name: Samar Sadeghi
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

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Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	X None	
3	Royalties or licenses	X None	

4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
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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13	Other financial or non-financial interests	TICEBA GmbH	Employee

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ICMJE DISCLOSURE FORM

Date: 27.07.2021
Your Name: Seda Ballikaya
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

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Time frame: past 36 months			
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3	Royalties or licenses	X None	

4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
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	
11	Stock or stock options	<input checked="" type="checkbox"/> None	
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13	Other financial or non-financial interests	TICEBA GmbH	Employee

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X 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: 27.07.2021
Your Name: Leoni Erdinger
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

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Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	X None	
3	Royalties or licenses	X None	

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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	
11	Stock or stock options	<input checked="" type="checkbox"/> None	
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13	Other financial or non-financial interests	RHEACELL GmbH & Co.KG	Employee

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ICMJE DISCLOSURE FORM

Date: 29.07.2021

Your Name: Franziska Schauer

Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa

Manuscript number (if known):

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1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	<input type="checkbox"/> None FS is supported by the Berta-Ottenstein Advanced Clinician Scientist Programme of the University of Freiburg	
Time frame: past 36 months			
2		<input checked="" type="checkbox"/> None	

	Grants or contracts from any entity (if not indicated in item #1 above).		
3	Royalties or licenses	<input checked="" type="checkbox"/> None	
4	Consulting fees	<input type="checkbox"/> None FS received fees from Amryt Pharma.	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
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	
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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ICMJE DISCLOSURE FORM

Date: 27.07.2021

Your Name: Stella Gewert

Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa

Manuscript number (if known): _____

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3	Royalties or licenses	x None	
4	Consulting fees	x None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	x None	
6	Payment for expert testimony	x None	
7	Support for attending meetings and/or travel	x None	
8	Patents planned, issued or pending	x None	
9	Participation on a Data Safety Monitoring Board or Advisory	x None	

	Board		
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	x None	
11	Stock or stock options	x None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	x None	
13	Other financial or non-financial interests	x None	

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

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

27.07.2021

Gewert

ICMJE DISCLOSURE FORM

Date: 3-AUG-2021

Your Name: Martin Laimer

Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa

Manuscript number (if known): _____

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 following questions apply to the author's relationships/activities/interests as they relate to the current manuscript only.

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.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

		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)
Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	___ None	Research/Clinical Trial Support: Rheacell GmbH Co KG
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	_X_ None	
3	Royalties or licenses	X_ None	

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	
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 type="checkbox"/> None	Secretary General, Austrian Society of Dermatology
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: 03/8/2021

Your Name: Johann W. Bauer

Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa

Manuscript number (if known): _____

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 following questions apply to the author's relationships/activities/interests as they relate to the current manuscript only.

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In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

		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)
Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	<input type="checkbox"/> None	
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input type="checkbox"/> None	

3	Royalties or licenses	<input type="checkbox"/> None	
4	Consulting fees	<input type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input type="checkbox"/> None	
6	Payment for expert testimony	<input type="checkbox"/> None	Abbvie, Allmirall
7	Support for attending meetings and/or travel	<input type="checkbox"/> None	
8	Patents planned, issued or pending	<input type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input type="checkbox"/>	President Austrian Society of Dermatology and Venerology; Board Member EADV
11	Stock or stock options	<input type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input type="checkbox"/> None	
13	Other financial or non-financial interests	<input 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.

4.8.21


UNIKLINIKUM SALZBURG
LANDESKRANKENHAUS
Universitätsklinik für Dermatologie
und Allergologie der PMU
Vorstand:
Prim. Univ.-Prof. Dr. Johann Bauer, MBA
A-5020 Salzburg | Müllner Hauptstraße 48

ICMJE DISCLOSURE FORM

Date: August 2, 2021

Your Name: Hovnanian Alain

Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa

Manuscript number (if known): _____

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			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	__X__ None	
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	__X__ None	
3	Royalties or licenses	__X__ None	

4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
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	
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:

X 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: 23/07/21 _____

Your Name: Giovanna Zambruno _____

Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa

Manuscript number (if known): _____

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 following questions apply to the author's relationships/activities/interests as they relate to the current manuscript only.

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In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

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Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	<input checked="" type="checkbox"/> None	
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	DEBRA INTERNATIONAL	Research grant to my hospital
3	Royalties or licenses	<input checked="" type="checkbox"/> None	

4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input type="checkbox"/> RHEACELL	Travel expenses for meeting attendance reimbursed to myself
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	DEBRA INTERNATIONAL MSAP	No fees, only reimbursement of travel/accomodation expenses to myself
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> None	
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: 23/07/21

Your Name: May El Hachem

Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa

Manuscript number (if known): _____

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 following questions apply to the author's relationships/activities/interests as they relate to the current manuscript only.

