

**BETH C. DRAIN, CA CSR NO. 7152**

BEFORE THE  
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE AND THE  
APPLICATION REVIEW SUBCOMMITTEE  
TO THE  
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE  
ORGANIZED PURSUANT TO THE  
CALIFORNIA STEM CELL RESEARCH AND CURES ACT  
REGULAR MEETING

LOCATION: VIA ZOOM

DATE: JULY 27, 2023  
9:30 A.M.

REPORTER: BETH C. DRAIN, CA CSR  
CSR. NO. 7152

FILE NO.: 2023-25

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**BETH C. DRAIN, CA CSR NO. 7152**

**I N D E X**

<b>ITEM DESCRIPTION</b>	<b>PAGE NO.</b>
<b>OPEN SESSION</b>	
1. CALL TO ORDER	3
2. ROLL CALL	3
<b>ACTION ITEMS</b>	
3. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL STAGE PROJECTS PROGRAM ANNOUNCEMENT (CLIN 1 OR 2)	5
<b>CLOSED SESSION</b>	
NONE	
4. DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO APPLICATIONS SUBMITTED IN RESPONSE TO AGENDA ITEM 3 ABOVE. (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
<b>DISCUSSION ITEMS</b>	
5. GENERAL COMMENTS ON ARS PROCESS	NONE
6. PUBLIC COMMENT	NONE
7. ADJOURNMENT	42

**BETH C. DRAIN, CA CSR NO. 7152**

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JULY 27, 2023; 9:30 A.M.

MR. TOCHER: GOOD MORNING, EVERYONE. THIS IS SCOTT AT THE CIRM HEADQUARTERS. I BELIEVE WE HAVE A QUORUM NOW, READY FOR THE APPLICATION REVIEW SUBCOMMITTEE MEETING. VITO, IF YOU WOULD LIKE TO KICK THINGS OFF. YOU'RE MUTED, VITO.

CHAIRMAN IMBASCIANI: THANK YOU. WE CAN START WITH THE ROLL CALL PLEASE.

MS. DEQUINA-VILLABLANCA: DAN BERNAL. MARIA BONNEVILLE. JUDY CHOU. LEONDR A CLARK-HARVEY.

MS. CLARK-HARVEY: PRESENT.

MS. DEQUINA-VILLABLANCA: ANNE-MARIE DULIEGE. YSABEL DURON. MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: HERE.

MS. DEQUINA-VILLABLANCA: FRED FISHER.

DR. FISHER: HERE.

MS. DEQUINA-VILLABLANCA: ELENA FLOWERS.

DR. FLOWERS: PRESENT.

MS. DEQUINA-VILLABLANCA: DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. DEQUINA-VILLABLANCA: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: HERE.

MS. DEQUINA-VILLABLANCA: STEVE JUELSGAARD.

**BETH C. DRAIN, CA CSR NO. 7152**

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MR. JUELSGAARD: PRESENT.

MS. DEQUINA-VILLABLANCA: RICH LAJARA.

MR. LAJARA: PRESENT.

MS. DEQUINA-VILLABLANCA: CHRISTINE  
MIASKOWSKI.

DR. MIASKOWSKI: PRESENT.

MS. DEQUINA-VILLABLANCA: LAUREN  
MILLER-ROGEN.

MS. MILLER-ROGEN: HERE.

MS. DEQUINA-VILLABLANCA: ADRIANA PADILLA.

DR. PADILLA: PRESENT.

MS. DEQUINA-VILLABLANCA: JOE PANETTA.  
MARVIN SOUTHARD.

DR. SOUTHARD: HERE.

MS. DEQUINA-VILLABLANCA: KAROL WATSON.

DR. WATSON: HERE.

MS. DEQUINA-VILLABLANCA: KEVIN XU.

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1 MR. BERNAL: I WAS HAVING PROBLEMS  
2 UNMUTING AS WELL.

3 MS. DEQUINA-VILLABLANCA: DAN?

4 MR. BERNAL: YEAH.

5 MS. DEQUINA-VILLABLANCA: WE CAN PROCEED.

6 MR. TOCHER: VITO, YOU'RE MUTED.

7 CHAIRMAN IMBASCIANI: AGAIN. SORRY. IT  
8 WAS ACCIDENTAL. WE CAN START NOW. I DON'T HAVE MY  
9 AGENDA IN FRONT OF ME, BUT I THINK AT THIS POINT GIL  
10 TAKES OVER.

11 MR. TOCHER: THAT'S RIGHT. GIL, ARE YOU  
12 READY TO GO?

13 DR. SAMBRANO: YES. I WILL BE SHARING THE  
14 PRESENTATION. TODAY I HAVE WITH ME DR. HAYLEY LAM.  
15 SHE IS THE ASSOCIATE DIRECTOR OF THE REVIEW OFFICE.  
16 SHE'S GOING TO HELP ME GO THROUGH THE SIX DIFFERENT  
17 APPLICATIONS THAT WE HAVE FOR CONSIDERATION TODAY.

18 AND THESE SIX APPLICATIONS, JUST AS WE  
19 BEGIN, COVER ACTUALLY TWO DIFFERENT CYCLES OF MAY  
20 AND JUNE OF THE GRANTS WORKING GROUP. SO THAT'S  
21 JUST SOMETHING TO TAKE NOTE OF.

22 AS ALWAYS, WE START WITH OUR MISSION,  
23 WHICH IS TO ACCELERATE WORLD-CLASS SCIENCE TO  
24 DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE  
25 TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE

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1 CALIFORNIA AND WORLD.

2 OUR BUDGET FOR THIS FISCAL YEAR, WHICH  
3 STARTS IN JULY, WE ARE JUST AT THE BEGINNING OF  
4 THIS. SO WE HAD AN ALLOCATION THAT WAS APPROVED BY  
5 THE BOARD OF 252 MILLION. THE AMOUNT REQUESTED  
6 TODAY IN TOTAL FROM THE SIX APPLICATIONS IS ABOUT 50  
7 MILLION, LEAVING, IF APPROVED, ABOUT 200 MILLION  
8 BALANCE FOR THE REMAINDER OF THE FISCAL YEAR.

9 THE SCIENTIFIC SCORING SYSTEM THAT'S USED  
10 TO GRADE THE APPLICATIONS THAT COME INTO THE  
11 CLINICAL PROGRAM USES A SYSTEM OF 1, 2, OR 3. A  
12 SCORE OF 1 MEANS THAT AN APPLICATION HAS EXCEPTIONAL  
13 MERIT AND WARRANTS FUNDING. AND THAT'S THE CASE FOR  
14 ALL THE APPLICATIONS THAT YOU ARE GOING TO BE SEEING  
15 TODAY. SOME APPLICATIONS WILL RECEIVE A SCORE OF 2.  
16 THOSE TYPICALLY GO BACK TO THE APPLICANT TO ADDRESS  
17 CONCERNS FROM THE REVIEW PANEL AND WILL RESUBMIT  
18 WITHIN A SHORT TIME. AND THEN THOSE THAT RECEIVE A  
19 SCORE OF 3 MEANS THOSE ARE SUFFICIENTLY FLAWED THAT  
20 THEY DON'T WARRANT FUNDING, AND THOSE CAN'T BE  
21 RESUBMITTED FOR SIX MONTHS.

22 THE SCIENTIFIC REVIEW CRITERIA THAT THE  
23 GRANTS WORKING GROUP USES IN ORDER TO COME UP WITH A  
24 SCORE IS BASED ON THE FOLLOWING FIVE QUESTIONS:  
25 FIRST, DOES THE PROJECT HOLD THE NECESSARY

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1 SIGNIFICANCE AND POTENTIAL FOR IMPACT? MEANING WHAT  
2 VALUE DOES IT OFFER? IS THIS SOMETHING THAT IS  
3 WORTH DOING? DOES IT HAVE A GOOD RATIONALE? IS IT  
4 WELL PLANNED AND DESIGNED? AND IS IT FEASIBLE,  
5 INCLUDING HAVING THE APPROPRIATE QUALIFIED  
6 INDIVIDUALS AND ALL THE RESOURCES TO CARRY OUT THE  
7 ACTIVITIES THAT ARE PROPOSED? AND THEN, FINALLY,  
8 DOES THE PROJECT UPHOLD THE PRINCIPLES OF DIVERSITY,  
9 EQUITY, AND INCLUSION IN THE PROJECT?

10 THAT LAST COMPONENT, THE DEI, IS BOTH  
11 CONSIDERED BY THE SCIENTIFIC MEMBERS AS JUST  
12 MENTIONED UNDER THE FIFTH REVIEW CRITERION, BUT IT  
13 IS ALSO CONSIDERED SEPARATELY BY OUR BOARD MEMBERS,  
14 PATIENT ADVOCATE MEMBERS, THAT SERVE ON THE GRANTS  
15 WORKING GROUP THROUGH A SEPARATE DEI SCORE. WE  
16 PROVIDE A RUBRIC, WHICH IS SHOWN IN THE IMAGE THAT  
17 WE DON'T EXPECT YOU TO READ, BUT JUST SO YOU ARE  
18 AWARE THAT THAT RUBRIC EXISTS AND HELPS GUIDE THE  
19 SCORING FOR OUR BOARD MEMBERS. AND THE SCORING  
20 SYSTEM FOR DEI IS BASED ON A SCALE OF 0 TO 10 WITH  
21 10 BEING THE MOST OUTSTANDING RESPONSE OR SCORE.

