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

REGULAR MEETING

LOCATION: VIA ZOOM

DATE: AUGUST 24, 2021
20 A.M.

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

FILE NO.: 2021-18

I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION:	
1. CALL TO ORDER.	3
2. ROLL CALL	3
ACTION ITEMS:	
3. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO DISC2: PARTNERING OPPORTUNITY FOR DISCOVERY STAGE RESEARCH PROJECTS PRESENTATION?	28
4. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL STAGE PROJECTS PROGRAM ANNOUNCEMENT (CLIN 1,2 OR 3).	6
5. CLOSED SESSION	NONE
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 ITEMS 3 AND 4 ABOVE. (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
6. DISCUSSION ITEMS	NONE
7. PUBLIC COMMENT.	NONE
8. ADJOURNMENT.	60

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AUGUST 24, 2021; 10:00 A.M.

CHAIRMAN THOMAS: OKAY. THANK YOU, EVERYBODY. AND GOOD MORNING AND WELCOME TO THE AUGUST 24TH MEETING OF THE ICOC AND THE APPLICATION REVIEW SUBCOMMITTEE. MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: DAN BERNAL.

MR. BERNAL: PRESENT.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: YSABEL DURON.

MS. DURON: PRESENT.

MS. BONNEVILLE: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: HERE.

MS. BONNEVILLE: FRED FISHER.

DR. FISHER: HERE.

MS. BONNEVILLE: ELENA FLOWERS.

DR. FLOWERS: PRESENT.

MS. BONNEVILLE: LEONDRA CLARK-HARVEY. DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: HERE.

MS. BONNEVILLE: RICH LAJARA. I THINK I

SAW RICH. ARE YOU ON MUTE?

MR. LAJARA: PRESENT.

MS. BONNEVILLE: THANK YOU SO MUCH. DAVE MARTIN. I SEE DAVE. I CAN'T HEAR DAVE. OH, THUMBS UP. I SEE YOU. OKAY. THANK YOU.

CHRISTINE MIASKOWSKI.

DR. MIASKOWSKI: HERE.

MS. BONNEVILLE: LAUREN MILLER-ROGEN.

ADRIANA PADILLA.

DR. PADILLA: HERE.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: HERE.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: HERE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: HERE. AND WELCOME, RICH, TO YOUR FIRST MEETING HERE.

MS. BONNEVILLE: CAROL WATSON.

DR. WATSON: HERE.

MS. BONNEVILLE: SHLOMO MELMED.

DR. MELMED: HERE.

MS. BONNEVILLE: LARRY GOLDSTEIN.

DR. GOLDSTEIN: HERE.

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MS. BONNEVILLE: ARE THERE ANY BOARD MEMBERS WHOSE NAME I DID NOT CALL? OKAY. THANK YOU. WE HAVE A QUORUM.

CHAIRMAN THOMAS: THANK YOU, MARIA. AND FOLLOWING ON ART'S COMMENT, I WANT TO WELCOME RICH LAJARA, OUR NEWEST BOARD MEMBER, TO THE ICOC. AND IT IS OUR CUSTOM, RICH, IF YOU JUST GIVE A FEW WORDS OF INTRODUCTION TO THE REST OF THE BOARD, THAT WOULD BE MUCH APPRECIATED.

MR. LAJARA: DEFINITELY. THANK YOU. SO HONORED AND PROUD TO BE A NEW BOARD MEMBER WITH CIRM, PARTICULARLY AS A PATIENT ADVOCATE FOR SPINAL CORD INJURIES.

SO JUST A BRIEF BACKGROUND ABOUT MY JOURNEY. 2011, I WAS AT A RIVER WITH SOME FRIENDS IN A VERY REMOTE AREA, HAD A SLIP AND FALL OFF A SUBSTANTIAL LEDGE THAT LEFT ME PARALYZED FROM THE WAIST DOWN AMONGST OTHER INJURIES. LUCKILY I WAS RESCUED FROM THAT AREA AND TAKEN TO A HOSPITAL. AND WITHIN A FEW DAYS AT THE HOSPITAL, I WAS PRESENTED WITH THE OPPORTUNITY TO PARTICIPATE IN A STEM CELL CLINICAL TRIAL. THAT WAS A PRETTY AMAZING OPPORTUNITY IN IT ENDED UP BEING THAT I WAS CALIFORNIA'S FIRST EMBRYONIC STEM CELL PATIENT AND THE FIRST CLINICAL TRIAL FUNDED BY CIRM. IT WAS A

PHASE 1 CLINICAL TRIAL FOR SAFETY.

IF WE FAST-FORWARD A FEW YEARS, I BECAME A PATIENT ADVOCATE WITH AN AMAZING GROUP CALLED AMERICANS FOR CURES. IT GAVE ME A LOT OF EXPOSURE TO THE IMPORTANCE OF STEM CELLS AND REALLY OPENED MY EYES TO ALL THE POSSIBILITIES TO HELP PEOPLE WITH UNMET MEDICAL NEEDS. SO UP TO THIS POINT, I'M PROUD OF WHAT I'VE DONE AND BEEN A PART OF OVER THE PAST DECADE AND LOOKING FORWARD TO THE FUTURE WITH STEM CELLS. WITH THAT, I'LL TURN IT OVER.

CHAIRMAN THOMAS: RIGHT. THANKS VERY MUCH, RICH. AND WE ARE DELIGHTED TO HAVE YOU WITH US AND GREATLY LOOK FORWARD TO WORKING WITH YOU AS WE PROCEED ALONG ON OUR MISSION HERE. SO THANK YOU FOR YOUR INTEREST.

MR. LAJARA: THANK YOU.

CHAIRMAN THOMAS: OKAY. WE'RE GOING TO GO FROM THAT INTO THE APPLICATION REVIEW SUBCOMMITTEE MEETING. I'M GOING TO TAKE THINGS A BIT OUT OF ORDER AND DEAL WITH THE CLINICAL AWARDS FIRST. SO THAT ITEM SPECIFICALLY IS CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL STAGE PROJECTS PROGRAM REVIEW ANNOUNCEMENT, PROGRAM RECORD ANNOUNCEMENT, CLINS 1, 2, AND 3. WE'RE GOING TO HAVE A PRESENTATION HERE BY DR. SAMBRANO.

DR. SAMBRANO: THANK YOU, MR. CHAIRMAN. GOOD MORNING, EVERYONE. LET ME JUST SHARE MY SCREEN. OKAY. YOU SHOULD ALL BE ABLE TO SEE THE PRESENTATION. IF YOU CAN'T, JUST LET ME KNOW.

SO WE ARE RECOMMEND -- WE ARE PRESENTING THE RECOMMENDATIONS FROM THE GRANTS WORKING GROUP RELATED TO THIS LATEST CYCLE OF CLINICAL STAGE PROJECTS. AND JUST AS A GENERAL REMINDER, THIS OPPORTUNITY IS FOR THREE DIFFERENT PROGRAM ANNOUNCEMENTS. SO CLIN1, WHICH SUPPORTS LATE STAGE PRECLINICAL PROJECTS; CLIN2, WHICH SUPPORTS THE CLINICAL TRIALS; AND CLIN3, WHICH OFFERS SUPPLEMENTAL ACCELERATING ACTIVITIES.

SO FOR THIS PARTICULAR CYCLE WE HAVE THREE CLINICAL TRIALS THAT WERE REVIEWED AND ARE BEING CONSIDERED.

HERE WE HAVE JUST A REMINDER OF WHAT THE CLINICAL BUDGET FOR THIS FISCAL YEAR IS. SO WE ARE ACTUALLY STARTING A NEW FISCAL YEAR THAT BEGAN IN JULY, AND SO THIS IS THE FIRST CYCLE THAT IS UTILIZING THOSE FUNDS. WE HAVE AN ANNUAL ALLOCATION FOR THIS FISCAL YEAR OF 162 MILLION. AND SO AS SUCH, THERE'S NO APPROVED AWARDS YET. SO THAT'S WHY YOU DON'T SEE ANY ORANGE ON THIS PIE CHART. BUT IF THE AWARDS THAT ARE UP FOR CONSIDERATION, IF THEY

WERE ALL TO BE FUNDED, THAT WOULD BE A TOTAL OF 31 MILLION. THAT WOULD LEAVE ABOUT 131 REMAINING FOR THE REMAINDER OF THE YEAR.

THIS IS A REMINDER OF THE REVIEW CRITERIA THAT IS USED BY THE GRANTS WORKING GROUP TO ASSESS THE MERIT OF THE PROJECTS. SO WHEN LOOKING AT THESE CLINICAL TRIAL PROJECTS, THEY CONSIDER WHETHER THE PROJECT HAS THE NECESSARY SIGNIFICANCE AND POTENTIAL FOR IMPACT, WHETHER IT HAS A SOUND RATIONALE; WHETHER IT'S WELL-PLANNED AND DESIGNED; WHETHER IT'S FEASIBLE; AND IF IT ADDRESSES THE NEEDS OF UNDERSERVED COMMUNITIES.

THE SCORING SYSTEM IS BASED ON A SCALE OF 1, 2, OR 3. A 1 MEANS THAT IT HAS EXCEPTIONAL MERIT AND WARRANTS FUNDING. IT MIGHT HAVE SOME MINOR RECOMMENDATIONS OR ADJUSTMENTS, BUT THOSE DON'T REQUIRE ANY FURTHER REVIEW BY THE GRANTS WORKING GROUP. A SCORE OF 2 WOULD MEAN THAT IT NEEDS IMPROVEMENT, WOULDN'T WARRANT FUNDING. AND SO THOSE USUALLY GO BACK TO THE APPLICANT FOR REVISIONS AND CLARIFICATIONS AND WILL COME BACK IN THE NEXT AVAILABLE CYCLE. A SCORE OF 3 MEANS THAT IT'S SUFFICIENTLY FLAWED THAT IT WOULDN'T WARRANT FUNDING, AND SO WE DON'T ALLOW THOSE TO COME BACK FOR ANOTHER SIX MONTHS.

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SO SOME OF THE ELEMENTS THAT HAVE BEEN ADDED TO THE APPLICATION AND TO THE REVIEW PROCESS, AND I'VE SPOKEN ABOUT THIS BEFORE, JUST WANT TO CONTINUE TO EMPHASIZE IS THE NEW REVIEW CRITERION ON ADDRESSING THE NEEDS OF THE UNDERSERVED COMMUNITIES. AND SO THIS IS A SECTION THAT DESCRIBES THE APPLICANT'S PLAN FOR OUTREACH AND ENROLLMENT OF A DIVERSE PATIENT COHORT THAT ACCOUNT FOR RACIAL, ETHNIC, AND GENDER DIVERSITY. AND SO THAT ELEMENT IS EVALUATED BY THE GRANTS WORKING GROUP AND INCORPORATED INTO THE OVERALL SCORE OF THE APPLICATION OR THE SCIENTIFIC MERIT SCORE OF 1, 2, OR 3.