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.

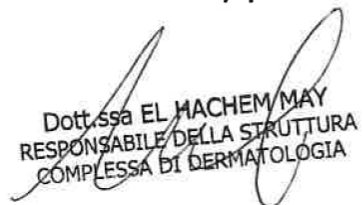
In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

		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)
Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	RHEA CELL	Site non activated
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	AMRYT	Contract with my institution for a clinical trial
3	Royalties or licenses	<input checked="" type="checkbox"/> None	

4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
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	
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.


Dott.ssa EL MACHEM MAY
RESPONSABILE DELLA STRUTTURA
COMPLESSA DI DERMATOLOGIA

ICMJE DISCLOSURE FORM

Date: Wednesday 4th August 2021

Your Name: Bourrat Emmanuelle

Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa

Manuscript number (if known) : unknown

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 following questions apply to the author's relationships/activities/interests as they relate to the current manuscript only.

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.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

		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)
Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	___ None	
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	___ None	
3	Royalties or licenses	___ None	

4	Consulting fees	<input type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input type="checkbox"/> None	
6	Payment for expert testimony	<input type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input type="checkbox"/> None	
8	Patents planned, issued or pending	<input type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input type="checkbox"/> None	
11	Stock or stock options	<input type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input type="checkbox"/> None	
13	Other financial or non-financial interests	<input 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: Wednesday 4th August 2021

Your Name: Maria Papanikolaou

Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa

Manuscript number (if known): not known

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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		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)
Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	___ None	
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	___ None	
3	Royalties or licenses	___ None	

4	Consulting fees	<input type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input type="checkbox"/> None	
6	Payment for expert testimony	<input type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input type="checkbox"/> None	
8	Patents planned, issued or pending	<input type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input type="checkbox"/> None	
11	Stock or stock options	<input type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input type="checkbox"/> None	
13	Other financial or non-financial interests	<input type="checkbox"/> None	

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

X 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: 3/8/21
 Your Name: Gabriela Petrof
 Manuscript Title: Phase I/IIa clinical trial of ABCBS + dermal MSCs for RDEB
 Manuscript number (if known): _____

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 following questions apply to the author's relationships/activities/interests as they relate to the current manuscript only.

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.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

		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)
Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	<input checked="" type="checkbox"/> None Acted as sub-investigator collected and reviewed data No directly paid work	
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input checked="" type="checkbox"/> None	
3	Royalties or licenses	<input checked="" type="checkbox"/> None	

4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
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	
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: 23-JUL-2021

Your Name: Dr. Sophie Kitzmüller

Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa

Manuscript number (if known): _____

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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In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

		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)
Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	___ None	
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	DEBRA Austria	Salary paid by DEBRA Austria
3	Royalties or licenses	___ None	

4	Consulting fees	<input type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	Amryt Pharma Plc Mölnlycke Health Care AB	Honoraria for educational talks
6	Payment for expert testimony	<input type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input type="checkbox"/> None	
8	Patents planned, issued or pending	<input type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input type="checkbox"/> None	
11	Stock or stock options	<input type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input type="checkbox"/> None	
13	Other financial or non-financial interests	<input 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: 22 July 2021

Your Name: Christen L. Ebens, MD MPH

Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa

Manuscript number (if known): 151922-JCI-CMED

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 following questions apply to the author's relationships/activities/interests as they relate to the **current manuscript only**.

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.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

		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)
Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	<input checked="" type="checkbox"/> None	
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input type="checkbox"/> None	Contract with sponsor (Rheacell GmbH & Co) for conduct of clinical trial of allo-AP22-EB MSCs in RDEB, outcomes described in this manuscript
3	Royalties or licenses	<input checked="" type="checkbox"/> None	

4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
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	
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: 07/23/2021

Your Name: Markus H. Frank

Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa

Manuscript number (if known): 151922-INS-CMED-TR-2

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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In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

		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)
Time frame: Since the initial planning of the work			
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		Ticeba GmbH	Paid Scientific Advisor
		Rheacell GmbH & Co KG	Scientific Advisor, Past Corporate Sponsored Research Support
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	___ None	
		NIH/NEI	RO1EY025794 and R24EY028767
3	Royalties or licenses	___ None	
		Patent Royalties	MHF is inventor or co-inventor of US and international patents assigned to Brigham and Women's Hospital and/or Boston Children's Hospital, Boston, MA, USA,

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4	Consulting fees	<input type="checkbox"/> None Ticeba GmbH	Scientific Advisor
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
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 type="checkbox"/> None Patents	MHF is inventor or co-inventor of US and international patents assigned to Brigham and Women's Hospital and/or Boston Children's Hospital, Boston, MA, USA, licensed to TICEBA GmbH, Heidelberg, Germany, and RHEACELL GmbH & Co. KG, Heidelberg, Germany.
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input type="checkbox"/> None Ticeba GmbH Rheacell GmbH & Co KG	Scientific Advisory Board Scientific Advisory Board
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> None	
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.