22 THE COMPOSITION OF THE GRANTS WORKING  
23 GROUP ITSELF INCLUDES SEVERAL ROLES. THERE ARE THE  
24 SCIENTIFIC GRANTS WORKING GROUP MEMBERS OF WHICH  
25 THERE ARE 15. AND THEY PROVIDE SCIENTIFIC

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1 EVALUATION. AND WE PUT TOGETHER PANELS THAT INCLUDE  
2 DIVERSE EXPERTISE, INCLUDING DISEASE AREA EXPERTISE,  
3 REGULATORY, CMC, PRODUCT DEVELOPMENT, AND SO ON.  
4 AND SO THEY PROVIDE THE SCIENTIFIC SCORE THAT YOU  
5 SEE. AS ALSO MENTIONED, WE HAVE OUR GRANTS WORKING  
6 GROUP BOARD MEMBERS WHO ARE PATIENT ADVOCATE OR  
7 NURSE MEMBERS OF THE BOARD. THEY CONDUCT THE DEI  
8 EVALUATION, PROVIDE A PATIENT PERSPECTIVE ON THE  
9 SIGNIFICANCE AND IMPACT OF THESE PROJECTS, AND  
10 PROVIDE OVERSIGHT ON THE OVERALL REVIEW PROCESS  
11 ITSELF. AND THEN, LASTLY, WE HAVE SCIENTIFIC  
12 SPECIALISTS WHO ARE NONVOTING MEMBERS. SO THEY  
13 PARTICIPATE ON AN AD HOC BASIS WHENEVER WE NEED  
14 ADDITIONAL EXPERTISE. THEY PROVIDE A SCIENTIFIC  
15 EVALUATION, BUT THEY DON'T PROVIDE A FINAL  
16 SCIENTIFIC SCORE.

17 ALL RIGHT. SO THE FIRST APPLICATION THAT  
18 WE'RE GOING TO CONSIDER TODAY AND, JUST TO NOTE,  
19 HAYLEY AND I ARE GOING TO GO BACK AND FORTH A LITTLE  
20 BIT GIVEN THE ORDER. THE APPLICATIONS WERE ARRANGED  
21 BASED ON OUR ABILITY TO HAVE ALL MEMBERS  
22 PARTICIPATING AND VOTING ON THESE.

23 SO THE FIRST ONE THAT WE'RE GOING TO  
24 CONSIDER IS CLIN2-14068. THIS ONE IS ENTITLED  
25 "TREATMENT OF SEVERE APLASTIC ANEMIA BY INDUCTION OF



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1 MIXED CHIMERISM USING CD4+ T-CELL DEPLETED  
2 HAPLOIDENTICAL DONOR STEM CELL TRANSPLANT."

3 THIS THERAPY IS A DONOR BLOOD STEM CELL  
4 TRANSPLANT THAT HAS ITS T-CELLS DEPLETED IN ORDER TO  
5 AVOID GRAFT VERSUS HOST DISEASE, AND IT'S COMBINED  
6 WITH A LOW TOXIC CONDITIONING REGIMEN. AND THE  
7 INDICATION IS FOR PATIENTS WITH SEVERE APLASTIC  
8 ANEMIA. AND THEIR GOAL IS TO COMPLETE A PHASE 1  
9 FIRST-IN-HUMAN CLINICAL TRIAL. THE FUNDS REQUESTED  
10 IS JUST OVER 9 MILLION. NO CO-FUNDING IS REQUIRED  
11 FOR THIS APPLICANT.

12 JUST SOME BACKGROUND ON THE SEVERE  
13 APLASTIC ANEMIA. THIS IS A LIFE THREATENING DISEASE  
14 OF THE IMMUNE SYSTEM IN WHICH THE BLOOD CELLS, BLOOD  
15 LYMPHOCYTES SPECIFICALLY, DESTROY OTHER BLOOD CELLS  
16 RESULTING IN SEVERE ANEMIA AND BONE MARROW DAMAGE.  
17 IT IS, IN EFFECT, AN AUTOIMMUNE DISEASE. THE  
18 CONDITION CAN BE CURED WITH A BONE MARROW  
19 TRANSPLANT, BUT THE APPROACH IS LESS EFFECTIVE IN  
20 OLDER PATIENTS, TYPICALLY OVER 40, WHO EXPERIENCE A  
21 HIGHER INCIDENCE OF THE GRAFT FAILURE OR GRAFT  
22 VERSUS HOST DISEASE. AND ADDITIONALLY, PATIENTS  
23 THAT DON'T HAVE A FULLY MATCHED DONOR, WHICH OFTEN  
24 IS THE CASE FOR MANY UNDERSERVED GROUPS, ARE  
25 ASSOCIATED WITH INFERIOR SURVIVAL OUTCOMES.

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1 SO THE PROPOSED THERAPY OFFERS THE  
2 POTENTIAL FOR IMPROVED OUTCOMES BY SIGNIFICANTLY  
3 DECREASING THE OCCURRENCE OF GVHD AND ELIMINATING  
4 THE NEED FOR A FULLY MATCHED DONOR.

5 WHY IS THIS A STEM CELL OR GENE THERAPY  
6 PROJECT? THIS INVOLVES A STEM CELL TRANSPLANT.

7 CURRENTLY WE DON'T HAVE ANYTHING IN OUR  
8 ACTIVE AWARDS PORTFOLIO THAT ADDRESSES SEVERE  
9 APLASTIC ANEMIA. SO THIS WOULD ADD A NEW PROJECT TO  
10 THAT PORTFOLIO.

11 IN TERMS OF PREVIOUS FUNDING BY THE  
12 APPLICANT TEAM, THERE IS A RELATED PROJECT BY ONE OF  
13 THE TEAM MEMBERS, NOT THE SAME PI, BUT THE TEAM  
14 ESSENTIALLY IS LARGELY THE SAME. THIS WAS A CLIN2  
15 STAGE PROJECT THAT WAS FOCUSED ON SICKLE CELL  
16 DISEASE. THE PROJECT OUTCOME WAS A PHASE 1 CLINICAL  
17 TRIAL. THEY HAD SEVERAL MILESTONES. THE PROJECT  
18 WAS NOT COMPLETED IN PART BECAUSE OF THE COVID  
19 PANDEMIC THAT SEVERELY IMPACTED PATIENT RECRUITMENT.  
20 AND I BELIEVE SUBSEQUENTLY THE PI HAS RETIRED. SO  
21 THAT PROJECT HAS NOT CONTINUED.

22 THE GRANTS WORKING GROUP RECOMMENDATION  
23 FOR THIS APPLICATION IS AS FOLLOWS: THERE WERE 11  
24 MEMBERS THAT GAVE THIS A SCORE OF 1, TWO THAT GAVE  
25 IT A SCORE OF 2. THE DEI SCORE IS 8. AND THE CIRM

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1 TEAM RECOMMENDS FUNDING IN CONCURRENCE WITH THE  
2 GRANTS WORKING GROUP RECOMMENDATION FOR THE AMOUNT  
3 OF JUST OVER 9 MILLION.

4 SO, DR. IMBASCIANI, IT'S BACK TO YOU FOR  
5 ANY DISCUSSION OR QUESTIONS.

6 CHAIRMAN IMBASCIANI: THANK YOU. I'D LIKE  
7 TO OPEN IT UP FIRST FOR COMMENTS FROM THE BOARD  
8 MEMBERS. THANK YOU, GIL.

9 MR. TOCHER: IT MIGHT BE APPROPRIATE TO  
10 ASK IF THERE IS A MOTION ON THE TABLE TO FUND THE  
11 APPLICATION.

12 CHAIRMAN IMBASCIANI: THAT'S RIGHT. THANK  
13 YOU, SCOTT. SO I NEED A MOTION AND A SECOND, OF  
14 COURSE, TO LAUNCH DISCUSSION.

15 DR. SOUTHARD: MOVED.

16 CHAIRMAN IMBASCIANI: MARVIN MOVES. DO I  
17 HEAR A SECOND?

18 MR. JUELSGAARD: I'LL SECOND.

19 CHAIRMAN IMBASCIANI: THAT WAS STEVE  
20 JUELSGAARD. THANK YOU. OKAY. DISCUSSION FIRST  
21 FROM THE BOARD.

22 MARIANNE, I CAN ONLY SEE A FEW BOARD  
23 MEMBERS AT A TIME.

24 MS. DEQUINA-VILLABLANCA: THERE ARE NONE.  
25 THERE ARE NO HANDS -- WAIT. HOLD ON. THERE ARE NO

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1 HANDS RAISED AT THE MOMENT.

2 CHAIRMAN IMBASCIANI: OKAY. ARE THERE ANY  
3 MEMBERS OF THE PUBLIC ATTENDING THE MEETING THAT  
4 WOULD LIKE TO COMMENT?

5 MS. DEQUINA-VILLABLANCA: IF THERE ARE,  
6 PRESS STAR NINE TO GET PUT IN THE QUEUE AND THEN  
7 STAR SIX TO UNMUTE. I DO NOT SEE ANY POPPING UP.