BUT WE ALSO HAVE A DIFFERENT SECTION, SEPARATE SECTION, THAT WE REFER AS THE DIVERSITY, EQUITY, AND INCLUSION IN RESEARCH. AND SO THIS DESCRIBES HOW THE APPLICANT TEAM INCORPORATES DIVERSITY AND DIVERSE PERSPECTIVES AND EXPERIENCE TO IMPROVE THE PROJECT. AND SO THAT MAY INCLUDE THE COMPOSITION OF THE TEAM AND OTHER APPROACHES THEY MAY TAKE TO DIVERSIFY AND BRING DIVERSITY TO THE PROJECT. THAT SECTION IS EVALUATED AND SCORED BY OUR PATIENT ADVOCATE AND NURSE MEMBERS OF THE BOARD. AND THE SCORE ON THAT ELEMENT IS SHOWN IN THE DEI SCORE, WHICH HAS A RANGE FROM ZERO TO TEN. AND ON

THAT -- WITH TEN BEING THE BEST. AND SO THAT IS SOMETHING I WILL SHOW YOU AS WELL.

SO THE FIRST APPLICATION FOR CONSIDERATION IS CLIN2-12379. SO THIS IS A CELL THERAPY FOR CHRONIC ISCHEMIC SUBCORTICAL STROKE. THE THERAPY ITSELF IS A HUMAN EMBRYONIC STEM CELL-DERIVED NEURAL STEM CELL FOR PATIENTS WHO HAVE SUFFERED A SUBCORTICAL STROKE AND EXHIBIT CHRONIC MOTOR DEFICITS. AND THIS IS AFTER SIX MONTHS, BETWEEN SIX MONTHS AND FIVE YEARS.

SO THE GOAL OF THIS PROJECT IS TO COMPLETE A PHASE 1-2A TRIAL TO ASSESS SAFETY AND INITIAL EFFICACY OF THIS THERAPY. THE FUNDS REQUESTED ARE JUST UNDER 12 MILLION. THERE IS NO COFUNDING PROVIDED OR REQUIRED FOR THIS PHASE 1.

SO A LITTLE BACKGROUND ON THE INDICATION OF STROKE. SO EVERY YEAR THERE ARE MORE THAN 795,000 PEOPLE IN THE U.S. THAT HAVE A STROKE AND ABOUT 610,000 OF THESE ARE FIRST OR NEW STROKES, AND ABOUT 185,000 STROKES, NEARLY ONE IN FOUR ARE PEOPLE WHO HAVE HAD A PREVIOUS STROKE. AND CURRENTLY THERE ARE NO THERAPIES THAT ALLOW FOR RECOVERY FOLLOWING STROKE. THE CURRENT STANDARD OF CARE IS NEURAL REHABILITATION THAT FOLLOWS THAT STROKE. HOWEVER, MANY PATIENTS EXPERIENCE A DECLINE IN FUNCTION AND

LIVE WITH SOME NEUROLOGICAL IMPAIRMENT OR DISABILITY.

AND SO THE PROPOSED ALLOGENEIC CELL THERAPY MAY PROMOTE RECOVERY AND IMPROVE MOTOR FUNCTION THAT WOULD HELP SUCH PATIENTS. AND THIS PROJECT IS A STEM CELL PROJECT OR QUALIFIES AS A STEM CELL PROJECT BECAUSE IT UTILIZES HUMAN EMBRYONIC STEM CELLS THAT ARE DIFFERENTIATED INTO A NEURAL STEM CELL PRODUCT.

OKAY. SO IN TERMS OF SIMILAR CIRM PORTFOLIO PROJECTS, WE DON'T CURRENTLY HAVE ANY ACTIVE CLINICAL PROJECTS RELATED TO STROKE. THE APPLICANT DOES HAVE PREVIOUS CIRM FUNDING. SO THERE WERE SEVERAL AWARDS THAT HAVE GONE TO THIS PARTICULAR APPLICANT THAT INCLUDE THE PRECURSOR STUDIES, THE IND-ENABLING WORK THAT LED TO THIS PROPOSED CLINICAL TRIAL VIA CLIN1. THERE WAS ALSO A DISEASE TEAM AWARD THAT LED TO A LOT OF THE IND-ENABLING AND PRECLINICAL TRANSLATIONAL WORK THAT FACILITATED THIS, AS WELL AS SOME STUDIES ON BASIC MECHANISMS. SO THIS IS A BASIC BIOLOGY AWARD TO INVESTIGATE SOME OF THE MECHANISMS OF ACTION OF THE CANDIDATE.

SO THE GRANTS WORKING GROUP RECOMMENDATION FOR THIS PROJECT IS A SCORE OF 1. WE HAD 11 MEMBERS

OF THE GRANTS WORKING GROUP GIVE THIS APPLICATION A SCORE OF 1, NONE GAVE IT A SCORE OF 2, AND ONE GAVE IT A SCORE OF 3. THE DEI SCORE IS A NINE OUT OF TEN. AND THE CIRM RECOMMENDATION IS TO FUND THIS APPLICATION IN CONCURRENCE WITH THE GRANTS WORKING GROUP FOR THE AMOUNT OF 11.9 MILLION. SO BACK TO YOU, J.T.

CHAIRMAN THOMAS: THANKS, GIL. DO WE HAVE A MOTION TO APPROVE THIS GRANT?

DR. DULIEGE: I CAN MAKE THE MOTION OR SECOND IT.

CHAIRMAN THOMAS: MOVED BY ANNE-MARIE.

MS. BONNEVILLE: WHO WAS THE SECOND?

DR. FISCHER-COLBRIE: SECOND. MARK FISCHER-COLBRIE.

MS. BONNEVILLE: THANK YOU, MARK.

CHAIRMAN THOMAS: OKAY. IT'S BEEN MOVED AND SECONDED. ARE THERE ANY COMMENTS BY MEMBERS OF THE BOARD?

DR. FISHER: I GUESS I HAVE A QUESTION. THE SCORING LEADS ME TO WONDER HOW 11 OF THE 12 PEOPLE THOUGHT IT SHOULD ABSOLUTELY BE FUNDED AND ONE PERSON COMPLETELY REJECTED THAT IDEA, IF I UNDERSTAND THE SYSTEM. ARE WE IN A POSITION TO HAVE ANY INSIGHT ABOUT WHAT THAT OBJECTION WAS ABOUT?

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DR. SAMBRANO: SO I CAN'T TELL YOU PRECISELY WHAT THE OBJECTION IS, BUT I CAN TELL YOU THERE WERE CONCERNS FROM SOME REVIEWERS THAT I THINK MAY HAVE LED THEM TO FEEL THAT THEY WOULD LIKE MORE DATA OR INFORMATION. SO I THINK RELATED TO THAT, I THINK THERE WERE CONCERNS ABOUT THE MECHANISM OF ACTION WHICH WAS UNCLEAR. SO THERE WAS A LOT OF PRELIMINARY DATA THAT SHOWED EFFICACY WHICH EVERYONE AGREED WITH, BUT IT WAS UNCLEAR BASICALLY WHY IT WORKED OR WHY IT SEEMED TO WORK. AND SOME OF THE REVIEWERS MAY HAVE FELT THAT MORE WORK TOWARDS UNDERSTANDING THAT MIGHT BE HELPFUL.

THERE WERE COMMENTS TO ADD STUDIES IN OLDER ANIMALS BECAUSE MANY OF THE STUDIES THAT WERE CONDUCTED WERE IN YOUNG ANIMALS THAT MAY NOT NECESSARILY BE AS PREDICTIVE OF WHAT HAPPENS IN THE OLDER POPULATION THAT STROKES AFFECT.

THERE WAS A QUESTION OF WHETHER IMMUNOSUPPRESSION WAS A NECESSARY COMPONENT SINCE THE CELLS THAT ARE INTRODUCED DON'T NORMALLY LAST FOR A VERY LONG TIME AND THEY DON'T EXPECT IT TO, SO SOME THOUGHT THAT THAT MIGHT NOT HAVE BEEN NECESSARY.

SO I THINK THOSE ELEMENTS WHICH THE VAST MAJORITY OF THE REVIEWERS FELT WERE RELATIVELY

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MINOR, I THINK, FOR THAT ONE REVIEWER MAY HAVE BEEN ENOUGH TO SUGGEST THAT THAT -- THAT THEY WOULDN'T FEEL COMFORTABLE MOVING IT FORWARD. SO I MEAN I THINK THAT'S THE ONLY INSIGHT I CAN PROVIDE.

DR. FISHER: THAT'S REALLY HELPFUL. THANK YOU.

AND JUST AS A GENERAL COMMENT, I THINK WE ARE AT THE VERY EARLY STAGES OF UNDERSTANDING HOW STEM CELL THERAPIES, PARTICULARLY IN THE NEURAL SPACE, CAN BE EFFECTIVE AND WHY. FROM THE PATIENT POINT OF VIEW, I CAN TELL YOU THEY DON'T CARE AS LONG AS THEY WORK. BUT A PHASE 1-2 TRIAL, A BIG PART OF THAT IS WHAT CAN BE LEARNED TO INFORM AND ANSWER THOSE QUESTIONS ALONG THE WAY. AND SO IT SEEMS LIKE A GOOD IDEA TO ME.

CHAIRMAN THOMAS: THANKS, FRED.

DR. MARTIN: THIS IS DAVE MARTIN. I HAVE A QUESTION OF GIL. I PRESUME IT'S TRUE, BUT IS IT THAT THE PREVIOUS FUNDING TO THIS PARTICULAR TEAM WAS ALONG THE SAME PATHWAY TO SUPPORT THIS CLINICAL TRIAL?

DR. SAMBRANO: YES. SO THEY HAD A CLIN1 AWARD THAT SUPPORTED THE IND-ENABLING WORK. THE DISEASE TEAM WAS DEVELOPING A CANDIDATE THAT THEY ULTIMATELY ENDED UP CHANGING. IT WAS STILL THE CELL

THERAPY, SAME INDICATION, BUT I THINK IT WAS VERY EARLY. SO THEY WENT THROUGH A LONG PATH TO GET TO WHERE THEY ARE; BUT, YES, THAT FUNDING SUPPORTED THIS PROPOSED CLINICAL TRIAL.

