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 <u>current</u> <u>manuscript only</u>.

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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.) <b>No time limit for this item.</b>	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 fromes post	2C months
2	Grants or contracts from any entity (if not indicated in item #1 above).	Time frame: past 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	None	
10	in other board, society, committee or advocacy group, paid or unpaid		
11	Stock or stock options	None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	None	
13	Other financial or non- financial interests	None	

Date:27.07.2021Your Name:Kathrin DieterManuscript Title:Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive<br/>dystrophic epidermolysis bullosaManuscript 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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		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.) <b>No time limit for this item.</b>	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	x None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	X None	
6	Payment for expert	X None	
-	testimony		
7	Support for attending meetings and/or travel	X None	
8	Patents planned, issued or pending	X None	
0	Douticipation on a Data	V Neze	
9	Participation on a Data Safety Monitoring Board or	X None	
	Advisory Board		
10	Leadership or fiduciary role in other board, society,	X None	
	committee or advocacy		
11	group, paid or unpaid	X None	
11	Stock or stock options		
12	Receipt of equipment, materials, drugs, medical writing, gifts or other	X None	
	services		
13	Other financial or non-	RHEACELL GmbH & Co.KG	Employee
	financial interests		

Date:27.07.2021Your Name:Elke Niebergall-RothManuscript Title:Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive<br/>dystrophic epidermolysis bullosaManuscript number (if known):151922-INS-CMED-RV-3

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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)
	l.	Time frame: Since the initial	planning of the work
1	All support for the present manuscript (e.g., funding,	X None	
	provision of study materials,		
	medical writing, article		
	processing charges, etc.)		
	No time limit for this item.		
_		Time frame: past	36 months
2	Grants or contracts from any entity (if not indicated	X None	
	in item #1 above).		
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	X None	
0	testimony		
7	Support for attending meetings and/or travel	X None	
8	Patents planned, issued or pending	X None	
0	Deuticipation on a Data	V Nore	
9	Participation on a Data Safety Monitoring Board or	X None	
	Advisory Board		
10	Leadership or fiduciary role in other board, society,	X None	
	committee or advocacy		
	group, paid or unpaid		
11	Stock or stock options	X None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other	X None	
	services		
13	Other financial or non-	TICEBA GmbH	Employee
	financial interests		

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

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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.) <b>No time limit for this item.</b>	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	x None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	X None	
6	Payment for expert	X None	
-	testimony		
7	Support for attending meetings and/or travel	X None	
8	Patents planned, issued or pending	X None	
0	Douticipation on a Data	V Neze	
9	Participation on a Data Safety Monitoring Board or	X None	
	Advisory Board		
10	Leadership or fiduciary role in other board, society,	X None	
	committee or advocacy		
11	group, paid or unpaid	X None	
11	Stock or stock options		
12	Receipt of equipment, materials, drugs, medical writing, gifts or other	X None	
	services		
13	Other financial or non-	RHEACELL GmbH & Co.KG	Employee
	financial interests		

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

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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)
	l.	Time frame: Since the initial	planning of the work
1	All support for the present manuscript (e.g., funding,	X None	
	provision of study materials,		
	medical writing, article		
	processing charges, etc.)		
	No time limit for this item.		
_		Time frame: past	36 months
2	Grants or contracts from any entity (if not indicated	X None	
	in item #1 above).		
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	X None	
-	testimony		
7	Support for attending meetings and/or travel	X None	
8	Patents planned, issued or pending	X None	
0	Douticipation on a Data	V Neze	
9	Participation on a Data Safety Monitoring Board or	X None	
	Advisory Board		
10	Leadership or fiduciary role in other board, society,	X None	
	committee or advocacy		
11	group, paid or unpaid	X None	
11	Stock or stock options		
12	Receipt of equipment, materials, drugs, medical writing, gifts or other	X None	
	services		
13	Other financial or non-	RHEACELL GmbH & Co.KG	Employee
	financial interests		