8 CHAIRMAN IMBASCIANI: ALL RIGHT. AND,  
9 SCOTT, COULD YOU PLEASE TAKE A ROLL CALL VOTE.

10 MR. TOCHER: SURE. SO THIS IS TO FUND  
11 APPLICATION 14068.

12 CHAIRMAN IMBASCIANI: YES.

13 MR. TOCHER: DAN BERNAL.

14 MR. BERNAL: AYE.

15 MR. TOCHER: MARK FISCHER-COLBRIE.

16 DR. FISCHER-COLBRIE: YES.

17 MR. TOCHER: FRED FISHER.

18 DR. FISHER: AYE.

19 MR. TOCHER: ELENA FLOWERS.

20 DR. FLOWERS: YES.

21 MR. TOCHER: DAVID HIGGINS.

22 DR. HIGGINS: YES.

23 MR. TOCHER: VITO IMBASCIANI.

24 CHAIRMAN IMBASCIANI: YES.

25 MR. TOCHER: STEVE JUELSGAARD.

**BETH C. DRAIN, CA CSR NO. 7152**

1 MR. JUELSGAARD: YES.  
2 MR. TOCHER: RICH LAJARA.  
3 MR. LAJARA: YES.  
4 MR. TOCHER: CHRISTINE MIASKOWSKI.  
5 DR. MIASKOWSKI: YES.  
6 MR. TOCHER: LAUREN MILLER-ROGEN.  
7 MS. MILLER-ROGEN: YES.  
8 MR. TOCHER: ADRIANA PADILLA.  
9 DR. PADILLA: YES.  
10 MR. TOCHER: MARVIN SOUTHARD.  
11 DR. SOUTHARD: YES.  
12 MR. TOCHER: KAROL WATSON.  
13 DR. WATSON: YES.  
14 MR. TOCHER: SORRY, LEONDRA. CALL YOUR  
15 NAME. LEONDRA CLARK-HARVEY. LEONDRA, ARE YOU  
16 MUTED? I'M SORRY. WE SHOW YOU MUTED.  
17 CHAIRMAN IMBASCIANI: OKAY. THANK YOU  
18 VERY MUCH. GIL, WE CAN PROCEED WITH THE SECOND  
19 APPLICATION.  
20 DR. SAMBRANO: SO THE SECOND APPLICATION  
21 HAS TWO RECUSALS, MARIA BONNEVILLE AND STEVE  
22 JUELSGAARD, JUST TO BE AWARE.  
23 THIS APPLICATION IS CLIN2-14748. THE  
24 TITLE IS "EVALUATION OF SAFETY AND FEASIBILITY OF  
25 CYTOMEGALOVIRUS-SPECIFIC ANTI-HIV CHIMERIC ANTIGEN

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1 RECEPTOR T-CELLS IN PEOPLE WITH HIV."

2 SO THE THERAPY ITSELF IS A CMV-SPECIFIC  
3 T-CELL THAT EXPRESSES A CHIMERIC ANTIGEN RECEPTOR,  
4 SO IT'S A CAR-T, AND IT TARGETS HIV-INFECTED CELLS.  
5 THE INDICATION IS FOR PEOPLE LIVING WITH HIV/AIDS.  
6 THE GOAL IS COMPLETION OF A PHASE 1 FIRST-IN-HUMAN  
7 CLINICAL TRIAL. THE FUNDS REQUESTED IS 11.3  
8 MILLION, AND NO CO-FUNDING IS REQUIRED FOR THIS  
9 SPECIFIC PHASE AND APPLICANT TYPE.

10 BACKGROUND INFORMATION: HIV, AS WE KNOW,  
11 SEVERELY WEAKENS THE IMMUNE SYMPTOM AND INFECTED  
12 INDIVIDUALS BECOME SUSCEPTIBLE TO OTHER INFECTIONS  
13 AND SOME TYPES OF CANCER. ANTIRETROVIRAL THERAPY OR  
14 ART IS A LIFELONG TREATMENT THAT IS USED TO MANAGE  
15 HIV INFECTION, BUT IT IS NOT A CURE AND IT IS OFTEN  
16 ASSOCIATED WITH HIGH MORBIDITY AND COSTS. AND SO  
17 MORE EFFECTIVE POTENTIAL CURATIVE TREATMENTS ARE  
18 NEEDED.

19 PEOPLE LIVING WITH HIV MAINTAIN A PRETTY  
20 HIGH LEVEL OF T-CELLS THAT ARE SPECIFIC TO THE  
21 CYTOMEGALOVIRUS, AND THIS IS A VERY COMMON  
22 INFECTION. BY THE TIME ONE REACHES THE AGE OF 40,  
23 ABOUT HALF OF THE POPULATION HAS BEEN EXPOSED TO  
24 CMV. AND SO IN PEOPLE WITH HIV T-CELLS THAT ARE  
25 SPECIFIC TO THIS VIRUS CONTINUE TO BE QUITE

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1 FUNCTIONAL. AND SO THE PROPOSED APPROACH LEVERAGES  
2 THAT FACT TO CREATE A POTENTIALLY CURATIVE CAR-T  
3 CELL THERAPY THAT CAN RECOGNIZE AND DESTROY  
4 HIV-INFECTED CELLS AND THEN REMAIN ACTIVELY VIGILANT  
5 BY WAY OF THAT CMV SIGNALING.

6 WHY IS THIS A STEM CELL OR GENE THERAPY  
7 PROJECT? THE THERAPEUTIC CANDIDATE CONTAINS BLOOD  
8 PROGENITOR CELLS AND INVOLVES GENE MANIPULATION.

9 OTHER PROJECTS IN OUR PORTFOLIO THAT ARE  
10 SIMILAR, WE HAVE THREE OTHER CLINICAL STAGE PROJECTS  
11 THAT ARE FOR HIV/AIDS AS AN INDICATION, IN ONE CASE  
12 FOCUSED ON AIDS LYMPHOMA. THESE CANDIDATES AMONG  
13 THE THREE ARE VERY DIFFERENT APPROACHES. ONE IS A  
14 GENE THERAPY, THE OTHER IS A CAR-T CELL THAT'S  
15 SIMILAR TO THIS PROJECT, AND THEN THE LAST ONE  
16 UTILIZES GENETICALLY MODIFIED BLOOD STEM CELLS WHERE  
17 THE GOAL IS TO REPLACE THE IMMUNE SYSTEM WITH  
18 HIV-RESISTANT CELLS. ANOTHER HAS A SIMILAR  
19 APPROACH, BUT DOES NOT USE THE CMV ELEMENT AS A  
20 COMPONENT TO TRY TO MAKE THE THERAPY PERPETUAL AS IS  
21 DONE IN THIS PARTICULAR PROJECT THAT WE ARE  
22 CONSIDERING TODAY.

23 THE APPLICANT HAS HAD A LONG HISTORY OF  
24 FUNDING FROM CIRM. SO I INCLUDED IN THIS TABLE WHAT  
25 COULD FIT, BUT THERE IS ONE ADDITIONAL CIRM AWARD

**BETH C. DRAIN, CA CSR NO. 7152**

1 BEYOND THAT. THE APPLICANT HAS HAD A GOOD HISTORY  
2 IN TERMS OF PERFORMANCE WITH MILESTONES THAT ARE  
3 PROPOSED HAVING BEEN APPROPRIATELY ACCOMPLISHED,  
4 SOME WITH SOME MINOR DELAYS AND ONE THAT WAS  
5 SPECIFICALLY DELAYED BECAUSE OF THE COVID-19  
6 PANDEMIC, BUT OTHERWISE GENERALLY VERY GOOD  
7 PERFORMANCE ON ALL CIRM AWARDS.

8 THE GRANTS WORKING GROUP RECOMMENDATION  
9 FOR THIS PROJECT IS A SCORE OF 1 WITH 12 MEMBERS  
10 GIVING IT A SCORE OF 1. THERE WAS ONE MEMBER WHO  
11 GAVE IT A SCORE OF 2. NOBODY GAVE IT A SCORE OF 3.  
12 THE DEI SCORE WAS A VERY HIGH SCORE OF 10. AND CIRM  
13 TEAM RECOMMENDATION IS TO FUND THIS PROJECT FOR THE  
14 AWARD AMOUNT OF 11.3 MILLION.

15 CHAIRMAN IMBASCIANI: THANK YOU, GIL.  
16 GREAT PRESENTATION. LOOKS LIKE A GREAT APPLICATION.  
17 OPEN NOW TO -- I NEED A MOTION AND A SECOND TO --

18 MR. BERNAL: SO MOVED.

19 DR. FISHER: SECOND.

20 CHAIRMAN IMBASCIANI: THANK YOU, DAN. WHO  
21 SECONDED?

22 DR. FISHER: FRED FISHER.

23 CHAIRMAN IMBASCIANI: FRED FISHER. GREAT.  
24 THANK YOU.

25 SO, BOARD MEMBERS, COMMENTS?



**BETH C. DRAIN, CA CSR NO. 7152**

1 MS. DEQUINA-VILLABLANCA: THERE ARE NONE  
2 CURRENTLY.

3 CHAIRMAN IMBASCIANI: THERE ARE NONE.  
4 THIS INVESTIGATOR MUST HAVE -- MUST GO BACK VERY FAR  
5 IN TIME TO HAVE THAT MUCH EXPERIENCE WITH CIRM. A  
6 GREAT TRACK RECORD.