DR. MARTIN: THANK YOU.

CHAIRMAN THOMAS: ANY OTHER QUESTIONS FROM MEMBERS OF THE BOARD? ANY PUBLIC COMMENT? HEARING NONE, MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: SURE. DAN BERNAL.

MR. BERNAL: AYE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: AYE.

MS. BONNEVILLE: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: AYE.

MS. BONNEVILLE: FRED FISHER.

DR. FISHER: AYE.

MS. BONNEVILLE: ELENA FLOWERS.

DR. FLOWERS: AYE.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: YES.

MS. BONNEVILLE: RICH LAJARA.

MR. LAJARA: AYE.

MS. BONNEVILLE: DAVE MARTIN.

DR. MARTIN: YES.
MS. BONNEVILLE: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: YES.
MS. BONNEVILLE: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: MOTION CARRIES.
CHAIRMAN THOMAS: THANK YOU. GIL, ON TO NO. 2.
DR. SAMBRANO: OKAY. SO THE NEXT APPLICATION IS CLIN2-12595. THIS IS A CAR-T CELL THERAPY FOR BRAIN AND SPINAL TUMORS OR GLIOMAS. THERAPY IS AN AUTOLOGOUS CAR-T CELL THERAPY THAT TARGETS TD2, WHICH IS A SPECIFIC GANGLIOSIDE THAT IS EXPRESSED IN THOSE TUMORS. SO THE INDICATION IS FOR DIFFUSE INTRINSIC PONTINE GLIOMAS OR SPINAL DIFFUSION MIDLINE GLIOMAS, WHICH ARE SOME OF THE MOST DEVASTATING BRAIN TUMORS IN CHILDREN AND YOUNG

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ADULTS.

THE GOAL IS TO COMPLETE A PHASE 1 TRIAL TO ASSESS SAFETY AND DOSING. THE FUNDS REQUESTED IS JUST UNDER 12 MILLION. THERE IS NO COFUNDING PROVIDED AND NO COFUNDING REQUIRED UNDER THIS PARTICULAR CATEGORY.

SO SOME BACKGROUND ON THESE GLIOMAS. BRAIN TUMORS ARE THE LEADING CAUSE OF SOLID TUMOR CANCER DEATH IN CHILDREN BETWEEN THE AGES OF ZERO AND 14 AND THE SECOND MOST COMMON CANCER IN CHILDREN. AND THE PROGNOSIS FOR PEDIATRIC PATIENTS WITH AGGRESSIVE BRAIN TUMORS SUCH AS THESE PARTICULAR ONES THAT ARE TARGETED IS VERY POOR, OFTEN JUST A FEW MONTHS, AND RADIOTHERAPY IS REALLY THE ONLY OPTION AVAILABLE.

THE PROPOSED CAR-T THERAPY OFFERS THE POSSIBILITY OF IMPROVED PATIENT OUTCOMES, INCLUDING IMPROVEMENT IN NEUROLOGICAL DEFICITS. AND THIS QUALIFIES AS A STEM CELL PROJECT AS THE THERAPEUTIC CANDIDATE CONTAINS MEMORY STEM CELLS.

SO IN TERMS OF SIMILAR PROJECTS IN OUR PORTFOLIO, WE HAVE FUNDED OR ARE FUNDING FOUR OTHER ACTIVE PROJECTS THAT HAVE SOME SIMILARITY TO THIS. THERE IS A PHASE 1 CLINICAL TRIAL IN MALIGNANT PEDIATRIC GLIOMAS. THAT'S ALSO A CAR-T CELL THERAPY

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THAT INCLUDES A LYMPHODEPLETION APPROACH. IT'S A CHIMERIC ANTIGEN RECEPTOR APPROACH FOR IL-13 RECEPTOR ALPHA, SO IT'S A DIFFERENT TARGET THAT THAT IS USING. THERE IS ALSO AN IND-ENABLING STUDY THAT WE SUPPORT FOR PATIENTS THAT SUFFER FROM GLIOBLASTOMA, BUT IT'S FOCUSED ON MODIFYING THEIR HEMATOPOIETIC STEM CELLS IN ORDER TO CONFER PROTECTION FROM CHEMOTHERAPY. THERE IS A PHASE 1 CLINICAL TRIAL FOR MALIGNANT GLIOMA IN ADULTS WHICH IS BASICALLY THE SAME PRODUCT AS THE TOP ONE, THE PHASE 1 CLINICAL TRIAL FOR CHILDREN. AND THEN, LASTLY, THERE IS A CLINICAL TRIAL FOR HER2 POSITIVE BRAIN METASTASIS, SO THIS IS BASICALLY BREAST CANCER THAT HAS METASTASIZED TO THE BRAIN AND IS USING THE CAR-T CELL THERAPY APPROACH FOR THAT. SO THOSE ARE FOUR SIMILAR PROJECTS THAT EXIST IN OUR PORTFOLIO.

FOR THIS PARTICULAR APPLICANT, THEY HAVE ANOTHER ACTIVE CLINICAL TRIAL THAT WE HAVE FUNDED AND SUPPORTED. IT'S A VERY SIMILAR CAR-T CELL APPROACH, BUT IT'S FOR REFRACTORY B-CELL MALIGNANCIES THAT WAS AWARDED TO THEM. THE PROJECT STARTED IN 2018 AND IS EXPECTED TO COMPLETE IN 2022.

SO THE GRANTS WORKING GROUP REVIEW OF THIS APPLICATION AND THEIR RECOMMENDATION IS AS FOLLOWS: THIS HAD RECEIVED A SCORE OF 1. THERE WERE 14

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MEMBERS THAT GAVE IT A SCORE OF 1. THERE WERE NO MEMBERS THAT SCORED IT A 2 OR A 3. THE DEI IS EIGHT OUT OF TEN, AND THE CIRM TEAM RECOMMENDATION IS TO FUND IN CONCURRENCE WITH THE GWG RECOMMENDATION FOR AN AWARD AMOUNT OF 11.99 MILLION.

SO, MR. CHAIRMAN.

CHAIRMAN THOMAS: THANK YOU, GIL. DO WE HEAR A MOTION TO APPROVE THIS GRANT?

MR. ROWLETT: THIS IS AL. I'LL MOVE IT.

CHAIRMAN THOMAS: THANK YOU, AL. SECOND?

MR. BERNAL: SECOND. THIS IS DAN.

CHAIRMAN THOMAS: THANK YOU, DAN. COMMENTS BY MEMBERS OF THE BOARD?

DR. DULIEGE: ONE QUICK QUESTION. HOW MANY VOLUNTEERS ARE PLANNED TO BE INCLUDED IN THIS APPLICATION? I KNOW IT'S A PHASE 1 TRIAL, AND I KNOW WELL THAT THERE'S A HIGH COST TO CAR-T CELL DEVELOPMENT, BUT I FIND IT PRETTY EXPENSIVE. AND I DON'T KNOW IF THERE'S ALSO A CO-FUNDING MECHANISM FOR THIS APPLICATION.

DR. SAMBRANO: SO THERE'S NO COFUNDING PROVIDED FOR THIS ONE. IT'S A PHASE 1 FROM AN ACADEMIC CENTER, SO NO COFUNDING IS REQUIRED. THE NUMBER OF PATIENTS THAT WOULD BE TREATED IS GOING TO ULTIMATELY DEPEND BECAUSE THEY'RE DOING A DOSE

FINDING STUDY. BUT IT WILL RANGE FROM, I BELIEVE, SOMEWHERE AROUND 18 TO 20 UP TO 60 PATIENTS FOR ALL THE DIFFERENT THINGS THAT THEY ARE DOING. AND SO IN THEIR BUDGET, I THINK THE WAY THEY'VE CALCULATED IT IS ASSUMING THAT THEY WOULD HAVE TO TREAT UP TO 60 PATIENTS. OF COURSE, WE SET UP MILESTONES DEPENDENT ON HOW MANY PATIENTS THEY ULTIMATELY TREAT, WHICH MEANS THAT ALL OF THE FUNDS THAT ARE APPROVED WOULDN'T NECESSARILY BE USED BY THE APPLICANT IF THEY ULTIMATELY DON'T TREAT THAT MANY PATIENTS.

DR. DULIEGE: THANK YOU, GIL. VERY CLEAR ANSWER. APPRECIATE IT. THAT MAKES A LOT OF SENSE. THANK YOU VERY MUCH.

DR. SAMBRANO: THANKS.

DR. MARTIN: THIS IS DAVE MARTIN. THIS IS A VERY COMPETITIVE FIELD, PARTICULARLY FOR GD2. I AM AWARE OF SEVERAL ENTITIES PURSUING GD2, AND THERE ARE SOME SERIOUS PROBLEMS WITH THE GD2 TARGET. THE BIGGEST ONE IS PAIN, SEVERE PAIN, IN THESE PEDIATRIC PATIENTS.

AND SO MY QUESTION IS NOT SO MUCH THE QUALIFICATION OF THE APPLICANTS, BUT WERE THE REVIEWERS REALLY EXPERIENCED IN PEDIATRIC CAR-T FOR SOLID TUMORS? BECAUSE WE WANT TO MAKE CERTAIN THAT WE ARE NOT JUST A ME TOO FUNDING ORGANIZATION, THAT

WE ARE DOING WHAT'S INNOVATIVE. AND SO I'VE NO IDEA WHO THE REVIEWERS WERE THAT HAD SOLID TUMOR, NEURAL SOLID TUMOR EXPERIENCE WITH CAR-T'S.

DR. SAMBRANO: YES. SO WE DID, OF COURSE, AS WE USUALLY DO WITH ALL OF THESE, TRY TO BRING CLINICAL EXPERTS WHO HAVE EXPERIENCE BOTH WITH THE DISEASE INDICATION AND THE APPROACH. SO WE DID HAVE ACTUALLY FOR THIS ONE TWO MEMBERS WHO HAVE DIRECT EXPERIENCE WITH GLIOMAS IN CHILDREN.

DR. MARTIN: THANK YOU.

DR. MONJE: MAY I ANSWER THE QUESTION ABOUT PAIN? I'M ONE OF THE PRINCIPAL INVESTIGATORS.

MS. BONNEVILLE: SURE. AS SOON AS THERE'S PUBLIC COMMENT, THE BOARD WILL ASK.

DR. MONJE: THANK YOU.

CHAIRMAN THOMAS: OTHER QUESTIONS OR COMMENTS FROM MEMBERS OF THE BOARD? HEARING NONE, PUBLIC COMMENT. MARIA?