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

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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.) <b>No time limit for this item.</b>	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	x None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	X None	
6	Payment for expert	X None	
0	testimony		
7	Support for attending meetings and/or travel	X None	
8	Patents planned, issued or pending	X None	
0	Deuticipation on a Data	V Nore	
9	Participation on a Data Safety Monitoring Board or	X None	
	Advisory Board		
10	Leadership or fiduciary role in other board, society,	X None	
	committee or advocacy		
	group, paid or unpaid		
11	Stock or stock options	X None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other	X None	
	services		
13	Other financial or non-	TICEBA GmbH	Employee
	financial interests		

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

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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.) <b>No time limit for this item.</b>	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	x None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	X None	
6	Payment for expert	X None	
0	testimony		
7	Support for attending meetings and/or travel	X None	
8	Patents planned, issued or pending	X None	
0	Deuticipation on a Data	V Nore	
9	Participation on a Data Safety Monitoring Board or	X None	
	Advisory Board		
10	Leadership or fiduciary role in other board, society,	X None	
	committee or advocacy		
	group, paid or unpaid		
11	Stock or stock options	X None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other	X None	
	services		
13	Other financial or non-	TICEBA GmbH	Employee
	financial interests		

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

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

Date:27.07.2021Your Name:Leoni ErdingerManuscript Title:Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive<br/>dystrophic epidermolysis bullosaManuscript number (if known):151922-INS-CMED-RV-3

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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.) <b>No time limit for this item.</b>	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	x None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	X None	
6	Payment for expert	X None	
-	testimony		
7	Support for attending meetings and/or travel	X None	
8	Patents planned, issued or pending	X None	
0	Douticipation on a Data	V Neze	
9	Participation on a Data Safety Monitoring Board or	X None	
	Advisory Board		
10	Leadership or fiduciary role in other board, society,	X None	
	committee or advocacy		
11	group, paid or unpaid	X None	
11	Stock or stock options		
12	Receipt of equipment, materials, drugs, medical writing, gifts or other	X None	
	services		
13	Other financial or non-	RHEACELL GmbH & Co.KG	Employee
	financial interests		

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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The author's relationships/activities/interests should be <u>defined broadly</u>. 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.

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

	Grants or contracts from		
	any entity (if not indicated		
	in item #1 above).		
3	Royalties or licenses	x None	
	,		
4	Consulting fees	None	
		FS received fees from	
		Amryt Pharma.	
5	Payment or honoraria for	x None	
	lectures, presentations,		
	speakers bureaus,		
	manuscript writing or		
	educational events		
6	Payment for expert	x None	
	testimony		
7		News	
7	Support for attending meetings and/or travel	_x None	
8	Patents planned, issued or pending	x None	
	pending		
9	Participation on a Data	x None	
	Safety Monitoring Board or		
	Advisory Board		
10	Leadership or fiduciary role	x_ None	
	in other board, society,		
	committee or advocacy		
	group, paid or unpaid		
11	Stock or stock options	x None	
12	Receipt of equipment,	x None	
	materials, drugs, medical		
	writing, gifts or other		
	services		
13	Other financial or non- financial interests	x None	
	intaricial interests		

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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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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<u>manuscript only</u>.

The author's relationships/activities/interests should be <u>defined broadly</u>. 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)
	Tin	ne frame: Since the initia	l planning of the work
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article	x None	
	processing charges, etc.)		
	No time limit for this item.		

		1	
		Time frame: past	36 months
2			
2	Grants or contracts from any entity (if not	x None	
	indicated in item #1		
	above).		
3	Royalties or licenses	x None	
4	Consulting fees	x None	
5	Payment or honoraria	x None	
	for lectures, presentations, speakers bureaus, manuscript writing or educational		
	events		
6	Payment for expert	x None	
	testimony		
7	Support for attending	x None	
<i>`</i>	meetings and/or travel		
8	Patents planned, issued	x None	
	or pending		
9	Participation on a Data	x None	
5	Safety Monitoring		
Board or Advisory			

	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	

\_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

Gewent

Date:_3-AUG-2021	
Your Name:Martin Laimer	_
Manuscript Title:Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for re-	cessive dystrophic
epidermolysis bullosa	
Manuscript number (if known):	

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		Name all entities with whom you have this relationship or indicate none (add rows as needed) Time frame: Since the initial	Specifications/Comments (e.g., if payments were made to you or to your institution)
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) <b>No time limit for this item.</b>	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	_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 Board	_X_ None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None	Secretary General, Austrian Society of Dermatology
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	

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.