7 SO NO COMMENTS FROM THE BOARD MEMBERS. IS  
8 THERE ANYONE RESPONDING FROM THE PUBLIC, MARIANNE?

9 MS. DEQUINA-VILLABLANCA: CHECKING. AND  
10 FOR PUBLIC, IF YOU DO HAVE A COMMENT, STAR NINE.  
11 AND I DON'T SEE ANY.

12 CHAIRMAN IMBASCIANI: OKAY. WE CAN  
13 PROCEED TO A VOTE ON THE APPLICATION NO. 14748.  
14 SCOTT, CAN YOU TAKE THE ROLL.

15 MR. TOCHER: SURE.

16 DAN BERNAL.

17 MR. BERNAL: AYE.

18 MR. TOCHER: LEONDRA CLARK-HARVEY. MARK  
19 FISCHER-COLBRIE.

20 DR. FISCHER-COLBRIE: YES.

21 MR. TOCHER: FRED FISHER.

22 DR. FISHER: AYE.

23 MR. TOCHER: ELENA FLOWERS.

24 DR. FLOWERS: YES.

25 MR. TOCHER: DAVID HIGGINS.

**BETH C. DRAIN, CA CSR NO. 7152**

1 DR. HIGGINS: YES.  
2 MR. TOCHER: VITO IMBASCIANI.  
3 CHAIRMAN IMBASCIANI: YES.  
4 MR. TOCHER: RICH LAJARA.  
5 MR. LAJARA: YES.  
6 MR. TOCHER: CHRISTINE MIASKOWSKI.  
7 DR. MIASKOWSKI: YES.  
8 MR. TOCHER: LAUREN MILLER-ROGEN.  
9 MS. MILLER-ROGEN: YES.  
10 MR. TOCHER: ADRIANA PADILLA.  
11 DR. PADILLA: YES.  
12 MR. TOCHER: MARVIN SOUTHARD.  
13 DR. SOUTHARD: YES.  
14 MR. TOCHER: KAROL WATSON.  
15 DR. WATSON: YES.  
16 MR. TOCHER: THANK YOU. AND I'LL CALL  
17 LEONDRA CLARK-HARVEY. JUST A MINUTE. I'M JUST  
18 DOING A LITTLE MATH. GREAT. THAT'S 12 AYES AND NO  
19 NOS. SO THE MOTION CARRIES.  
20 CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH,  
21 SCOTT.  
22 GIL, WE CAN NOW PROCEED TO THE THIRD OF  
23 THE SIX APPLICATIONS.  
24 DR. SAMBRANO: HAYLEY WILL PRESENT THIS  
25 NEXT ONE.

**BETH C. DRAIN, CA CSR NO. 7152**

1 DR. LAM: GOOD MORNING. SO THIS  
2 APPLICATION FOR DISCUSSION IS CLIN2-14787. AND THE  
3 TITLE OF THIS PROJECT IS "A PHASE 2B, RANDOMIZED,  
4 ASSESSOR-MASKED CLINICAL TRIAL TO ASSESS THE SAFETY  
5 AND EFFICACY OF A RETINAL PIGMENTED EPITHELIAL  
6 IMPLANT IN SUBJECTS WITH GEOGRAPHIC ATROPHY." AND  
7 THE PRODUCT ITSELF IS A PATCH WITH A LAYER OF STEM  
8 CELL-DERIVED RETINAL PIGMENTED EPITHELIAL CELLS ON A  
9 MATRIX. AND THE INDICATION THIS PRODUCT IS AIMING  
10 TO TREAT IS GEOGRAPHIC ATROPHY WHICH IS A LATE-STAGE  
11 FORM OF AGE-RELATED MACULAR DEGENERATION, AMD.

12 THE GOAL OF THIS PROJECT IS THE COMPLETION  
13 OF A PHASE 2B CLINICAL TRIAL. FUNDS REQUESTED ARE  
14 12.37 MILLION, AND CO-FUNDING IS PROVIDED OF 8.25  
15 MILLION, AND 40-PERCENT CO-FUNDING IS REQUIRED FOR  
16 THIS CATEGORY OF TRIAL AND APPLICANT.

17 SO A LITTLE BIT OF BACKGROUND INFORMATION  
18 ON AMD. SO IT'S A LEADING CAUSE OF VISION LOSS IN  
19 THE DEVELOPED WORLD. AS MENTIONED BEFORE, THE  
20 GEOGRAPHIC ATROPHY IS A LATE-STAGE FORM OF AMD, DRY  
21 AMD, WHERE THE SUPPORTIVE CELLS, THESE ARE RETINAL  
22 PIGMENTED EPITHELIAL CELLS, DEGENERATE OVER TIME.  
23 AND THIS DEGENERATION OF THESE CELLS OVER TIME  
24 CONTRIBUTES TO THE DEATH OF THE PHOTORECEPTORS THAT  
25 THEY SUPPORT WITHIN THE RETINA AND THEN LEADS TO

**BETH C. DRAIN, CA CSR NO. 7152**

1 VISUAL IMPAIRMENT AND SOMETIMES BLINDNESS IN THE  
2 LATE STAGES OF DISEASE.

3 SO THE PROPOSED THERAPY HERE WOULD BE  
4 POTENTIALLY A SCALABLE APPROACH TO REPLACE THE  
5 DISEASED PORTION OF THE EYE THAT IS DAMAGED AND  
6 PROMOTE SURVIVAL AND FUNCTION OF THE SUPPORTIVE RPE  
7 CELLS AND, THUS, PROTECT THE EYE FROM DISEASE  
8 PROGRESSION AND VISION LOSS, AND IN SOME CASES  
9 POTENTIALLY, IN FACT, IMPROVING VISION WITH THIS  
10 TREATMENT. SO THIS PROJECT IS A COMBINATION THERAPY  
11 WITH SUPPORTIVE MATRIX THAT ALSO CONTAINS STEM  
12 CELL-DERIVED RPE.

13 CURRENT CIRM PORTFOLIO PROJECTS THAT ARE  
14 ACTIVE, THERE'S ONE TRANSLATIONAL STAGE. THIS IS  
15 PRECLINICAL. AND ANOTHER THAT IS A CLIN1  
16 PRECLINICAL STAGE. AND BOTH ARE SLIGHTLY EARLIER  
17 STAGE THAN THIS ONE, WHICH WOULD BE A CLINICAL  
18 TRIAL.

19 PRIOR APPLICANT FUNDING FROM CIRM IS  
20 RELATED TO SOME OF THE KEY PERSONNEL THAT ARE ALSO  
21 ON THIS PROJECT WHO HAVE RECEIVED FUNDING FOR THE  
22 DEVELOPMENT OF THIS PROJECT ESSENTIALLY THROUGH TWO  
23 DISEASE TEAM AWARDS FOR THE EARLIER STAGE  
24 IND-ENABLING AND PHASE 1 STUDY OF THE SAME PRODUCT.

25 FINALLY, THE GWG RECOMMENDATION FOR THIS

**BETH C. DRAIN, CA CSR NO. 7152**

1 APPLICATION IS TO RECOMMEND FOR FUNDING WITH NINE  
2 VOTES AS A SCORE OF 1, FIVE VOTES AS A SCORE OF 2,  
3 AND NO VOTES FOR A SCORE OF 3, AND THE DEI SCORE OF  
4 9.5. THE CIRM TEAM CONCURS WITH THIS RECOMMENDATION  
5 AND FOR THE SAME AWARD MENTIONED EARLIER, 12.4  
6 MILLION.

7 CHAIRMAN IMBASCIANI: THANKS, VERY MUCH  
8 FOR THE PRESENTATION. MAY I HAVE A MOTION, PLEASE,  
9 FROM THE BOARD TO COMMENCE DISCUSSION?

10 DR. SOUTHARD: SO MOVED.

11 CHAIRMAN IMBASCIANI: MARVIN MOVES.

12 MR. JUELSGAARD: SECOND.

13 DR. FISCHER-COLBRIE: SECOND.

14 CHAIRMAN IMBASCIANI: THANK YOU, MARK, FOR  
15 THE SECOND.

16 SO COMMENTS FROM THE BOARD ON THIS  
17 PROPOSAL 14787?

18 MS. DEQUINA-VILLABLANCA: THERE ARE NO  
19 HANDS RAISED.

20 CHAIRMAN IMBASCIANI: NO HANDS ARE RAISED.  
21 WE ARE ALL STUNNED BY THE BRILLIANCE OF THE  
22 SCIENTIFIC COMMUNITY.

23 ANYONE FROM THE PUBLIC CARE TO COMMENT?

24 MS. DEQUINA-VILLABLANCA: VITO, ADRIANA  
25 RAISED HER HAND.

**BETH C. DRAIN, CA CSR NO. 7152**

1 DR. PADILLA: I JUST WANTED TO ASK THE  
2 TEAM, CAN THEY DISCUSS WHY THERE WAS FIVE ON A SCORE  
3 OF 2 JUST FOR OUR REVIEW?