MS. BONNEVILLE: MICHELLE, YOU HAVE PUBLIC COMMENT? PLEASE LIMIT IT TO THREE MINUTES.

DR. MONJE: MAY I SPEAK?

MS. BONNEVILLE: YES. NOW IT'S PUBLIC COMMENT.

DR. MONJE: OKAY. GREAT. SO IT IS TRUE THAT THE ANTI-GD2 ANTIBODIES THERAPIES THAT HAVE

BEEN DEVELOPED FOR NEUROBLASTOMA COME WITH -- CARRY WITH THEM A HIGH RISK FOR PAINFUL NEUROPATHY THAT HAS NOT, FOR REASONS WE DON'T FULLY UNDERSTAND, BEEN OBSERVED IN GD2 CAR-T CELL TRIALS AND HAS NOT BEEN SEEN IN THE FIRST ELEVEN PATIENTS WE'VE TREATED ON THIS CLINICAL TRIAL. SO THERE IS NOT THE SAME PAINFUL PERIPHERAL NEUROPATHY THAT HAPPENS WITH THE GD2 TARGETING ANTIBODIES.

DR. MARTIN: THANK YOU.

CHAIRMAN THOMAS: OTHER PUBLIC COMMENT? HEARING NONE, MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: DAN BERNAL.

MR. BERNAL: AYE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: AYE.

MS. BONNEVILLE: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: AYE.

MS. BONNEVILLE: FRED FISHER.

DR. FISHER: AYE.

MS. BONNEVILLE: ELENA FLOWERS.

DR. FLOWERS: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: YES.

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MS. BONNEVILLE: RICH LAJARA.
MR. LAJARA: AYE.
MS. BONNEVILLE: DAVE MARTIN.
DR. MARTIN: YES.
MS. BONNEVILLE: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: YES.
MS. BONNEVILLE: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: AYE.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: KAROL WATSON.
DR. WATSON: YES.
MS. BONNEVILLE: THANK YOU. THE MOTION CARRIES.
CHAIRMAN THOMAS: THANK YOU. GIL, ON TO THE THIRD GRANT PLEASE.
DR. SAMBRANO: OKAY. SO THE THIRD ONE IS

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CLIN2-12735. THIS IS A CELL THERAPY FOR HEART FAILURE.

THE THERAPY IS HUMAN EMBRYONIC STEM CELL-DERIVED CARDIOMYOCYTES OR HEART CELLS. THE INDICATION IS CHRONIC ISCHEMIC LEFT VENTRICULAR DYSFUNCTION, WHICH IS A TYPE OF HEART FAILURE. THE GOAL IS TO COMPLETE A PHASE 1 TRIAL TO ASSESS THE SAFETY AND INITIAL EFFICACY OF THIS THERAPY. THE FUNDS REQUESTED ARE JUST UNDER 7 MILLION. THERE IS NO COFUNDING PROVIDED OR REQUIRED FOR THIS PARTICULAR APPLICATION.

SO THE BACKGROUND INFORMATION, THERE IS ABOUT 6.2 MILLION ADULTS IN THE U.S. THAT HAVE HEART FAILURE. AND IT COSTS THE NATION APPROXIMATELY 30.7 BILLION, OR AT LEAST IT DID SO IN 2012, WHICH IS ONE OF THE LATEST ESTIMATES. THIS TOTAL INCLUDES THE COST OF HEALTHCARE SERVICES, MEDICINES TO TREAT HEART FAILURE, AND MISSED DAYS OF WORK.

AND SO ONE OF THE MAJOR ISSUES UNDERLYING HEART FAILURE IS THAT THERE IS A LARGE NUMBER OF HEART MUSCLE CELLS THAT ARE KILLED OR DAMAGED AS A RESULT OF ISCHEMIC INJURY. AND SO THE ADULT HEART ITSELF HAS NOT A GREAT CAPACITY TO REPLACE THOSE CELLS. AND SO THE GOAL OF THIS PROPOSED THERAPY IS TO OFFER THE POTENTIAL OPPORTUNITY TO IMPROVE

RECOVERY OF CARDIAC FUNCTION FOLLOWING A MYOCARDIAL INFARCTION BY REPLACING SOME OF THOSE CELLS AND HAVING SOME PARACRINE EFFECTS OF THOSE CELLS ON THE HEART TISSUE TO INDUCE SOME KIND OF RECOVERY AND REPAIR.

THIS IS A STEM CELL PROJECT AS IT USES HUMAN EMBRYONIC STEM CELL-DERIVED CARDIOMYOCYTES AS THE PRODUCT.

AND IN TERMS OF PROJECTS THAT ARE IN OUR PORTFOLIO THAT ARE SIMILAR TO THIS ONE, WE DON'T HAVE ANY CURRENT ACTIVE PROJECTS IN HEART FAILURE IN OUR CLINICAL PORTFOLIO. THIS PARTICULAR APPLICANT HAS HAD PREVIOUS CIRM FUNDING. THAT THEY'VE HAD AN IND-ENABLING AWARD THAT HAS NOW CLOSED THAT WAS AIMED AT DEVELOPING A THERAPY FOR HEART FAILURE. I BELIEVE THAT WAS A DISEASE TEAM AWARD. AND ALSO A TRANSLATIONAL AWARD WHICH WAS FOR A DIFFERENT PRODUCT. THIS WAS FOR A TOOL THAT WAS DEVELOPED AS A SCREEN FOR CARDIOTOXICITY AND TO PREDICT CARDIOTOXICITY IN DRUGS THAT ARE SCREENED.

THE RECOMMENDATIONS FROM THE GWG FOR THIS PARTICULAR APPLICATION ARE SHOWN HERE. THIS RECEIVED A SCORE OF 1 WITH TEN MEMBERS GIVING IT A SCORE OF 1. THERE WERE TWO MEMBERS THAT GAVE IT A SCORE OF 3. THE DEI SCORE WAS A 10, AND IT WAS

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NOTED TO BE ONE OF THE BEST PROJECTS TO HAVE PROVIDED A DEI COMPONENT THAT WE'VE SEEN. SO THAT WAS PERHAPS WORTH MENTIONING. AND THE CIRM TEAM RECOMMENDATION IS TO FUND, WHICH CONCURS WITH THE GWG RECOMMENDATION FOR AN AWARD AMOUNT OF 6.98 MILLION. MR. CHAIRMAN.

CHAIRMAN THOMAS: THANK YOU, GIL. DO WE HAVE A MOTION TO APPROVE THIS GRANT?

MR. ROWLETT: SO MOVED. THIS IS AL ROWLETT.

DR. MIASKOWSKI: SECOND. CHRIS MIASKOWSKI.

CHAIRMAN THOMAS: THANK YOU, AL AND CHRIS. DO WE HAVE COMMENTS OR QUESTIONS FROM MEMBERS OF THE BOARD? HEARING NONE, DO WE HAVE ANY PUBLIC COMMENT? GIL, MUST HAVE BEEN AN EXCELLENT, COMPREHENSIVE REVIEW. THANK YOU.

MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: DAN BERNAL.

MR. BERNAL: AYE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: AYE.

MS. BONNEVILLE: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: AYE.

MS. BONNEVILLE: FRED FISHER.

DR. FISHER: AYE.
MS. BONNEVILLE: ELENA FLOWERS.
DR. FLOWERS: AYE.
MS. BONNEVILLE: DAVID HIGGINS.
DR. HIGGINS: YES.
MS. BONNEVILLE: STEVE JUELSGAARD.
MR. JUELSGAARD: YES.
MS. BONNEVILLE: RICH LAJARA.
MR. LAJARA: AYE.
MS. BONNEVILLE: DAVE MARTIN.
DR. MARTIN: YES.
MS. BONNEVILLE: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: YES.
MS. BONNEVILLE: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.

MS. BONNEVILLE: KAROL WATSON.

DR. WATSON: YES.

MS. BONNEVILLE: THANK YOU. THE MOTION CARRIES.

CHAIRMAN THOMAS: THANK YOU, MARIA. THAT CONCLUDES THE CLINICAL AWARD PORTION OF THE AGENDA. WE ARE NOW GOING TO GO ON TO THE DISCOVERY 2 AWARDS WHICH READS: PARTNERING OPPORTUNITIES FOR DISCOVERY STAGE RESEARCH PROJECTS. WE'RE GOING TO START WITH A PRESENTATION BY GIL.

DR. SAMBRANO: THANK YOU, MR. CHAIRMAN. LET ME SHARE THAT PRESENTATION.

OKAY. SO THESE ARE THE RECOMMENDATIONS FROM THE GRANTS WORKING GROUPING RELATED TO THE DISC2 REVIEW. I JUST WANT TO GIVE YOU SOME BACKGROUND ON WHERE THE DISC2 FITS IN OUR OVERALL SET OF FUNDING OPPORTUNITIES SINCE IT'S BEEN A WHILE SINCE WE'VE SEEN THE DISCOVERY OPPORTUNITY COME TO THE BOARD.

SO THIS, AS YOU KNOW, IS PART OF OUR RELAUNCH OF THE THREE CORE PROGRAMS OF DISCOVERY, TRANSLATION, AND CLINICAL. AND SO THE DISCOVERY 2 OR QUEST, AS IT IS ALSO NAMED, FITS RIGHT AT THE BEGINNING. SO THIS IS A TWO-YEAR AWARD THAT IS INTENDED TO PRODUCE A SINGLE PRODUCT THAT WOULD BE

READY FOR TRANSLATIONAL WORK AND FEEDS THE WORK THAT GOES INTO OUR TRANSLATION OPPORTUNITY AND ULTIMATELY INTO THE CLINIC. AND SO -- OH, AND THEN JUST ONE MORE IMPORTANT ELEMENT. SO THE OFFERINGS THAT WE HAVE FOR THIS PROGRAM ARE TYPICALLY TWO PER YEAR. WE HAVE ANOTHER DEADLINE THAT'S JUST NEXT MONTH ON SEPTEMBER 9TH FOR THE QUEST2 WITH THE IDEA THAT WE WANT TO CONTINUE TO HAVE THESE OPPORTUNITIES AVAILABLE SO THAT APPLICANTS CAN BRING BACK THEIR APPLICATIONS AND REAPPLY. AND YOU WILL SEE THAT A LOT OF THE APPLICATIONS HAD DECENT SCORES IN THIS ROUND, AS THEY OFTEN DO, WITH THE IDEA FROM THE GRANTS WORKING GROUP THAT THESE WOULD COME BACK FOR A FUTURE CYCLE BY JUST SIMPLY ADDRESSING SOME OF THE CONCERNS THAT WERE BROUGHT UP.