Markus Frank, M.D.

ICMJE DISCLOSURE FORM

Date: 07/26/2021

Your Name: Natasha Frank

Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa

Manuscript number (if known): 151922-INS-CMED-TR-2

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Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	<input checked="" type="checkbox"/> None	
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input type="checkbox"/> None NIH/NEI	RO1EY025794 and R24EY028767
3	Royalties or licenses	<input type="checkbox"/> None Patent Royalties	NYF is inventor or co-inventor of US and international patents assigned to Brigham and Women's Hospital and/or Boston Children's Hospital, Boston, MA, USA,

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5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
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 type="checkbox"/> None Patents	NYF is inventor or co-inventor of US and international patents assigned to Brigham and Women's Hospital and/or Boston Children's Hospital, Boston, MA, USA, licensed to TICEBA GmbH, Heidelberg, Germany, and RHEACELL GmbH & Co. KG, Heidelberg, Germany.
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	
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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Natasha Frank

Natasha Frank, M.D.

ICMJE DISCLOSURE FORM

Date: 27.07.2021
Your Name: Christoph Ganss
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

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Time frame: past 36 months			
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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	
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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	TICEBA GmbH	CEO
		RHEACELL GmbH & Co. KG	CEO

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ICMJE DISCLOSURE FORM

Date: 22.7.2022
 Your Name: ANNA MARTINEZ
 Manuscript Title: Pharmacokinetic and clinical trial data
 Manuscript number (if known): MSCPJT
M&C

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	<input type="checkbox"/>	
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	<input checked="" type="checkbox"/>	
	<input type="checkbox"/>	
Time frame: past 36 months		
2	Grants or contracts from any entity (if not indicated in item #1 above).	
	<input checked="" type="checkbox"/> None	
	<input checked="" type="checkbox"/>	
	<input type="checkbox"/>	
3	Royalties or licenses	
	<input checked="" type="checkbox"/> None	
	<input checked="" type="checkbox"/>	
	<input type="checkbox"/>	

4	Consulting fees	<input checked="" type="checkbox"/> None	✓
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	✓
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	✓
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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Mabe

ICMJE DISCLOSURE FORM

Date: 05.08.2021
Your Name: Prof. Dr. John McGrath
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

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Time frame: Since the initial planning of the work			
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Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	None x	
3	Royalties or licenses	None x	

4	Consulting fees	None x	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None x	
6	Payment for expert testimony	None x	
7	Support for attending meetings and/or travel	None x	
8	Patents planned, issued or pending	None x	
9	Participation on a Data Safety Monitoring Board or Advisory Board	None x	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None x	
11	Stock or stock options	None x	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	None x	
13	Other financial or non-financial interests	None x	

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



John McGrath 5 August 2021

ICMJE DISCLOSURE FORM

Date: 22 July 2021
 Your Name: JAKUB JOLAR
 Manuscript Title: Pharmacokinetics and clinical trial of ACE2⁺ cells for RDEB.
 Manuscript number (if known): _____

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Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	<input type="checkbox"/> None <u>201-AP063070</u>	
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input checked="" type="checkbox"/> None	
3	Royalties or licenses	<input checked="" type="checkbox"/> None	

4	Consulting fees	<input checked="" type="checkbox"/> None For TICEBA.	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
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 type="checkbox"/> None TICEBA DSHB member.	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> None	
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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ICMJE DISCLOSURE FORM

Date: 22.07.2021
Your Name: Mark Andreas Kluth
Manuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic epidermolysis bullosa
Manuscript number (if known): 151922-INS-CMED-RV-3

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: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	X None	
3	Royalties or licenses	X None	

4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
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	
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	TICEBA GmbH	Employee, CSO
		RHEACELL GmbH & Co.KG	CSO