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The author's relationships/activities/interests should be <u>defined broadly</u>. 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.

		Name all entities with whom you have this relationship or indicate none (add rows as	Specifications/Comments (e.g., if payments were made to you or to your institution)
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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,	None	
	medical writing, article		
	processing charges, etc.)		
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		Time frame, use	26 months
2	Grants or contracts from	Time frame: past	36 months
2	any entity (if not indicated	None	
	in item #1 above).		

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

4.8.27 UNIKLIKDKU IRG LANDESKRANKENHAUS Oniversitätsklinik für Dermatologic Johnversitatskimik für Dermatologie und Allergologie der PMU Vorstand: Prim. Univ.-Prof. Dr. Johann Bauer, MBA A-5020 Salzburg | Müllner Haupistraße 48

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.) <b>No time limit for this item.</b>	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	XNone	

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

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.

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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 initia	l 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	t 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	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	_ RHEACELL	Travel expenses for meting attendance reimbursed to myself
8	Patents planned, issued or pending	X 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	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	

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e:23/07/21	
ır Name: May El Hachem	
nuscript Title: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive	
dystrophic epidermolysis bullosa	
nuscript 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.) <b>No time limit for this item.</b>	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	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 Board	X None
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

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

#### 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.

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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 initia	planning of the work
1	All support for the present manuscript (e.g., funding,	None	
	provision of study materials,		
	medical writing, article processing charges, etc.)		
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		Time frame: past	36 months
2	Grants or contracts from any entity (if not indicated	None	
	in item #1 above).		
3	Royalties or licenses	None	

4	Consulting fees	None	
5	Payment or honoraria for lectures, presentations,	None	
	speakers bureaus,		
	manuscript writing or educational events		
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	None	
	Advisory Board		
10	Leadership or fiduciary role in other board, society,	None	
	committee or advocacy		
	group, paid or unpaid		
11	Stock or stock options	None	
12	Receipt of equipment, materials, drugs, medical	None	
	writing, gifts or other		
-	services		
13	Other financial or non- financial interests	None	

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

Date: Wednesday 4<sup>th</sup> 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.

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

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

4	Consulting fees	None	
5	Payment or honoraria for lectures, presentations,	None	
	speakers bureaus,		
	manuscript writing or educational events		
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	None	
	Advisory Board		
10	Leadership or fiduciary role	None	
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	committee or advocacy		
	group, paid or unpaid		
11	Stock or stock options	None	
12	Receipt of equipment, materials, drugs, medical	None	
	writing, gifts or other		
	services		
13	Other financial or non- financial interests	None	

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

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speakers bureaus, manuscript writing or educational events       ✓       None         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       ✓       None         10       Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid       ✓       None         11       Stock or stock options       ✓       None         12       Receipt of equipment, materials, drugs, medical writing, gifts or other services       ✓       None	CO. 202	a second s	None	warpt Title <u>() + + + + + + + + + + + + + + + + + + +</u>
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Payment for expert testimony       Image: None         7       Support for attending meetings and/or travel       Image: None         8       Patents planned, issued or pending       Image: None         9       Participation on a Data Safety Monitoring Board or Advisory Board       Image: None         10       Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid       Image: None         11       Stock or stock options       Image: None         12       Receipt of equipment, materials, drugs, medical writing, gifts or other services       Image: None         13       Other financial or non-       Image: None				
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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       ✓       None         10       Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid       ✓       None         11       Stock or stock options       ✓       None         12       Receipt of equipment, materials, drugs, medical writing, gifts or other services       ✓       None         13       Other financial or non-       ✓       None				is adapted to the set of the set you to disclose at
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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.