SO ABOUT THE QUEST PROGRAM OR DISC2. THE GOAL OF THIS PROGRAM IS TO PROMOTE DISCOVERY OF PROMISING NEW STEM CELL OR GENE THERAPY-BASED TECHNOLOGIES THAT CAN BE TRANSLATED TO ENABLE BROAD USE AND ULTIMATELY IMPROVE PATIENT CARE. THE PROJECTS THAT ARE FUNDED UNDER THIS MECHANISM SHOULD PROPOSE TECHNOLOGIES THAT ARE UNIQUELY ENABLED BY HUMAN STEM PROGENITOR CELLS OR DIRECTLY REPROGRAMMED CELLS OR ARE IN SOME WAY UNIQUELY ENABLING FOR THE ADVANCEMENT OF THE STEM CELL-BASED OR A GENE

THERAPY.

AND WE ARE LOOKING FOR PROJECTS THAT ARE GOING TO ULTIMATELY BE ABLE TO DEVELOP A NOVEL CANDIDATE PRODUCT. THAT PRODUCT CAN BE A THERAPEUTIC, A DIAGNOSTIC, A MEDICAL DEVICE, OR A TOOL, BUT THE KEY IS THAT IT BE READY FOR TRANSLATIONAL STUDIES WITHIN TWO YEARS. AT THAT POINT THEY SHOULD SHOW DISEASE MODIFYING ACTIVITY IF IT'S A THERAPEUTIC CANDIDATE IN SOME RELEVANT MODEL OR HAVE DEVELOPED A PROTOTYPE WHERE THEY'VE SHOWN PROOF OF CONCEPT IF A DIAGNOSTIC DEVICE OR A TOOL. AND, OF COURSE, IF IT'S SUCCESSFULLY REALIZED, THE CANDIDATE SHOULD OFFER THE POTENTIAL TO IMPROVE PATIENT CARE OR IN SOME WAY FACILITATE DISCOVERY DEVELOPMENT OR USE OF THE STEM CELL OR GENE THERAPY.

AND JUST AS AN ILLUSTRATION OF WHERE THIS DISC2 PROGRAM FITS, AS MENTIONED, THIS IS A TWO-YEAR, 24-MONTH AWARD. AND SO OVER THOSE 24 MONTHS, THE EXPECTATION IS THAT THE APPLICANT WILL PRODUCE A SINGLE CANDIDATE THAT IS GOING TO BE READY FOR TRANSLATIONAL STUDIES. AND PART OF THAT MAY ALSO INCLUDE DEVELOPING A TAG PRODUCT PROFILE DEMONSTRATING THE DISEASE MODIFYING ACTIVITY OR PROOF OF CONCEPT.

THE REVIEW CRITERIA WHICH, AGAIN, SIMILAR

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TO THE REVIEW CRITERIA FOR CLIN, ARE FOCUSED ON DETERMINING THE NECESSARY SIGNIFICANCE AND POTENTIAL FOR IMPACT, WHETHER IT HAS SOUND RATIONALE, IF THE PROJECT IS WELL-PLANNED AND DESIGNED, IF IT'S FEASIBLE, AND IF IT ADDRESSES THE NEEDS OF THE UNDERSERVED.

THE SCORING SYSTEM IS A BIT DIFFERENT. IT IS A SCALE OF ONE TO A HUNDRED. SO THOSE THAT RECEIVE A SCORE BETWEEN 85 AND A HUNDRED ARE GIVEN A RECOMMENDATION TO FUND. THOSE THAT RECEIVE A SCORE BETWEEN 1 AND 84 ARE NOT RECOMMENDED FOR FUNDING. AND ALL APPLICATIONS ARE SCORED BY ALL THE SCIENTIFIC MEMBERS OF THE GRANTS WORKING GROUP THAT DON'T HAVE A CONFLICT, AND WE USE THE MEDIAN AS DETERMINANT OF THE SCORE.

A WORD ABOUT MINORITY REPORTS. SO YOU WILL SEE THAT THERE ARE A COUPLE OF APPLICATIONS THAT QUALIFIED FOR A MINORITY REPORT. AND SO THIS IS A NEW ELEMENT UNDER PROP 14. ANY APPLICATION THAT'S NOT RECOMMENDED FOR FUNDING BY THE GRANTS WORKING GROUP BUT WHICH RECEIVES 35 PERCENT OR MORE OF THE MEMBERS SCORING TO FUND THE APPLICATION MUST INCLUDE A MINORITY REPORT. SO ANYTHING THAT RECEIVES 50 PERCENT OR MORE OBVIOUSLY GETS RECOMMENDED; ANYTHING THAT IS BETWEEN 35 AND 50

WOULD HAVE A MINORITY REPORT. AND SO THE MINORITY REPORT IS INCLUDED IN THE REVIEW SUMMARY THAT WAS PROVIDED, AND IT'S A BRIEF SYNOPSIS OF THE OPINION OF REVIEWERS THAT SCORED THE APPLICATION 85 OR ABOVE. AND SO IN MOST CASES, THIS REPRESENTS AN AGGREGATION OF THOSE COMMENTS. IT DOESN'T NECESSARILY MEAN THAT THOSE MEMBERS CAME TOGETHER TO ARRIVE AT THIS SPECIFIC RECOMMENDATION.

SO ALSO A WORD ABOUT POSITIVE SELECTION OR A TWO-STAGE REVIEW PROCESS. SO WE USED THIS PROCESS IN THE DISC2 QUEST REVIEW IN THIS CYCLE. AND WE DO THIS WHEN WE HAVE A TOTAL NUMBER OF APPLICATIONS THAT EXCEEDS THE CAPACITY OF THE GRANTS WORKING GROUP TO REVIEW IN A SINGLE SESSION OR CYCLE. AND SO WHAT HAPPENS HERE IN THE FIRST STAGE, THE PANEL ITSELF, INCLUDING OUR PATIENT ADVOCATE MEMBERS, CONDUCT A PREREVIEW OF ALL OF THE APPLICATIONS AND THEY SELECT WHICH ONES TO ADVANCE TO A FULL REVIEW. AND THEN WE HAVE THE CIRM TEAM EXAMINE THE NONSELECTED APPLICATIONS TO DETERMINE IF ANY MERIT A FULL REVIEW. AND THEN SO THOSE THAT ARE NOT SELECTED ARE NOT CONSIDERED FURTHER.

AND FOR THIS PARTICULAR CYCLE, WE HAVE A TOTAL OF 103 ELIGIBLE APPLICATIONS THAT WERE REVIEWED AND 57 THAT WERE SELECTED TO ADVANCE TO THE

FULL DISCUSSION BY THE GRANTS WORKING GROUP.

SO THE GRANTS WORKING GROUP RECOMMENDATION, BASED ON THOSE 57, IS SHOWN HERE. THERE WERE TEN APPLICATIONS THAT WERE RECOMMENDED FOR FUNDING WITH A TOTAL APPLICANT REQUEST OF 12 MILLION THAT WOULD COVER THOSE TEN. WE HAVE 22 MILLION THAT WAS ALLOCATED FOR THE FIRST YEAR. THIS FALLS INTO THE FIRST FUNDING YEAR OF CIRM. SO WE HAD 22 MILLION AVAILABLE. SO CERTAINLY MORE THAN IS REQUESTED.

AND THEN JUST A NOTE THAT FOR EACH AWARD, THEY WON'T EXCEED THE AMOUNT APPROVED BY THE BOARD, AND IT ALSO WILL BE CONTINGENT ON CIRM'S SUBSEQUENT ASSESSMENT OF ALLOWABLE COSTS AND ACTIVITIES.

I DO WANT TO SAY THAT THE TEN THAT ARE RECOMMENDED DO REPRESENT A VARIETY OF APPROACHES THAT RANGE FROM CELL/GENE THERAPIES TO SMALL MOLECULES, AND SOME RESEARCH TOOLS. THERE'S ALSO A VARIETY OF INDICATIONS THAT ARE ADDRESSED, SUCH AS ANGELMAN SYNDROME, ALS, HEART FAILURE, DYSTROPHIC EPIDERMOLYSIS BULLOSA, PANCREATIC CANCER, AND OTHERS.

SO IN ADDITION, I WANT TO ADDRESS THE CIRM TEAM RECOMMENDATIONS. AND SO THE CIRM TEAM TYPICALLY REVIEWS THE RECOMMENDATIONS OF THE GRANTS

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WORKING GROUP INCLUDING THE MINORITY REPORTS AND PROCESS ELEMENTS THAT MAY HAVE IMPACTED ON THE REVIEW. AND SO OUR TEAM RECOMMENDATION CONCURS WITH THE GRANTS WORKING GROUP RECOMMENDATIONS FOR THE TEN THAT ARE RECOMMENDED FOR FUNDING, BUT WE ALSO SUPPORT THE MINORITY POSITION FOR APPLICATION DISC2-12358 AND ALSO RECOMMEND THE FUNDING OF THAT PARTICULAR APPLICATION.

AND SO THE TITLE OF THAT ONE IS "IPSC'S AS A SCREENING TOOL TO PREDICT THE RISK OF NONALCOHOLIC FATTY LIVER DISEASE." THE FUNDS REQUESTED FOR THAT ONE ARE 813,000, AND IT RECEIVED A SCORE OF 80.

NOW, THE RATIONALE FOR RECOMMENDING THIS ONE IS THAT THERE WAS A MAJOR CONCERN, AND IT SEEMED TO BE A SINGULAR CONCERN, THAT CAUSED MOST REVIEWERS TO SCORE THIS APPLICATION BELOW 85. AND THAT IS THAT THE PROPOSED, AND THIS IS FOR A DIAGNOSTIC, SO THE DIAGNOSTIC WOULD UTILIZE UNDIFFERENTIATED IPSC CELLS THAT DO NOT EXPRESS RELEVANT LIVER PATHWAY GENES RATHER THAN USING DIFFERENTIATED LIVER CELLS. HOWEVER, SEVERAL OF THE REVIEWERS, INCLUDING TWO OF THE ASSIGNED REVIEWERS, DISAGREED, CITING COMPELLING PRELIMINARY DATA SHOWING THAT THOSE RELEVANT GENES ARE INDEED EXPRESSED IN THE IPSC CELLS AS SHOWN BY THE APPLICANT BOTH IN THE PRELIMINARY DATA IN THE

APPLICATION AND IN A PUBLICATION THAT WAS SUBMITTED BY THE APPLICANTS FOLLOWING THE SUBMISSION OF THE APPLICATION THAT DIRECTLY ADDRESSES THE CONCERN.