4 DR. LAM: I CAN BRIEFLY MENTION THAT THERE  
5 WERE SOME QUESTIONS MAINLY AROUND -- SO THERE WAS  
6 MAYBE TWO THINGS. ONE WAS THAT THE TECHNIQUE FOR  
7 THE IMPLANTATION ITSELF, THEY THOUGHT, MIGHT BE  
8 CHALLENGING. SO THERE WAS SOME CONCERNS THAT MAYBE  
9 THERE WOULD BE SOME VARIABILITY ACROSS THE DIFFERENT  
10 TRIAL SITES. I DON'T THINK ANY OF THESE CONCERNS  
11 WERE SORT OF MAJOR CONCERNS, BUT THINGS THAT WERE  
12 BROUGHT UP BY THE REVIEWERS.

13 AND THEN THE OTHER CONCERN BY ONE OF THE  
14 PANEL MEMBERS WAS REGARDING THE PLACEBO GROUP, WHICH  
15 IT WASN'T CLEAR FROM THE STATISTICS THAT WERE  
16 PROPOSED BY THE GROUP ON HOW THE PLACEBO GROUP WOULD  
17 BE INTEGRATED INTO THE ANALYSIS OF THE TOTAL  
18 PATIENTS OR PEOPLE, PARTICIPANTS, WITHIN THE TRIAL  
19 ITSELF AND HOW THAT WOULD FEED INTO POTENTIALLY A  
20 PHASE 3 TRIAL.

21 SO I DON'T THINK THERE WERE ANY CONCERNS  
22 THAT NECESSARILY COULDN'T BE ADJUSTED IF THERE  
23 WERE -- IF IT CAME BACK AS A TIER II.

24 DR. SAMBRANO: I THINK ONE OTHER THING TO  
25 ADD IS TO REMEMBER THAT THE SCORE OF 2, TYPICALLY

**BETH C. DRAIN, CA CSR NO. 7152**

1 REVIEWERS GIVE A SCORE OF 2 WHERE THEY WANT  
2 CLARIFICATION OR ADDITIONAL INFORMATION. SO IT  
3 DOESN'T NECESSARILY INDICATE THAT THEY WOULD NOT  
4 WANT THE PROJECT FUNDED; BUT, RATHER, THAT THEY'RE  
5 LOOKING FOR ADDITIONAL INFORMATION TYPICALLY.

6 DR. PADILLA: WAS THAT GIVEN TO THE  
7 REVIEWERS?

8 DR. SAMBRANO: NO. I THINK REVIEWERS WILL  
9 TYPICALLY COME DOWN ON SCORING BETWEEN A 1 OR A 2.  
10 SO IF THEY SCORE A 2, THEY WILL PROVIDE COMMENTS  
11 WHERE THEY FEEL THEY WOULD HAVE LIKED ADDITIONAL  
12 INFORMATION OR CLARIFICATION, SO TO POINTS THAT  
13 HAYLEY RAISED. BUT THE MAJORITY FELT THAT THE  
14 PROJECT WAS FINE AS IT IS, THAT IT DIDN'T NEED TO  
15 COME BACK TO THE GRANTS WORKING GROUP.

16 SO WHEN QUESTIONS MAY BE LEFT OPEN LIKE  
17 THAT IN TERMS OF HAVING SOME OF THE GRANTS WORKING  
18 GROUP MEMBERS HAVING A QUESTION, WE USUALLY WILL  
19 FOLLOW UP WITH THEM.

20 DR. PADILLA: THAT'S WHAT I WANTED TO  
21 KNOW.

22 DR. SAMBRANO: SO WE WILL FOLLOW UP AS  
23 PART OF THE PROCESS PRIOR TO FUNDING TO MAKE SURE AT  
24 LEAST THOSE ARE POINTS THAT ARE CONSIDERED.

25 DR. PADILLA: PERFECT. THANK YOU.

**BETH C. DRAIN, CA CSR NO. 7152**

1           CHAIRMAN IMBASCIANI: ANY OTHER COMMENTS  
2 FROM THE BOARD MEMBERS? IF NOT, MARIANNE, JUST TAKE  
3 A LOOK FOR THE PUBLIC COMMENT.

4           MS. DEQUINA-VILLABLANCA: VITO, WE DO HAVE  
5 ONE IN THE ROOM. YOU HAVE THREE MINUTES FOR YOUR  
6 COMMENT.

7           DR. LEBKOWSKI: YES. THIS IS JANE  
8 LEBKOWSKI. I'M ACTUALLY THE PI AND APPLICANT ON  
9 THIS APPLICATION. JUST WANTED TO CLARIFY A COUPLE  
10 OF QUESTIONS THAT WERE BROUGHT UP ABOUT THE  
11 DIFFICULTY OF THE SURGERY. IN THE PHASE 1/2A  
12 CLINICAL TRIAL, WE SUCCESSFULLY IMPLANTED 15  
13 DIFFERENT PATIENTS. AND NOW WE ARE LOOKING IN THIS  
14 NEXT CLINICAL TRIAL, ONE OF THE MAJOR OBJECTIVES OF  
15 THE TRIAL GOING FORWARD IS TO LOOK AT HAVING MORE  
16 SURGEONS IMPLANT TO ESTABLISH THAT, IN FACT, THIS  
17 PROCEDURE CAN, IN FACT, BE ESTABLISHED ACROSS A WIDE  
18 GROUP OF RETINAL SURGEONS. WE DON'T BELIEVE THAT  
19 THAT WILL HAVE A -- THERE WILL BE A PROBLEM, BUT  
20 THAT IS PART OF THE OBJECTIVE OF THIS PARTICULAR  
21 GRANT.

22           THE SECOND QUESTION WAS ABOUT THE PLACEBO  
23 GROUP. WE ARE SORRY, ONE OF THE -- IT APPEARS THAT  
24 MAYBE ONE OF THE REVIEWERS HAD A -- DIDN'T  
25 UNDERSTAND THE ROLE OF THE PLACEBO GROUP. BUT WE



**BETH C. DRAIN, CA CSR NO. 7152**

1 ARE GOING TO COMPARE BOTH THE SAFETY AND EFFICACY,  
2 COMPARE THE RESULTS FROM THE TREATMENT GROUP VERSUS  
3 THE PLACEBO GROUP.

4 I THINK ONE OTHER QUESTION THAT WAS  
5 BROUGHT UP DURING THE REVIEW WAS WHAT IS THE ROLE OF  
6 A NATURAL HISTORY GROUP. WE ARE GOING TO IN THIS  
7 PROGRAM LOOK AT ALSO COMPARING THE DATA FROM A VERY  
8 BROAD RANGE OF CLINICAL TRIALS WHERE THE NATURAL  
9 HISTORY OR SHAM CONTROLLED GROUPS IN OTHER PEOPLE'S  
10 CLINICAL TRIALS. WE WILL ALSO COMPARE DATA FROM OUR  
11 TRIAL TO THOSE OF CONTROL GROUPS IN OTHER CLINICAL  
12 STUDIES.

13 MS. DEQUINA-VILLABLANCA: THANK YOU.

14 CHAIRMAN IMBASCIANI: THANK YOU,  
15 PROFESSOR, FOR YOUR EXPLANATORY COMMENTS.

16 ARE THERE ANY OTHER COMMENTS FROM THE  
17 PUBLIC?

18 MS. DEQUINA-VILLABLANCA: AND A REMINDER,  
19 STAR NINE IF YOU DO WANT TO BE PLACED IN THE QUEUE.  
20 AND I SEE NONE, VITO.

21 CHAIRMAN IMBASCIANI: OKAY. THANK YOU  
22 VERY MUCH, EVERYONE, FOR YOUR COMMENTS.

23 DISCUSSION IS CLOSED. SCOTT, WE CAN  
24 PROCEED TO A ROLL CALL VOTE ON THIS APPLICATION.

25 MR. TOCHER: AGAIN, JUST TO RESTATE, THE

**BETH C. DRAIN, CA CSR NO. 7152**

1 MOTION IS TO FUND APPLICATION 14787.  
2 DAN BERNAL.  
3 MR. BERNAL: AYE.  
4 MR. TOCHER: LEONDRA CLARK-HARVEY.  
5 ANNE-MARIE DULIEGE. MARK FISCHER-COLBRIE.  
6 DR. FISCHER-COLBRIE: AYE.  
7 MR. TOCHER: FRED FISHER.  
8 DR. FISHER: AYE.  
9 MR. TOCHER: ELENA FLOWERS.  
10 DR. FLOWERS: YES.  
11 MR. TOCHER: DAVID HIGGINS.  
12 DR. HIGGINS: YES.  
13 MR. TOCHER: VITO IMBASCIANI.  
14 CHAIRMAN IMBASCIANI: YES.  
15 MR. TOCHER: STEVE JUELSGAARD.  
16 MR. JUELSGAARD: YES.  
17 MR. TOCHER: RICH LAJARA.  
18 MR. LAJARA: YES.  
19 MR. TOCHER: CHRISTINE MIASKOWSKI.  
20 DR. MIASKOWSKI: YES.  
21 MR. TOCHER: LAUREN MILLER-ROGEN.  
22 MS. MILLER-ROGEN: YES.  
23 MR. TOCHER: ADRIANA PADILLA.  
24 DR. PADILLA: YES.  
25 MR. TOCHER: MARVIN SOUTHARD.