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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		Name all entities with whom you have this relationship or indicate none (add rows as	Specifications/Comments (e.g., if payments were made to you or to your institution)
		needed)	
·		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	

	1		
4	Consulting fees	None	
1	constraint rees	None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or	Amryt Pharma Plc	Honoraria for educational talks
		Mölnlycke Health Care AB	Honorana for Educational Carks
	educational events		
6	Payment for expert testimony	None	
7	Support for attending	None	
[ .	meetings and/or travel		
8	Patents planned, issued or pending	None	
-			
9	Participation on a Data Safety Monitoring Board or	None	
	Advisory Board		
10	Leadership or fiduciary role in other board, society,	None	
	committee or advocacy	1	
	group, paid or unpaid		
11	Stock or stock options	None	
12	Receipt of equipment,	None	
	materials, drugs, medical	None	
	writing, gifts or other services		
13	Other financial or non-	News	
10	financial interests	None	

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

A

Date:	22 July 2021
Your Name:	Christen L. Ebens, MD MPH
Manuscript Ti	itle: Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive dystrophic
epidermolysis	bullosa
Manuscript n	umber (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.

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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,	X None	
	provision of study materials,		
	medical writing, article processing charges, etc.)		
	No time limit for this item.		
		Time frame: past	36 months
2	Grants or contracts from any entity (if not indicated in item #1 above).	None	Contract with sponsor (Rheacell Gmbh & Co) for conduct of clinical trial of allo-APZ2-EB MSCs in RDEB, outcomes described in this manuscript
3	Royalties or licenses	_X None	

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

\_\_X\_ I certify that I have answered every question and have not altered the wording of any of the questions on this 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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		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	None	
	manuscript (e.g., funding,	Ticeba GmbH	Paid Scientific Advisor
	provision of study materials, medical writing, article	Rheacell GmbH & Co KG	Scientific Advisor, Past Corporate Sponsored Research Support
	processing charges, etc.)		
	No time limit for this item.		
		Time frame: past	36 months
2	Grants or contracts from any entity (if not indicated	None NIH/NEI	RO1EY025794 and R24EY028767
	in item #1 above).		
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,

			licensed to TICEBA GmbH, Heidelberg, Germany, and RHEACELL GmbH & Co. KG, Heidelberg, Germany.
4	Consulting fees	None Ticeba GmbH	Scientific Advisor
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	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	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	_x None	
11	group, paid or unpaid Stock or stock options	x None	
11			
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	x None	
13	Other financial or non- financial interests	_x None	

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Meulen Fan

Markus Frank, M.D.

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

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 <u>current</u> <u>manuscript only</u>.

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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,	x None	
	provision of study materials,		
	medical writing, article		
	processing charges, etc.)		
	No time limit for this item.		
		Time frame: past	36 months
2	Grants or contracts from	None	
	any entity (if not indicated	NIH/NEI	RO1EY025794 and R24EY028767
	in item #1 above).		
3	Royalties or licenses	None	NYF is inventor or co-inventor of US and international
		Patent Royalties	patents assigned to Brigham and Women's Hospital and/or Boston Children's Hospital, Boston, MA, USA,

4	Consulting fees Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or	x None	licensed to TICEBA GmbH, Heidelberg, Germany, and RHEACELL GmbH & Co. KG, Heidelberg, Germany.
6	educational events Payment for expert testimony	x None	
7	Support for attending meetings and/or travel	x None	
8	Patents planned, issued or pending	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	x None	
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	

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

Matasha Kank

Natasha Frank, M.D.

Date:27.07.2021Your Name:Christoph GanssManuscript Title:Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive<br/>dystrophic epidermolysis bullosaManuscript 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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_		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,	X None	
	medical writing, article processing charges, etc.)		
	No time limit for this item.		
		Time frame: past	36 months
2	Grants or contracts from any entity (if not indicated	X None	
	in item #1 above).		
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	X None	
9	Safety Monitoring Board or		
	Advisory Board		
10	Leadership or fiduciary role in other board, society,	X None	
	committee or advocacy		
11	group, paid or unpaid Stock or stock options	X None	
11	Stock of Stock options	X None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other	X None	
12	services	TICEDA Carbil	
13	Other financial or non-	TICEBA GmbH	CEO
	financial interests	RHEACELL GmbH & Co. KG	CEO

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

Date:		ICMUE DISCLOSURE FORM		
Your Name: Manuscript Title:	JUNY	MAADNEZ		
Manuscript number (i	f known):	in I he dinal	Mal date	MSCP.57