AND SO GIVEN THAT THE SCORE QUALIFIED THIS AS FOR A MINORITY REPORT, WE SOUGHT CLARIFICATION FROM REVIEWERS, DETERMINED THAT THE PRELIMINARY DATA AND THE PUBLICATION THAT WAS NOTED BY THE MINORITY GROUP WAS LIKELY MISSED BY THE SPECIALIST REVIEWER THAT RAISED THE CONCERN TO BEGIN WITH AND LED THE MAJORITY OF REVIEWERS TO SCORE THIS BELOW 85. AND SO WE BELIEVE THAT IF THIS ISSUE HAD BEEN CLARIFIED AT THE REVIEW, THE APPLICATION WOULD HAVE LIKELY RECEIVED A HIGHER SCORE. AND SO THAT'S THE REASON FOR SPECIFICALLY RECOMMENDING THIS ONE ABOVE OTHERS.

AND LET ME JUST END THIS SO I CAN SHOW YOU ALSO THE LIST OF APPLICATIONS. GIVE ME A SECOND. SO HOPEFULLY YOU CAN SEE THE APPLICATIONS, THE TEN THAT ARE RECOMMENDED SHOWN IN GREEN. THIS IS ONE UNDER THE LINE THAT HAS AN M HERE THAT HAD A MINORITY REPORT THAT RECEIVED A SCORE OF 84. THERE ARE, I BELIEVE, 15 APPLICATIONS THAT RECEIVED A SCORE OF 80, AMONG THEM THE ONE THAT WE ARE ALSO RECOMMENDING HERE, 12358.

SO, MR. CHAIRMAN.

CHAIRMAN THOMAS: THANK YOU, GIL. I JUST

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WANT TO, PARTICULARLY FOR THE NEWER BOARD MEMBERS, REITERATE CERTAIN OF THE POINTS THAT GIL JUST MADE. UNLIKE THE CLINICAL AWARDS, WE DO HAVE A DIFFERENT SCORING SYSTEM. THIS IS 85 AND ABOVE. IF AN APPLICATION IS RANKED BELOW 85 OR SCORED, I SHOULD SAY, BELOW 85, IT'S DONE SO FOR A REASON, WHICH ISN'T TO SAY IT'S NOT A GOOD GRANT, BUT IT IS A GRANT THAT HAS ISSUES THAT COULD BE RECTIFIED AND HELP THE APPLICATION IN A SUBSEQUENT REFILING. THE COMMENTS THAT ARE GIVEN TO THE APPLICANTS GO TO HELP THAT EFFORT. AND SO EVEN THOUGH SOMETHING MAY APPEAR TO BE VERY CLOSE TO AN 85, THE COLLECTIVE WISDOM OF THE GWG WAS SUCH THAT IT SHOULD NOT BE FUNDED AT THIS TIME, BUT COULD LIKELY BE FUNDED AT A LATER DATE UPON RESUBMISSION.

IT JUST SO HAPPENS HERE, AS GIL NOTED, THAT RESUBMISSION HERE IS IN LESS THAN THREE WEEKS. IT'S ON SEPTEMBER 9TH. SO THESE ARE PROJECTS THAT WILL ALL BE ABLE, SHOULD THEY SO CHOOSE, TO COME BACK TO THE BOARD -- I'M SORRY -- COME BACK TO THE GWG FOR A NEW REVIEW IN VERY SHORT ORDER.

THE OTHER THING TO MENTION, PLAYING OFF GIL'S COMMENTS AS WELL, IS THE INTERNAL CIRM TEAM WITH RESPECT TO ALL APPLICATIONS GOES BACK AND REVIEWS THE ANALYSIS AND SCORING OF THE GWG TO COME

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UP WITH ITS COLLECTIVE RECOMMENDATION TO THE BOARD FOR ANY PROJECTS THEY BELIEVE THAT WERE ORIGINALLY SCORED BELOW THE FUNDING LINE SHOULD BE ELEVATED INTO THE TIER I ABOVE 85.

AND SO WHAT YOU'RE HEARING TODAY IS THE PRODUCT OF -- COLLECTIVE PRODUCT OF THE GWG AND THE CIRM TEAM'S BEST ANALYSIS ON WHICH PROJECTS SHOULD BE FUNDED OR CONSIDERED FOR FUNDING BY THE BOARD AT THIS TIME. SO WITH THAT IN MIND, WE HAVE NOW BECAUSE WE HAVE SORT OF THE -- THIS IS A LITTLE DIFFERENT IN THE PROCESS HERE. FIRST OF ALL, WE HAVE DISC2-12358 WHICH GIL AND THE TEAM RECOMMEND BE MOVED FROM TIER II TO TIER I. WITH RESPECT TO THAT PROJECT SPECIFICALLY, DO WE HAVE A MOTION TO MOVE IT UP AS SUGGESTED?

DR. MARTIN: SO MOVED. IT'S DAVE MARTIN.

CHAIRMAN THOMAS: MOVED BY DAVE MARTIN. IS THERE A SECOND?

DR. HIGGINS: I'LL SECOND IT IN SAN DIEGO.

CHAIRMAN THOMAS: SECONDED BY DAVID HIGGINS. THANK YOU. QUESTIONS OR COMMENTS BY MEMBERS OF THE BOARD?

MS. DURON: MR. CHAIR, THIS IS YSABEL.

CHAIRMAN THOMAS: YES, MA'AM.

MS. BONNEVILLE: YSABEL, YOU CANNOT

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COMMENT ON THIS. THANK YOU.

MS. DURON: OH, I'M SORRY.

CHAIRMAN THOMAS: OKAY. OTHER COMMENTS, MEMBERS OF THE BOARD? IS THERE ANY PUBLIC COMMENT ON THIS ONE SPECIFIC APPLICATION?

MS. BONNEVILLE: THERE IS PUBLIC COMMENT.

CHAIRMAN THOMAS: MARIA, COULD YOU --

MS. BONNEVILLE: SURE. DR. MEDINA, WOULD YOU LIKE TO START. YOU HAVE THREE MINUTES FOR PUBLIC COMMENT.

DR. MEDINA: YES. THANK YOU SO MUCH. GOOD MORNING. MY NAME IS MARISA MEDINA, AND I'M AN ASSOCIATE PROFESSOR AT UCSF.

AND FIRST OFF, I'D REALLY LIKE TO THANK YOU IN ADVANCE FOR YOUR TIME AND CONSIDERATION TO -- FOR MY REQUEST TO FUND MY DISC2 APPLICATION.

YOU SHOULD KNOW THAT NONALCOHOLIC FATTY LIVER DISEASE WILL SOON BECOME THE LEADING CAUSE OF LIVER TRANSPLANT, AND THERE IS NO UNIVERSAL SCREENING FOR THIS DISEASE. THUS, PEOPLE WHO HAVE IT REMAIN UNDIAGNOSED UNTIL THEY ARE IN ADVANCED STAGES, WHICH IS TRULY UNFORTUNATE BECAUSE THERE ARE CURRENTLY NO TARGETED DRUGS TO TREAT THIS DISEASE. AND SO IF IT CAN BE CAUGHT EARLY, IT CAN ACTUALLY BE REVERSED AND PREVENTED WITH DIET AND LIFESTYLE

CHANGES.

IT'S WELL-KNOWN THAT NONALCOHOLIC FATTY LIVER DISEASE DISPROPORTIONATELY IMPACTS THE LATIN-X POPULATION AND IN PARTICULAR THOSE OF MEXICAN ORIGIN WHO SUFFER FROM BOTH GREATER DISEASE PREVALENCE AND MORE SEVERE DISEASE. AND THIS INCREASED RISK IS DUE IN PART TO GENETIC FACTORS. AND SO IF YOU CAN IDENTIFY HIGH RISK INDIVIDUALS EARLY ON, SUCH AS ADOLESCENTS WITH PARENTS NEWLY DIAGNOSED WITH SEVERE DISEASE, THAT COULD ENCOURAGE STRONGER EFFORTS TOWARDS DISEASE PREVENTION.

AND SO WE PROPOSE TO CREATE A RISK SCORE BASED ON THE FUNCTIONAL ASSESSMENT OF PATIENT-DERIVED IPSC'S TO PROTECT AN INDIVIDUAL'S FUTURE RISK FOR DEVELOPING NONALCOHOLIC FATTY LIVER DISEASE.

I BELIEVE THIS TYPE OF ASSAY WOULD REALLY HELP REALIZE THE PROMISE FOR THE USE OF IPSC'S IN PRECISION MEDICINE. AND AS DR. SAMBRANO SAID, THERE WAS A LOT OF ENTHUSIASM FOR THIS PROPOSAL. I THINK HE ALREADY INDICATED THAT THE MAJOR CONCERN WAS OUR USE OF UNDIFFERENTIATED IPSC'S; BUT AS WE SHOWED IN OUR PILOT DATA, WE BELIEVE THAT THE UNDIFFERENTIATED IPSC'S CAN STILL BE A VERY INFORMATIVE MODEL. AND IN A LOT OF CASES FOR STEM CELL APPLICATIONS,

DIFFERENTIATED CELLS ARE REALLY CRITICAL; BUT FOR A DIAGNOSTIC TEST, THAT'S NOT NECESSARILY TRUE WHERE THE TEST HAS TO BE ROBUST AND EASY TO IMPLEMENT, AS INEXPENSIVE AS POSSIBLE, BUT YET STILL PROVIDE CLINICALLY RELEVANT INFORMATION. AND OUR PILOT DATA REALLY SHOWS THAT THE UNDIFFERENTIATED IPSC'S CAN HIT ALL OF THESE MARKS.

AND SO, LASTLY, I JUST WANTED TO MENTION THAT THIS PROPOSAL UTILIZES THE CIRM IPSC REPOSITORY OF NOVEL CASES AND CONTROLS, AND SO I THINK IT BELIEVES -- INDICATES PRIOR SUPPORT FOR CIRM IN SUPPORTING NOVEL BASED RESEARCH AND ALSO THAT THIS PROJECT HAS SERVED AS THE BASIS FOR MY LAB TO MENTOR MANY HIGH SCHOOL STUDENTS OVER THE PAST SEVERAL SUMMERS THROUGH THE CIRM SPARK PROGRAM.

AND, AGAIN, I RESPECTFULLY REQUEST THAT YOU RECONSIDER MY PROPOSAL FOR FUNDING, AND I THANK YOU SO MUCH FOR YOUR TIME.

CHAIRMAN THOMAS: THANK YOU, DR. MEDINA. ADDITIONAL PUBLIC COMMENT?