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TREND Statement Checklist

Paper Section/ Topic	Item No	Descriptor	Reported?	
				Pg #
Title and Abstract				
Title and Abstract	1	• Information on how unit were allocated to interventions	✓	4
		• Structured abstract recommended	✓	4
		• Information on target population or study sample	✓	4
Introduction				
Background	2	• Scientific background and explanation of rationale	✓	6-8
		• Theories used in designing behavioral interventions	✓	6-8
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	✓	22
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	n.a.	n.a.
		• Recruitment setting	✓	22
		• Settings and locations where the data were collected	✓	22
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	✓	22-23
		○ Content: what was given?	✓	22-23
		○ Delivery method: how was the content given?	n.a.	n.a.
		○ Unit of delivery: how were the subjects grouped during delivery?	n.a.	n.a.
		○ Deliverer: who delivered the intervention?	✓	22
		○ Setting: where was the intervention delivered?	✓	22
		○ Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	✓	23
		○ Time span: how long was it intended to take to deliver the intervention to each unit?	✓	23
○ Activities to increase compliance or adherence (e.g., incentives)	n.a.	n.a.		
Objectives	5	• Specific objectives and hypotheses	✓	8
Outcomes	6	• Clearly defined primary and secondary outcome measures	✓	23-24
		• Methods used to collect data and any methods used to enhance the quality of measurements	n.a.	n.a.
		• Information on validated instruments such as psychometric and biometric properties	✓	23
Sample Size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	n.a.	n.a.
Assignment Method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	✓	22
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	n.a.	n.a.
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	n.a.	n.a.

TREND Statement Checklist

Blinding (masking)	9	<ul style="list-style-type: none"> Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed. 	✓	22
Unit of Analysis	10	<ul style="list-style-type: none"> Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community) 	✓	24
		<ul style="list-style-type: none"> If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis) 	n.a.	n.a.
Statistical Methods	11	<ul style="list-style-type: none"> Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data 	✓	24
		<ul style="list-style-type: none"> Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis 	✓	24
		<ul style="list-style-type: none"> Methods for imputing missing data, if used 	✓	23
		<ul style="list-style-type: none"> Statistical software or programs used 	✓	24
Results				
Participant flow	12	<ul style="list-style-type: none"> Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended) 	✓	Fig. 1B
		<ul style="list-style-type: none"> <ul style="list-style-type: none"> Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study 	✓	Fig. 1B
		<ul style="list-style-type: none"> <ul style="list-style-type: none"> Assignment: the numbers of participants assigned to a study condition 	✓	Fig. 1B
		<ul style="list-style-type: none"> <ul style="list-style-type: none"> Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention 	✓	Fig. 1B
		<ul style="list-style-type: none"> <ul style="list-style-type: none"> Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition 	✓	Fig. 1B
		<ul style="list-style-type: none"> <ul style="list-style-type: none"> Analysis: the number of participants included in or excluded from the main analysis, by study condition 	✓	Fig. 1B
		<ul style="list-style-type: none"> Description of protocol deviations from study as planned, along with reasons 	✓	9
Recruitment	13	<ul style="list-style-type: none"> Dates defining the periods of recruitment and follow-up 	✓	9
Baseline Data	14	<ul style="list-style-type: none"> Baseline demographic and clinical characteristics of participants in each study condition 	✓	Table 1
		<ul style="list-style-type: none"> Baseline characteristics for each study condition relevant to specific disease prevention research 	n.a.	n.a.
		<ul style="list-style-type: none"> Baseline comparisons of those lost to follow-up and those retained, overall and by study condition 	n.a.	n.a.
		<ul style="list-style-type: none"> Comparison between study population at baseline and target population of interest 	n.a.	n.a.
Baseline equivalence	15	<ul style="list-style-type: none"> Data on study group equivalence at baseline and statistical methods used to control for baseline differences 	n.a.	n.a.

TREND Statement Checklist

Numbers analyzed	16	<ul style="list-style-type: none"> Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible 	✓	Figures and Tables
		<ul style="list-style-type: none"> Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses 	✓	24
Outcomes and estimation	17	<ul style="list-style-type: none"> For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision 	✓	9-13
		<ul style="list-style-type: none"> Inclusion of null and negative findings 	✓	9-13
		<ul style="list-style-type: none"> Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any 	n.a.	n.a.
Ancillary analyses	18	<ul style="list-style-type: none"> Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory 	n.a.	n.a.
Adverse events	19	<ul style="list-style-type: none"> Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals) 	✓	12-13, Table 2
DISCUSSION				
Interpretation	20	<ul style="list-style-type: none"> Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study 	✓	14-21
		<ul style="list-style-type: none"> Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations 	✓	14-21
		<ul style="list-style-type: none"> Discussion of the success of and barriers to implementing the intervention, fidelity of implementation 	✓	14-21
		<ul style="list-style-type: none"> Discussion of research, programmatic, or policy implications 	✓	20-21
Generalizability	21	<ul style="list-style-type: none"> Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other contextual issues 	✓	20-21
Overall Evidence	22	<ul style="list-style-type: none"> General interpretation of the results in the context of current evidence and current theory 	✓	14-21

From: Des Jarlais, D. C., Lyles, C., Crepaz, N., & the Trend Group (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. *American Journal of Public Health*, 94, 361-366. For more information, visit: <http://www.cdc.gov/trendstatement/>