**BETH C. DRAIN, CA CSR NO. 7152**

1 DR. SOUTHARD: YES.

2 MR. TOCHER: KAROL WATSON.

3 DR. WATSON: YES.

4 MR. TOCHER: MARIA BONNEVILLE.

5 VICE CHAIR BONNEVILLE: YES.

6 MR. TOCHER: THAT WORKED. THANK YOU,  
7 MARIA.

8 AND THE MOTION CARRIES 14 TO 0.

9 CHAIRMAN IMBASCIANI: WONDERFUL. GREAT.  
10 SO GIL'S TEAM, WHOEVER IS GOING TO PRESENT THE NEXT  
11 ONE, THE FOURTH APPLICATION.

12 DR. LAM: THAT WILL BE ME. SO THE NEXT  
13 APPLICATION IS CLIN2-15087. TITLE OF THIS  
14 APPLICATION IS "PHASE 1 STUDY OF CHIMERIC ANTIGEN  
15 RECEPTOR ENGINEERED T-CELLS TARGETING CD33 FOR THE  
16 TREATMENT OF RELAPSED REFRACTORY ACUTE MYELOID  
17 LEUKEMIA."

18 THIS TREATMENT IS IMMUNE T-CELLS FROM A  
19 PATIENT'S TRANSPLANT DONOR ENGINEERED FOR TARGETED  
20 LEUKEMIA KILLING. THE INDICATION IS RELAPSED  
21 REFRACTORY AML. THE GOAL IS COMPLETION OF A PHASE 1  
22 CLINICAL TRIAL. AND THEY ARE REQUESTING JUST UNDER  
23 12 MILLION WITH NO CO-FUNDING REQUIRED FOR THIS  
24 APPLICATION.

25 SOME BACKGROUND INFORMATION, THE CLINICAL

**BETH C. DRAIN, CA CSR NO. 7152**

1 BACKGROUND. SO RELAPSED REFRACTORY AML IS A TYPE OF  
2 LEUKEMIA THAT'S EITHER RETURNED AFTER PRIOR  
3 TREATMENT OR HASN'T RESPONDED TO PRIOR TREATMENT.  
4 AND AVAILABLE TREATMENTS RIGHT NOW ARE NOT VERY  
5 EFFECTIVE, AND THIS TYPE OF LEUKEMIA IS KNOWN TO  
6 HAVE POOR OUTCOMES. SO THE PROPOSED THERAPY, GIVEN  
7 THE THERAPY OPTIONS ARE LIMITED, NEW OPTIONS FOR  
8 PATIENTS ARE NEEDED. AND THE PROPOSED THERAPY USES  
9 A TARGETED APPROACH TO KILL THE CANCER CELLS AND  
10 HOPEFULLY LEAD TO IMPROVED OUTCOMES FOR PATIENTS.  
11 THIS IS A GENE-MODIFIED CELL THERAPY.

12 AND SIMILAR CIRM PORTFOLIO PROJECTS THAT  
13 ARE ACTIVE RIGHT NOW, THERE IS CURRENTLY A CLIN2  
14 PHASE 1 TRIAL USING A MONOCLONAL ANTIBODY. AND  
15 THERE'S A CLIN1 IND PRECLINICAL PROJECT THAT IS A  
16 VACCINE CANDIDATE. AND THIS PARTICULAR APPLICANT  
17 TEAM HAS NOT RECEIVED PRIOR CIRM FUNDING.

18 SO THE RECOMMENDATION FROM THE GRANTS  
19 WORKING GROUP IS TO RECOMMEND FUNDING WITH 13 VOTES  
20 IN THE SCIENTIFIC SCORE OF 1, TWO VOTES IN  
21 SCIENTIFIC SCORE OF 2, AND NO VOTES FOR SCORE OF 3.  
22 THE DEI SCORE RECEIVED BY THIS TEAM WAS A 10. AND  
23 THE CIRM TEAM CONCURS WITH THE RECOMMENDATION TO  
24 FUND THIS APPLICATION FOR JUST UNDER 12 MILLION.

25 CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH

**BETH C. DRAIN, CA CSR NO. 7152**

1 FOR THE PRESENTATION AND THE RECOMMENDATION. MAY I  
2 ENTERTAIN A MOTION TO DISCUSS?

3 DR. SOUTHARD: MOVED.

4 CHAIRMAN IMBASCIANI: THANK YOU, MARVIN.

5 DR. MIASKOWSKI: SECOND.

6 CHAIRMAN IMBASCIANI: DID YOU GET THAT,  
7 MARIANNE?

8 MR. TOCHER: WHO WAS THE SECOND?

9 DR. MIASKOWSKI: CHRIS.

10 CHAIRMAN IMBASCIANI: I COULDN'T TELL.  
11 THANK YOU. OKAY.

12 THE FLOOR IS OPEN FOR DISCUSSION FROM  
13 BOARD MEMBERS.

14 MS. DEQUINA-VILLABLANCA: NO HANDS ARE  
15 RAISED, VITO.

16 CHAIRMAN IMBASCIANI: OKAY. ARE YOU  
17 SCANNING FOR PUBLIC COMMENT?

18 MS. DEQUINA-VILLABLANCA: I AM. REMINDER  
19 FOR PUBLIC COMMENT STAR NINE. I DON'T CURRENTLY SEE  
20 ANY.

21 CHAIRMAN IMBASCIANI: OKAY. IF THERE'S  
22 ANY MEMBER OF THE PUBLIC OUT THERE WHO'S STRUGGLED  
23 WITH MAKING A COMMENT, WE CAN ALWAYS COME BACK AT  
24 THE END OF THE MEETING. NO. I GUESS WE CAN'T AFTER  
25 THE VOTE IS HELD. SORRY. LET'S PROCEED TO A ROLL

**BETH C. DRAIN, CA CSR NO. 7152**

1 CALL VOTE, SCOTT.

2 MR. TOCHER: AND TO RESTATE THE MOTION,  
3 IT'S TO FUND APPLICATION 15087.

4 DAN BERNAL.

5 MR. BERNAL: AYE.

6 MR. TOCHER: MARIA BONNEVILLE.

7 VICE CHAIR BONNEVILLE: YES.

8 MR. TOCHER: MARK FISCHER-COLBRIE.

9 DR. FISCHER-COLBRIE: YES.

10 MR. TOCHER: FRED FISHER.

11 DR. FISHER: YES.

12 MR. TOCHER: ELENA FLOWERS.

13 DR. FLOWERS: YES.

14 MR. TOCHER: DAVID HIGGINS. DAVID, I'M  
15 NOT HEARING YOU. ARE YOU MUTED? HE'S LOOKING FOR  
16 IT, I THINK.

17 CHAIRMAN IMBASCIANI: DAVID, YOU'RE STILL  
18 MUTED.

19 MR. TOCHER: HE'S LOOKING FOR IT. I'LL  
20 COME BACK.

21 VITO IMBASCIANI.

22 CHAIRMAN IMBASCIANI: YES.

23 MR. TOCHER: STEVE JUELSGAARD.

24 MR. JUELSGAARD: YES.

25 MR. TOCHER: RICH LAJARA.

**BETH C. DRAIN, CA CSR NO. 7152**

1 MR. LAJARA: YES.  
2 MR. TOCHER: CHRISTINE MIASKOWSKI.  
3 DR. MIASKOWSKI: YES.  
4 MR. TOCHER: LAUREN MILLER-ROGEN.  
5 MS. MILLER-ROGEN: YES.  
6 MR. TOCHER: ADRIANA PADILLA.  
7 DR. PADILLA: YES.  
8 MR. TOCHER: MARVIN SOUTHARD.  
9 DR. SOUTHARD: YES.  
10 MR. TOCHER: KAROL WATSON.  
11 DR. WATSON: YES.  
12 MR. TOCHER: AND DAVID HIGGINS.  
13 DR. HIGGINS: YES.  
14 MR. TOCHER: VERY GOOD. THANK YOU, DAVID.  
15 AND THE MOTION CARRIES 14 TO 0.  
16 CHAIRMAN IMBASCIANI: OKAY. THANK YOU  
17 VERY MUCH.  
18 SO, GIL, I'M GOING TO TURN IT OVER AGAIN  
19 NOW FOR THE FIFTH APPLICATION FOR CONSIDERATION.  
20 DR. SAMBRANO: OKAY. FOR THIS NEXT  
21 APPLICATION, JUST TO NOTE, MARK FISCHER-COLBRIE IS  
22 RECUSED.  
23 THE APPLICATION IS CLIN1-14607. THE TITLE  
24 IS "CANCER STEM CELL INTERCEPTION WITH A SMALL  
25 MOLECULE SPLICING INHIBITOR." THIS THERAPY IS A

**BETH C. DRAIN, CA CSR NO. 7152**

1 SMALL MOLECULE DRUG OF SPLICING THAT SELECTIVELY  
2 ERADICATES THERAPY-RESISTANT CANCER STEM CELLS.

3 THE INDICATION THAT IS SOUGHT HERE IS TO  
4 TREAT SECONDARY ACUTE MYELOID LEUKEMIA OR SAML OR  
5 HIGH-RISK MYELOFIBROSIS. THE GOAL IS TO COMPLETE  
6 IND-ENABLING STUDIES AND FILE AN IND WITH THE FDA  
7 THAT WILL ALLOW THEM TO BEGIN A CLINICAL TRIAL.  
8 FUNDS REQUESTED ARE 3.2 MILLION. CO-FUNDING IS  
9 800,000, WHICH IS 20 PERCENT, THAT'S REQUIRED UNDER  
10 THIS PROJECT.