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 blas. 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)
L		Time frame: Since the initia	al 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.	K-None	
		Time frame: pas	t 35 months
2	Grants or contracts from any entity (if not indicated in item #1 above).	KNone	
14	Royalties or licenses		

-	Consulting fees	-X None	
10	<ul> <li>Payment or bonoraris for lectures, presentations, speakers bureaus, manuscript writing or educational events</li> </ul>	L None	
6		- those	
7	Support for attending meetings and/or travel	L None	
8	Patents planned, issued or pending	-X None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	- KNONE	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid		
11	Stock or stock options		
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<u>K</u> None	
13	Other financial or non- financial interests	+ None	

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

Make

Date:05.08.2021Your Name:Prof. Dr. John McGrathManuscript Title:Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive<br/>dystrophic epidermolysis bullosaManuscript 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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The author's relationships/activities/interests should be <u>defined broadly</u>. 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.

		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.) <b>No time limit for this item.</b>	None x	
		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	

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.

John McGrath 5 August 2021

Date: 227	July 20LI				
Your Name:		TOLAR	1	t	1
Manuscript Title:	Phone 1/11 x	Union FUM	MASCES	aus	TOURDES.
Manuscript numbe	r (if known):		Q		

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 ≥01-×≥063070	
		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	FOR TICESA .	1.8.6.7.000
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None	and the construction of the second
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	- None TICESA DSMB Member.	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None None	
11	Stock or stock options	None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	None	
13	Other financial or non- financial interests	None	

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

Date:22.07.2021Your Name:Mark Andreas KluthManuscript Title:Phase I/IIa clinical trial of ABCB5-positive dermal mesenchymal stem cells for recessive<br/>dystrophic epidermolysis bullosaManuscript 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: 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.) <b>No time limit for this item.</b>	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	x None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or	X None	
6	educational events	N Alexa	
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	
0			
9	Participation on a Data Safety Monitoring Board or	X None	
	Advisory Board		
10	Leadership or fiduciary role in other board, society,	X None	
	committee or advocacy		
11	group, paid or unpaid	X None	
11	Stock or stock options		
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	X None	
12	Other financial or non-	TICEBA GmbH	Employee, CSO
13	financial interests	RHEACELL GmbH & Co.KG	CSO
		MILACELL GIIIDH & CO.KG	