MS. BONNEVILLE: YES. I SEE ANTONIO MUNOZ POWELL HAS HIS HAND RAISED. IF YOU'D LIKE, IT'S THREE MINUTES. THANK YOU.

CHAIRMAN THOMAS: PLEASE INTRODUCE YOURSELF AS WELL.

MR. MUNOZ: YEAH. HELLO. I'D LIKE TO SAY THANK YOU TO THE BOARD FOR HEARING MY PUBLIC COMMENT. MY NAME IS ANTONIO MUNOZ. I'M ACTUALLY A RESEARCH TECHNICIAN IN DR. MEDINA'S LABORATORY. I'VE BEEN WORKING DIRECTLY WITH THIS PROJECT FOR THE PAST FIVE YEARS. MY MASTER'S DEGREE, WHICH GOT AWARDED TWO WEEKS AGO, ACTUALLY WAS BASED ON THIS PROJECT.

I JUST WANT TO POINT OUT THAT THIS PROJECT SORT OF HAS A PERSONAL TOUCH FOR ME BECAUSE THIS DISEASE SORT OF RUNS IN MY FAMILY. MY MOM WAS RECENTLY DIAGNOSED WITH IT BASED ON A LIVER BIOPSY. AND SO WITH THE KIND OF IMPACT, I THINK, THAT THIS SORT OF DIAGNOSTIC TEST WOULD HAVE, YOU KNOW, I'M YOUNG ENOUGH PERSONALLY TO BE ABLE TO ADJUST MY LIFESTYLE AND DIET ACCORDINGLY, BUT I THINK THAT THIS SORT OF WORK WOULD HAVE AN IMPACT ON OTHER FOLKS WHO IT MIGHT RUN IN THEIR FAMILY AS WELL.

AND SO I JUST WANT TO SAY THANK YOU TO THE BOARD AGAIN FOR HEARING MY PUBLIC COMMENT, AND I HOPE YOU TAKE IT INTO CONSIDERATION. THANK YOU.

CHAIRMAN THOMAS: THANK YOU. MARIA, ANY ADDITIONAL PUBLIC COMMENT?

MS. BONNEVILLE: NONE THAT I SEE.

CHAIRMAN THOMAS: OKAY. THANK YOU. COULD

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YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: DAN BERNAL.

MR. BERNAL: AYE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE. MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: AYE.

MS. BONNEVILLE: FRED FISHER.

DR. FISHER: AYE.

MS. BONNEVILLE: LEONDRA CLARK-HARVEY. DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: YES.

MS. BONNEVILLE: RICH LAJARA.

MR. LAJARA: AYE.

MS. BONNEVILLE: DAVE MARTIN.

DR. MARTIN: YES.

MS. BONNEVILLE: LAUREN MILLER-ROGEN.

MS. MILLER-ROGEN: YES.

MS. BONNEVILLE: ADRIANA PADILLA.

DR. PADILLA: YES.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: YES.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: YES.

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MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: THE MOTION CARRIES.

CHAIRMAN THOMAS: THANK YOU. OKAY. THE NEXT QUESTION IS ARE THERE ANY MOTIONS BY THE MEMBERS OF THE BOARD TO MOVE ANY OF THE TIER II APPLICATIONS UP TO TIER I?

MR. PANETTA: MR. CHAIRMAN.

CHAIRMAN THOMAS: YES.

MR. PANETTA: JOE PANETTA. MAY I ASK A QUESTION FIRST PLEASE?

CHAIRMAN THOMAS: CERTAINLY.

MR. PANETTA: I WOULD, I THINK, LIKE TO MAKE A MOTION TO MOVE APPLICATION 12694 TO TIER I. IT'S THE ONE THAT FALLS JUST BELOW THE LINE, BUT MY QUESTION ACTUALLY IS IF WE COULD POSSIBLY GET MORE EXPLANATION AS TO WHY THIS APPLICATION SITS WHERE IT DOES BECAUSE IT RECEIVED A SIGNIFICANT AMOUNT OF SUPPORT FROM THE GRANTS WORKING GROUP AND THE STAFF.

CHAIRMAN THOMAS: GIL.

DR. SAMBRANO: SO, YES, ABSOLUTELY. SO THIS APPLICATION SCORED AN 84. AND SO I CAN GIVE YOU A LITTLE BIT OF BACKGROUND ON IT. SO THE TITLE OF IT IS "PRECLINICAL DEVELOPMENT OF AN EXHAUSTION-RESISTANT CAR-T STEM CELL FOR CANCER

IMMUNOTHERAPY." SO THE IDEA BEHIND THIS IS TO CREATE A FOUNDATION BASICALLY FOR DEVELOPING CAR-T CELLS THAT CAN BE EFFECTIVE AGAINST DIFFERENT CANCER TYPES AND THAT WILL ENHANCE THE CAR-T IN A WAY THAT ALLOWS IT TO PERSIST FOR A LONGER PERIOD OF TIME, WHICH IS AN ISSUE IN SOME CASES FOR SOME CAR-T CELL THERAPIES.

AND SO THE UNDERLYING REASON WHY IT WAS NOT RECOMMENDED OR WHY IT FELL JUST BELOW THE LINE, CERTAINLY THIS IS A GREAT GOAL AND A GOOD IDEA. I THINK REVIEWERS FELT THAT THE WAY THE STUDY WAS DESIGNED WAS A BIT TOO AMBITIOUS AND UNFOCUSED. SO THERE WERE PERHAPS TOO MANY INDICATIONS THAT WERE BEING PURSUED UNDER A SINGLE AWARD. AND THE LIKELIHOOD OF GETTING A GOOD CANDIDATE AND GOOD DATA TO SUPPORT IT WOULD END UP BECOMING LESS FEASIBLE. AND SO I THINK THAT REALLY WAS THE CORE OF IT. THEY WERE, LIKE MANY OF THE APPLICATIONS BELOW THAT, DESPITE THIS ONE SCORING AN 84 VERSUS THE 16 THAT SCORED AN 80 BELOW IT, I THINK THERE WAS A GENERAL THEME WITH THE GRANTS WORKING GROUP THAT THERE WERE MANY PROMISING PROPOSALS THAT THEY FELT HAD REALLY GOOD IDEAS AND HAD GOOD POTENTIAL OUTCOMES, BUT NEEDED SOME TWEAKING OR ADJUSTMENT TO EITHER THEIR PLAN, I THINK AS IN THIS CASE, IN TERMS OF HOW

THEY -- WHAT THEY PROPOSE TO DO SPECIFICALLY UNDER THIS AWARD TO MAKE IT ACHIEVABLE AS WELL AS ANY OTHER TWEAK. SO THAT'S THE REASON WHY IT FELL AT JUST BELOW THE LINE.

CHAIRMAN THOMAS: AND, GIL, JUST, AGAIN, TO MAKE SURE, THE DATES OUT THERE, FOR THE THIRD TIME, THIS IS A PRIME EXAMPLE OF A PROJECT THAT COULD REAPPLY ON SEPTEMBER 9TH FACTORING IN COMMENTS FROM THE GWG, CORRECT?

DR. SAMBRANO: CORRECT.

MR. PANETTA: MR. CHAIRMAN, I THINK THAT ANSWERS MY QUESTION. IT WAS AN APPLICATION THAT RECEIVED ALMOST A SPLIT VOTE AND A HIGH SCORE OF 87 AND CERTAINLY, AS GIL SAID, VERY IMPORTANT AREA OF RESEARCH. AND I WOULD HOPE THAT THE APPLICANTS THEN WOULD COME BACK IN A FEW WEEKS WITH A MORE FOCUSED APPLICATION AND THAT IT WOULD BE RECONSIDERED.

CHAIRMAN THOMAS: THANK YOU, JOE.

ANY MEMBERS OF THE BOARD, JUST TO REPEAT, WANT TO MOVE TO ELEVATE ANY OF THE GRANTS IN TIER II TO TIER I? HEARING NONE, ARE THERE ANY MEMBERS OF THE BOARD WHO WOULD LIKE TO DEMOTE ANY OF THE GRANTS IN TIER I TO TIER II? OKAY. HEARING NONE, THEN DO WE HAVE A MOTION TO NOT FUND THE REMAINING APPLICATIONS IN TIER II?

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MR. ROWLETT: SO MOVED GIVEN THAT THE APPLICATIONS HAVE AN OPPORTUNITY TO -- THE APPLICATIONS THAT SCORED HIGH, ALTHOUGH NOT IN THE FUNDING LEVEL, HAVE AN OPPORTUNITY TO RESUBMIT IN THE VERY NEAR FUTURE.

CHAIRMAN THOMAS: MOVED BY MR. ROWLETT. IS THERE A SECOND?

MR. JUELSGAARD: STEVE JUELSGAARD. I SECOND.

CHAIRMAN THOMAS: SECONDED BY MR. JUELSGAARD. ANY COMMENTS OR QUESTIONS FROM MEMBERS OF THE BOARD? ANY PUBLIC COMMENT?

MS. BONNEVILLE: FOR MEMBERS OF THE PUBLIC WHO WISH TO MAKE A COMMENT THAT ARE ON THE PHONE, YOU CAN PRESS STAR NINE AND THEN IT SHOULD SHOW UP THAT YOU WOULD LIKE TO MAKE A COMMENT. SO I'LL GIVE EVERYONE AN OPPORTUNITY FOR THAT. YEP. SEE A COUPLE HANDS RAISED. LET'S START WITH THE FIRST ONE WHICH IS FROM PHONE NO. 310-985-3454. IF YOU COULD UNMUTE YOURSELF, AND YOU HAVE THREE MINUTES FOR PUBLIC COMMENT.

DR. MARTIN: HI. GREETINGS. THIS IS DR. MARTIN. I'M ACTUALLY CALLING IN SUPPORT OF DISC2-12532. I'D LIKE TO THANK THE ICOC COMMITTEE FOR ALLOWING ME TO SPEAK REGARDING MY OWN EXPERIENCE

WITH ORAL MUCOSITIS, WHICH IS ACTUALLY THE FOCUS OF THIS PARTICULAR GRANT.

AS I MENTIONED, MY NAME IS DR. MARTIN. I'M A PROFESSOR OF PEDIATRICS AND VICE CHAIR OF ACADEMIC AFFAIRS IN TRANSLATIONAL RESEARCH AND A MEMBER OF THE BROAD STEM CELL FOUNDATION AT UCLA.