11 BACKGROUND ON SECONDARY ACUTE MYELOID  
12 LEUKEMIA, THIS IS A CANCER THAT CAN DEVELOP FROM  
13 PRE-EXISTING HIGH-RISK MYELOFIBROSIS, WHICH ITSELF  
14 IS A BLOOD CANCER THAT DISRUPTS THE BODY'S NORMAL  
15 PRODUCTION OF BLOOD CELLS. THE FIVE-YEAR SURVIVAL  
16 RATE FOR PATIENTS WITH SECONDARY AML IS ONLY 26  
17 PERCENT. AND STANDARD OF CARE THERAPIES ARE  
18 GENERALLY NOT CURATIVE AND CAN RESULT IN SIGNIFICANT  
19 MORBIDITY.

20 A KEY FACTOR FOR THE SEVERITY AND  
21 RECURRENCE OF MANY OF THESE CANCERS AND OTHER BLOOD  
22 CANCERS AS WELL IS THE PERSISTENCE OF CANCER STEM  
23 CELLS OF THE TUMOR. SO IN TERMS OF THE VALUE  
24 PROPOSITION, THIS PROPOSED THERAPY BLOCKS A KEY  
25 RNA-MODIFYING ENZYME THAT TENDS TO PROMOTE CANCER



**BETH C. DRAIN, CA CSR NO. 7152**

1 STEM CELL PERSISTENCE. AS A SMALL MOLECULE DRUG,  
2 THE APPROACH, IF SUCCESSFUL, COULD PROVIDE A VERY  
3 PRACTICAL AND FEASIBLE OPTION FOR PATIENTS WITH THIS  
4 DISEASE.

5 WHY IS THIS A STEM CELL OR GENE THERAPY?  
6 THE CANDIDATE IS A SMALL MOLECULE THAT ACTS ON  
7 CANCER STEM CELLS.

8 IN TERMS OF OTHER PROJECTS IN OUR  
9 PORTFOLIO OF ACTIVE PROGRAMS, WE HAVE A CLIN2 THAT'S  
10 ADDRESSING AML AND CMML, IT'S A MONOCLONAL ANTIBODY,  
11 AND CLIN1 THAT'S A VACCINE FOR AML. THESE ARE THE  
12 SAME PROJECTS THAT HAYLEY MENTIONED REGARDING THE  
13 OTHER AML PROJECT.

14 IN TERMS OF PREVIOUS CIRM FUNDING FOR THE  
15 APPLICANT TEAM, WE HAVE ANOTHER PERSON WHO HAS ALSO  
16 HAD A LONG HISTORY OF CIRM FUNDING AND MIGHT EVEN  
17 OUTDO THE PREVIOUS ONE WITH THREE PROJECTS THAT ARE  
18 NOT ON THIS SLIDE. IN ALL CASES THESE PROJECTS,  
19 WHICH HAVE VARIED FROM INFRASTRUCTURE PROGRAMS, SUCH  
20 AS THE ALPHA CLINICS, TRANSLATIONAL DISEASE TEAM,  
21 AND EARLY STAGE CANDIDATE DISCOVERY, HAVE BEEN ALL  
22 COMPLETED ON TIME WITH FEW, IF ANY, DELAYS IN THE  
23 PROJECT. SO THEY HAVE A VERY GOOD TRACK RECORD WITH  
24 PREVIOUS CIRM FUNDING.

25 THE GRANTS WORKING GROUP RECOMMENDATION

**BETH C. DRAIN, CA CSR NO. 7152**

1 FOR THIS PROJECT IS TO FUND WITH A SCORE OF 1, AND  
2 IT RECEIVED A UNANIMOUS SCORE BY 15 MEMBERS. THERE  
3 WERE NO SCORES THAT WERE A 2 OR A 3. THE DEI SCORE  
4 IS A SCORE OF 9. AND CIRM TEAM RECOMMENDS TO FUND  
5 IN CONCURRENCE WITH THE GRANTS WORKING GROUP  
6 RECOMMENDATION FOR THE AMOUNT OF 3.2 MILLION. DR.  
7 IMBASCIANI.

8 CHAIRMAN IMBASCIANI: YES. THANK YOU,  
9 GIL. I'M GOING TO OPEN THE FLOOR TO A MOTION TO  
10 CONSIDER DISCUSSION OF 14607.

11 DR. FISHER: SO MOVED.

12 CHAIRMAN IMBASCIANI: THANK YOU, FRED.

13 DR. DULIEGE: I'M HAPPY TO SECOND.

14 CHAIRMAN IMBASCIANI: THANK YOU,  
15 ANNE-MARIE.

16 DR. DULIEGE: HELLO TO EVERYBODY, BY THE  
17 WAY.

18 CHAIRMAN IMBASCIANI: OKAY. THE FLOOR IS  
19 OPEN TO DISCUSSION. WAS THERE A HAND, ANNE-MARIE?

20 DR. DULIEGE: NO.

21 MS. DEQUINA-VILLABLANCA: NO HANDS RAISED.

22 CHAIRMAN IMBASCIANI: MARIANNE. I HAD IT  
23 BACKWARDS.

24 MS. DEQUINA-VILLABLANCA: NO HANDS RAISED.

25 CHAIRMAN IMBASCIANI: NO HANDS ARE RAISED.

**BETH C. DRAIN, CA CSR NO. 7152**

1 ANY COMMENTS FROM THE PUBLIC?

2 MS. DEQUINA-VILLABLANCA: STAR NINE FROM  
3 THE PUBLIC IF YOU WANT TO MAKE A COMMENT. I DON'T  
4 SEE ANY.

5 CHAIRMAN IMBASCIANI: OKAY. THAT BEING  
6 THE CASE, SCOTT, WE CAN PROCEED TO A ROLL CALL VOTE  
7 ON CLIN1-14607.

8 MR. TOCHER: AND THE MOTION IS TO FUND  
9 14607.

10 DAN BERNAL.

11 MR. BERNAL: AYE.

12 MR. TOCHER: MARIA BONNEVILLE.

13 VICE CHAIR BONNEVILLE: YES.

14 MR. TOCHER: FRED FISHER.

15 DR. FISHER: YES.

16 MR. TOCHER: ELENA FLOWERS.

17 DR. FLOWERS: YES.

18 MR. TOCHER: DAVID HIGGINS.

19 DR. HIGGINS: YES.

20 MR. TOCHER: VITO IMBASCIANI.

21 CHAIRMAN IMBASCIANI: YES.

22 MR. TOCHER: STEVE JUELSGAARD.

23 MR. JUELSGAARD: YES.

24 MR. TOCHER: RICH LAJARA.

25 MR. LAJARA: YES.

**BETH C. DRAIN, CA CSR NO. 7152**

1 MR. TOCHER: CHRISTINE MIASKOWSKI.  
2 DR. MIASKOWSKI: YES.  
3 MR. TOCHER: LAUREN MILLER-ROGEN.  
4 MS. MILLER-ROGEN: YES.  
5 MR. TOCHER: ADRIANA PADILLA.  
6 DR. PADILLA: YES.  
7 MR. TOCHER: MARVIN SOUTHARD.  
8 DR. SOUTHARD: YES.  
9 MR. TOCHER: KAROL WATSON.  
10 DR. WATSON: YES.  
11 MR. TOCHER: ANNE-MARIE DULIEGE.  
12 DR. DULIEGE: YES.  
13 MR. TOCHER: GREAT. THE MOTION CARRIES 14  
14 TO 0.  
15 CHAIRMAN IMBASCIANI: MOTION CARRIES.  
16 THANK YOU VERY MUCH. OKAY.  
17 GIL OR HAYLEY, I DON'T KNOW WHO'S GOT THE  
18 LAST PRESENTATION.  
19 DR. LAM: JUST A NOTE, THAT THERE'S A  
20 CONFLICT WITH ONE MEMBER OF THE ARS, FRED FISHER.  
21 AND TO MOVE ON TO THE APPLICATION ITSELF, I BELIEVE  
22 THIS IS THE LAST ONE. SO CLIN1-14933, THE TITLE OF  
23 THIS APPLICATION IS "MANUFACTURING OF AN ANTISENSE  
24 OLIGONUCLEOTIDES FOR A PHASE 1/2 CLINICAL TRIAL FOR  
25 AMYOTROPHIC LATERAL SCLEROSIS." AND THE THERAPY IS

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1 AN ANTISENSE OLIGONUCLEOTIDE, AND THE INDICATION IS  
2 ALS. AND THE GOAL OF THIS IS TO COMPLETE THE  
3 MANUFACTURING ACTIVITIES AND FILE AN IND WITH THE  
4 FDA. FUNDS REQUESTED ARE JUST UNDER 2.2 MILLION AND  
5 WITH A 20-PERCENT CO-FUNDING THAT'S REQUIRED OF JUST  
6 OVER HALF A MILLION, AND THE MAXIMUM FUNDS FOR THIS  
7 CATEGORY IS 4 MILLION.