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

## **TREND Statement Checklist**

Paper	Item	Descriptor		Reported?	
Section/ Topic	No		$\checkmark$	Pg #	
Title and Abst	ract				
Title and	1	Information on how unit were allocated to interventions	$\checkmark$	4	
Abstract		Structured abstract recommended		4	
		Information on target population or study sample	$\checkmark$	4	
Introduction					
Background	2	Scientific background and explanation of rationale	$\checkmark$	6-8	
0		Theories used in designing behavioral interventions	V V	6-8	
Methods					
Participants	3	Eligibility criteria for participants, including criteria at different levels in			
i al cloipanto	5	recruitment/sampling plan (e.g., cities, clinics, subjects)	$\checkmark$	22	
		<ul> <li>Method of recruitment (e.g., referral, self-selection), including the</li> </ul>	· · · · · · · · · · · · · · · · · · ·		
		sampling method if a systematic sampling plan was implemented	n.a.	n.a.	
		Recruitment setting	$\overline{\mathbf{V}}$	22	
		Settings and locations where the data were collected	V.	22	
Interventions	4	Details of the interventions intended for each study condition and how	./	22-23	
Interventions		and when they were actually administered, specifically including:	····		
		<ul> <li>Content: what was given?</li> <li>Delivery method: how was the content given?</li> </ul>	· · · · · · · · · · · · · · · · · · ·	22-23	
		<ul> <li>Delivery method: how was the content given?</li> <li>Unit of delivery: how were the subjects grouped during delivery?</li> </ul>	n.a. n.a.	n.a.	
		<ul> <li>Deliverer: who delivered the intervention?</li> </ul>	/	n.a. 22	
		<ul> <li>Setting: where was the intervention delivered?</li> </ul>	· · · · · · · · · · · · · · · · · · ·	22	
		<ul> <li>Exposure quantity and duration: how many sessions or episodes or</li> </ul>	•		
		events were intended to be delivered? How long were they intended to last?	$\checkmark$	23	
		<ul> <li>Time span: how long was it intended to take to deliver the intervention to each unit?</li> </ul>	$\checkmark$	23	
		<ul> <li>Activities to increase compliance or adherence (e.g., incentives)</li> </ul>	n.a.	n.a.	
Objectives	5	Specific objectives and hypotheses	$\checkmark$	8	
Outcomes	6	Clearly defined primary and secondary outcome measures	$\checkmark$	23-24	
		<ul> <li>Methods used to collect data and any methods used to enhance the quality of measurements</li> </ul>	n.a.	n.a.	
		<ul> <li>Information on validated instruments such as psychometric and biometric properties</li> </ul>	✓ 23	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	<ul> <li>Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)</li> </ul>	$\checkmark$	22	
		<ul> <li>Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)</li> </ul>	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> <li>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.</li> </ul>	<b>v</b>	22
Unit of Analysis	10	<ul> <li>Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)</li> </ul>	$\checkmark$	24
		<ul> <li>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)</li> </ul>	n.a.	n.a.
Statistical Methods	11	<ul> <li>Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data</li> </ul>	$\checkmark$	24
		<ul> <li>Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis</li> </ul>	$\checkmark$	24
		Methods for imputing missing data, if used	$\checkmark$	23
		Statistical software or programs used	$\checkmark$	24
Results				
Participant flow	12	• Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended)	$\checkmark$	Fig. 1B
		<ul> <li>Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study</li> </ul>	$\checkmark$	Fig. 1B
		<ul> <li>Assignment: the numbers of participants assigned to a study condition</li> </ul>	$\checkmark$	Fig. 1B
		<ul> <li>Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention</li> </ul>	$\checkmark$	Fig. 1B
		<ul> <li>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</li> </ul>	$\checkmark$	Fig. 1B
		<ul> <li>Analysis: the number of participants included in or excluded from the main analysis, by study condition</li> </ul>	$\checkmark$	Fig. 1B
		<ul> <li>Description of protocol deviations from study as planned, along with reasons</li> </ul>	$\checkmark$	9
Recruitment	13	Dates defining the periods of recruitment and follow-up	$\checkmark$	9
Baseline Data	14	Baseline demographic and clinical characteristics of participants in each     study condition	$\checkmark$	Table 1
		Baseline characteristics for each study condition relevant to specific disease prevention research	n.a.	n.a.
		Baseline comparisons of those lost to follow-up and those retained, overall     and by study condition	n.a.	n.a.
		Comparison between study population at baseline and target population     of interest	n.a.	n.a.
Baseline equivalence	15	<ul> <li>Data on study group equivalence at baseline and statistical methods used to control for baseline differences</li> </ul>	n.a.	n.a.

## **TREND Statement Checklist**

Numbers analyzed	16	<ul> <li>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</li> </ul>	$\checkmark$	Figures and Tables
		<ul> <li>Indication of whether the analysis strategy was "intention to treat" or, if not, description of how non-compliers were treated in the analyses</li> </ul>	$\checkmark$	24
Outcomes and estimation	17	• 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	$\checkmark$	9-13
		Inclusion of null and negative findings	$\checkmark$	9-13
		<ul> <li>Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any</li> </ul>	n.a.	n.a.
Ancillary analyses	18	<ul> <li>Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory</li> </ul>	n.a.	n.a.
Adverse events	19	<ul> <li>Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals)</li> </ul>	~	12-13, Table 2
DISCUSSION				
Interpretation	20	• 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	$\checkmark$	14-21
		<ul> <li>Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations</li> </ul>	$\checkmark$	14-21
		• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	$\checkmark$	14-21
		<ul> <li>Discussion of research, programmatic, or policy implications</li> </ul>	$\checkmark$	20-21
Generalizability	21	• 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> <li>General interpretation of the results in the context of current evidence and current theory</li> </ul>	$\checkmark$	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: <u>http://www.cdc.gov/trendstatement/</u>