8 SO A LITTLE BIT OF BACKGROUND INFORMATION.  
9 ALS IS A NEURODEGENERATIVE DISEASE AND RESULTS IN  
10 THE DEATH OF NERVE CELLS IN THE BRAIN AND SPINAL  
11 CORD, CAUSING THE MUSCLES IN THE BODY TO GRADUALLY  
12 WEAKEN AND EVENTUALLY LEADING TO THE LOSS OF LIMB  
13 FUNCTION, DIFFICULTY BREATHING, PARALYSIS, AND  
14 EVENTUALLY DEATH. SO THERE ARE MEDICATIONS  
15 CURRENTLY THAT CAN SLOW DOWN THE PROGRESSION, BUT NO  
16 CURE FOR THIS DISEASE. PROPOSED PRODUCT WOULD OFFER  
17 AN OPPORTUNITY TO TREAT ALS PATIENTS WITH VARIOUS  
18 CAUSES, UNDERLYING CAUSES, AND POTENTIALLY HAVE A  
19 GREATER IMPACT ON PATIENT QUALITY OF LIFE THAN THE  
20 CURRENT STANDARD OF CARE. AND THE THERAPEUTIC  
21 CANDIDATE IS A GENE THERAPY.

22 SO CURRENT CIRM PORTFOLIO PROJECTS, THERE  
23 IS A CLIN2 PHASE 1 CLINICAL TRIAL RUNNING RIGHT NOW  
24 FOR THE SAME INDICATION. AND THIS IS A DIFFERENT  
25 APPROACH WITH GENETICALLY ENGINEERED STEM CELLS.

**BETH C. DRAIN, CA CSR NO. 7152**

1 THE APPLICANT DOES NOT HAVE PRIOR CIRM FUNDING.  
2 AND, FINALLY, THE SCIENTIFIC RECOMMENDATION FROM THE  
3 GRANTS WORKING GROUP WAS A RECOMMENDATION TO FUND  
4 WITH 13 VOTES FOR TIER I, ONE VOTE FOR TIER II, AND  
5 NONE FOR TIER III, WITH A DEI SCORE OF 7. AND THE  
6 CIRM TEAM RECOMMENDATION IS TO FUND THE APPLICATION  
7 FOR THE AMOUNT OF 2.2 MILLION.

8 DR. IMBASCIANI.

9 CHAIRMAN IMBASCIANI: YES. GREAT. THANK  
10 YOU. SO FOR THIS FINAL APPLICATION, COULD WE HAVE A  
11 MOTION TO DISCUSS?

12 DR. DULIEGE: I CAN MAKE THE MOTION TO  
13 DISCUSS.

14 CHAIRMAN IMBASCIANI: ANNE-MARIE MOVES.

15 DR. SOUTHARD: SECOND.

16 CHAIRMAN IMBASCIANI: MARVIN SECONDS.

17 THANK YOU.

18 COMMENTS NOW FROM BOARD MEMBERS.

19 MS. DEQUINA-VILLABLANCA: THERE ARE NO  
20 HANDS RAISED. HOLD ON. THERE'S ADRIANA.

21 DR. PADILLA: CAN THE TEAM JUST SUMMARIZE.  
22 WHAT WERE SOME OF THE ISSUES REGARDING THE DEI SCORE  
23 OF 7, PLEASE?

24 DR. LAM: I THINK THE MAIN CONCERNS WERE  
25 THAT IT DIDN'T SEEM LIKE THERE WAS A LOT OF EARLY

**BETH C. DRAIN, CA CSR NO. 7152**

1     ENGAGEMENT, DEI ENGAGEMENT COMMITTEES TO BE  
2     CONDUCTED UNDER THIS SPECIFIC AWARD.  AND IT WASN'T  
3     CLEAR FROM THE EXPLANATION OF THE APPLICANT HOW THIS  
4     THERAPY WOULD POTENTIALLY IMPACT UNDERSERVED AND  
5     DISPROPORTIONATELY AFFECTED COMMUNITIES.

6             DR. PADILLA:  DOES THE TEAM GO BACK AND  
7     ASK THE APPLICANT TO ADDRESS THOSE ISSUES?

8             DR. LAM:  SO I THINK THAT THE CIRM TEAM  
9     CAN WORK WITH THE AWARDEE, IF FUNDED, TO IMPROVE  
10    THOSE DEI PLANS AS PART OF AWARD ADMINISTRATION HERE  
11    AT CIRM.

12            DR. PADILLA:  OKAY.  THANK YOU.

13            CHAIRMAN IMBASCIANI:  ADRIANA, THANK YOU.  
14    THOSE WERE THE QUESTIONS I WAS HOPING WOULD BE  
15    ASKED.  ANY OTHER COMMENTS FROM BOARD MEMBERS?

16            DR. DULIEGE:  JUST MAYBE A CLARIFICATION  
17    ON MY PART.  AND I APOLOGIZE BECAUSE I HAVEN'T HAD A  
18    CHANCE TO REALLY LOOK AT THE MOST RECENT EXCHANGE OF  
19    EMAILS IN GREAT DETAIL.  BUT IS THERE ANY ISSUE  
20    HERE?  WHAT I SEE IS UNANIMITY, AT LEAST FROM A  
21    SCIENTIFIC PERSPECTIVE, IF I'M CORRECT, AS WELL AS  
22    THE CIRM TEAM CONCURS WITH THE GWG.  SO DO I MISS  
23    SOMETHING IS MY QUESTION?

24            CHAIRMAN IMBASCIANI:  GIL.

25            DR. SAMBRANO:  NO.  NOT THAT I CAN TELL.

**BETH C. DRAIN, CA CSR NO. 7152**

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DR. DULIEGE: THANK YOU.

CHAIRMAN IMBASCIANI: SCANNING ONCE MORE  
FOR THE PUBLIC, STAR NINE.

MS. DEQUINA-VILLABLANCA: THERE ARE NONE.

CHAIRMAN IMBASCIANI: OKAY. THERE ARE  
NONE.

SCOTT, WE CAN PROCEED THEN TO A VOTE ON  
THIS FINAL APPLICATION.

MR. TOCHER: AND THE MOTION IS TO FUND  
APPLICATION 14933.

DAN BERNAL.

MR. BERNAL: AYE.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: YES.

MR. TOCHER: ELENA FLOWERS.

DR. FLOWERS: YES.

MR. TOCHER: DAVID HIGGINS.

DR. HIGGINS: YES.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YES.

MR. TOCHER: STEVE JUELSGAARD.



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MR. JUELSGAARD: YES.  
MR. TOCHER: RICH LAJARA.  
MR. LAJARA: YES.  
MR. TOCHER: CHRISTINE MIASKOWSKI.  
DR. MIASKOWSKI: YES.  
MR. TOCHER: LAUREN MILLER-ROGEN.  
MS. MILLER-ROGEN: YES.  
MR. TOCHER: ADRIANA PADILLA.  
DR. PADILLA: YES.  
MR. TOCHER: MARVIN SOUTHARD.  
DR. SOUTHARD: YES.  
MR. TOCHER: KAROL WATSON.  
DR. WATSON: YES.  
MR. TOCHER: THANK YOU VERY MUCH. THE

MOTION CARRIES 14 TO 0.

CHAIRMAN IMBASCIANI: GOOD. THANK YOU,  
SCOTT.

JUST AN EDITORIAL COMMENT FROM THE CHAIR.  
I WANT TO COMPLIMENT THE APPLICANTS ON THE QUALITY  
OF THEIR APPLICATIONS SUBMITTED TO THIS SESSION OF  
THE BOARD TO JUDGE BY THE NEAR UNANIMITY OF PEOPLE  
DOING THE EVALUATIONS AND, WITH THE EXCEPTION OF THE  
LAST, THE SIXTH APPLICATION, THE HIGH SCORES IN THE  
DEI CATEGORY. I DON'T HAVE A LONG INSTITUTIONAL  
MEMORY. I THINK THIS QUESTION IS RHETORICAL, BUT I

**BETH C. DRAIN, CA CSR NO. 7152**

1 WONDER IF WE'VE EVER HAD A MEETING WITH SO MANY HIGH  
2 SCORING DEI'S PRESENTED AT THE SAME TIME. I'M SURE  
3 SCOTT OR GIL WILL TELL ME THAT ANSWER LATER.

4 THANK YOU, EVERYONE. IS THERE ANY OTHER  
5 BUSINESS FOR THE BOARD MEMBERS, SCOTT?

6 MR. TOCHER: NO, THERE ISN'T. THAT  
7 CONCLUDES THE BUSINESS OF THE ARS UNLESS THERE'S ANY  
8 OTHER PUBLIC COMMENT REGARDING AN ITEM NOT ON THE  
9 AGENDA.

10 MS. DEQUINA-VILLABLANCA: THERE ARE NONE.

11 CHAIRMAN IMBASCIANI: THERE ARE NONE. CAN  
12 WE ADJOURN, OR DO WE NEED A MOTION?

13 MR. TOCHER: YOU CAN ADJOURN.

14 CHAIRMAN IMBASCIANI: WE CAN ADJOURN.

15 THANK YOU, EVERYONE. THIS WAS A VERY, VERY  
16 PRODUCTIVE MEETING UNDER AN HOUR. I APPRECIATE YOUR  
17 PARTICIPATION. THANK YOU.

18 (THE MEETING WAS THEN CONCLUDED AT 10:24 A.M.)

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**REPORTER'S CERTIFICATE**

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE VIRTUAL PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE AND THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON JULY 27, 2023, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

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