IN LATE 2010 I HAD AN OPPORTUNITY TO SPEAK IN THE SAME VENUE REGARDING MY CIRM GRANT INVOLVING HUMAN INTESTINAL STEM CELLS. I WAS FORTUNATE TO HAVE SEVERAL FAMILY MEMBERS WITH CHILDREN WITH INTESTINAL FAILURE THAT SPOKE ON MY BEHALF. I NEVER COULD HAVE ANTICIPATED THAT I WOULD WALK DOWN THOSE SAME PATHS JUST TWO WEEKS LATER WHEN I WAS DIAGNOSED WITH HEAD AND NECK CANCER.

BY CHANCE, MOMENTS AFTER STARTING MY FIRST I.V. CHEMOTHERAPY, I RECEIVED A WONDERFUL PHONE CALL FROM DR. SAMBRANO THAT I WAS AWARDED A CIRM GRANT. AND IT WAS THEN WHEN I ENTERED WHAT SOON I REALIZED WAS THE ENDLESS ABYSS OF CHEMOTHERAPY AND RADIATION THERAPY. AND, ONCE AGAIN, THIS FOCUSES ON ORAL MUCOSITIS. SO UNDOUBTEDLY PROBABLY THE WORST PORTION OF MY YEAR-LONG TREATMENT AND RECOVERY WAS SINGULARLY MY ORAL MUCOSITIS THAT WAS LIMITED BY DIET TO MARGINAL AMOUNTS OF FOOD, LIQUID, FORMULA, AND WATER. I SEARCHED ENDLESSLY FOR FOODS THAT I

COULD TOLERATE. EVENTUALLY I REALIZED THAT EVEN BABY FOODS WERE IMPOSSIBLE FOR ME TO EAT BECAUSE OF THE PAIN RESULTING FROM THE SEVERE ORAL MUCOSITIS. DESPITE THIS, I CONSIDER MYSELF FORTUNATE THAT IT DIDN'T REQUIRE GASTRONOMY TUBES. THIS PROLONGED COURSE OF DISCOMFORT SLOWLY DISSIPATED AFTER NINE MONTHS, BUT EVENTUALLY ADVANCING TO SEMISOLID FOODS WAS A STRUGGLE BECAUSE OF ORAL AVERSION.

SO CURRENT TREATMENTS FOR ORAL MUCOSITIS IS SUPPORTED AT BEST AIMED AT SYMPTOM CONTROL AND/OR SIMPLE MOUTHWASH SOLUTIONS CONSISTING OF SALINE AND ORAL OR SYSTEMIC ANALGESIC CONTROL WITH TOPICAL LIDOCAINE OR ORAL NARCOTICS. SO THIS PROPOSED THERAPY FAILED -- THE CURRENT THERAPIES FAILED TO TARGET THE UNDERLYING BASIS OF MUCOSITIS, AND I BELIEVE THAT THE PROPOSAL COULD PROVIDE BREAKTHROUGH THAT ADDRESSES AN ESSENTIAL UNMET NEED IN ORAL MUCOSITIS.

CHAIRMAN THOMAS: THANK YOU.

MS. BONNEVILLE: NEXT PUBLIC COMMENT IS FROM, I BELIEVE, 650-888-3616. SO IF YOU COULD UNMUTE YOURSELF PLEASE. OKAY. LET'S GO ON TO DR. D'LIMA, WHO'S NEXT ON THE LIST WITH HIS HAND RAISED.

DR. D'LIMA: THANK YOU, DR. BONNEVILLE. I

THANK THE MEMBERS OF THE ICOC COMMITTEE FOR THIS OPPORTUNITY TO SPEAK. I'M THE PI ON THE APPLICATION NUMBER DISC2-12610 FOR MENISCAL REGENERATION AND REPAIR. AND IN GENERAL ORTHOPEDIC DISEASES ARE UNDERREPRESENTED IN CIRM'S PORTFOLIO ESPECIALLY GIVEN THE LARGE NUMBER OF PATIENTS AFFECTED WITH ORTHOPEDIC DISORDERS AND THE NUMBER OF ROGUE STEM CELL CLINICS THAT THE FDA IS CONCERNED ABOUT. AND MORE SPECIFICALLY, MENISCAL DEGENERATION IS NOT IN THE CIRM PORTFOLIO. AND OUR APPLICATION WAS RANKED VERY HIGH ON SIGNIFICANCE AND IMPACT.

ONE WEAKNESS LISTED IN THE SCIENTIFIC REVIEW WAS THAT I SHOULD HAVE PROVIDED PRELIMINARY DATA SHOWING IN VIVO EVIDENCE OF TISSUE FORMATION WITH THE PROPOSED CELL LINE. I AGREE THAT THIS IS VERY IMPORTANT FOR CLINICAL TRANSLATION, BUT GENERATING THIS DATA IS THE OBJECTIVE OF A DISC2 QUEST AWARD. WE DID PRESENT IN VITRO EVIDENCE WITH OUR PROPOSED CELL LINE AND IN VIVO EVIDENCE WITH OTHER STEM CELL LINES.

THE REASON WE SELECTED OUR PROPOSED CELL LINE AS A THERAPEUTIC CANDIDATE OVER THE OTHERS WAS BECAUSE OF THE EXCELLENT PROVENANCE OF THE CELLS, THE VERY CLEAN SAFETY PROFILE, AND THE FACT THAT THESE CELL LINES HAVE ALREADY BEEN PREVIOUSLY

APPROVED BY THE FDA FOR CLINICAL TRIALS.

THE REVIEWERS WERE ALSO CONCERNED ABOUT ALLOGENEIC RESPONSE. WE HAVE CLINICAL EVIDENCE THAT THE MENISCUS IS AN IMMUNOPRIVILEGED TISSUE AND TOLERATES ALLOGENEIC CELLS VERY WELL. WE HAVE IMPLANTED LIVE MENISCAL ALLOGRAPHS IN PATIENTS WITH NO EVIDENCE OF ALLOGENEIC REJECTION. AND OUR PROPOSED CELL LINES RESEMBLE MESENCHYMAL STEM CELLS AND, AS SUCH, DON'T HAVE THE ANTIGENS THAT TRIGGER AN ALLOGENEIC RESPONSE. WE HAVE INJECTED OUR EMBRYONIC STEM CELL LINES IN MOUSE AND RABBIT KNEES AND HAVE IMPLANTED THESE CELLS IN SHEEP KNEES WITHOUT SEEING ANY XENOGENETIC REJECTION. AND WE HAVE A LETTER FROM THE FDA STATING THAT THEY AGREE WITH OUR CONCLUSION.

NEVERTHELESS, IN OUR APPLICATION WE HAVE PROPOSED TO CAREFULLY RULE OUT IMMUNE REJECTION IN OUR ANIMAL STUDIES. IT IS MY UNDERSTANDING THAT A QUEST AWARD FOR THE DISCOVERY PHASE OF A STEM CELL THERAPY SHOULD NOT BE JUDGED ON ITS APPARENT WEAKNESSES. I TRULY APPRECIATE THIS OPPORTUNITY TO SPEAK, AND I'D LIKE TO THANK YOU FOR YOUR SERVICE TO CIRM AS WELL AS A PROGRAM WHICH HAS TREMENDOUS POTENTIAL TO ENHANCE LIVES IN CALIFORNIA AND ALL OVER THE WORLD. THANK YOU.

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CHAIRMAN THOMAS: THANK YOU.

MS. BONNEVILLE: THANK YOU. NEXT I BELIEVE KEVIN MCCORMACK HAS FURTHER COMMENT TO MAKE FROM DON REED.

YOU HAVE TO UNMUTE YOURSELF, KEVIN. OKAY. PERHAPS HE CANNOT GET THROUGH. ALL RIGHT. THERE SEEMS TO BE NO FURTHER PUBLIC COMMENT.

DR. D'LIMA: IF I MAY SPEAK, I HAVE THE LETTER THAT DON REED SENT KEVIN.

MS. BONNEVILLE: OKAY. GREAT.

MR. PAMNANI: HI. THIS IS RAVI PAMNANI, CEO OF INTACT. I WAS TRYING TO UNMUTE MYSELF. WOULD IT BE OKAY TO MAKE A PUBLIC COMMENT?

MS. BONNEVILLE: RAVI, CAN YOU PLEASE -- WE HAVE ONE OTHER PUBLIC COMMENT THAT'S ABOUT TO BE MADE, AND THEN WE WILL MOVE TO YOUR PUBLIC COMMENT IF THAT'S OKAY.

MR. PAMNANI: OH, SURE. THANK YOU. THANK YOU VERY MUCH.

MS. BONNEVILLE: GO AHEAD, DR. D'LIMA.

DR. D'LIMA: YEAH. THANK YOU. SO THIS IS A LETTER FROM DON REED:

"DEAR MEMBERS OF THE ICOC BOARD. IN THE LAST YEARS OF HER LIFE, MY BELOVED GLORIA SUFFERED GREATLY FROM OSTEOARTHRITIS OF THE KNEES. SHE WOULD

PLAN HER DAY SO SHE ONLY HAD TO WALK DOWN THE STEPS ONCE IN THE MORNING AND BACK UP AT NIGHT. SHE HAD BASICALLY NO CARTILAGE REMAINING IN HER KNEE JOINTS. SO WHEN SHE WALKED, THERE WAS NO SHOCK ABSORBER, JUST BONE ON BONE, AND THE PAIN WAS STABBING.

"GLORIA WAS NOT ALONE. AN ESTIMATED 30 MILLION OTHER AMERICANS NEED TODAY WHAT DR. DARRYL D'LIMA IS ATTEMPTING TO PROVIDE, NEW KNEES, HYPHEN, HOMEGROWN. AS I UNDERSTAND IT, DR. D'LIMA WANTS TO DEVELOP A KNEE IMPLANT WITH A FIBROUS STRUCTURE OF BIODEGRADABLE SCAFFOLDS SEEDED WITH CELLS PROGRAMMED TO CHANGE THE MENISCAL CARTILAGE. IMAGINE LIVING IN CONSTANT PAIN FOR YEARS, MAYBE DECADES, AND THEN TO HAVE THAT SUFFERING STOP. THERE IS NO LUXURY GREATER THAN RELIEF FROM PAIN. IT WILL BE DIFFICULT, OF COURSE, BUT WHAT IS THAT COMPARED TO THE POSSIBLE REWARD FOR ALL AMERICANS? THINK PARTICULARLY OF THE YOUNG SUFFERERS WHO MIGHT OTHERWISE HAVE TO ENDURE CONTINUAL AGONY FOR DECADES. IT'S BAD ENOUGH TO BE 75 AND HAVE PAIN, BUT TO BE 50 AND SEE NO RELIEF AHEAD UNTIL THE END OF LIFE AND DR. D IS THE MAN TO CHANGE THAT MISERABLE SITUATION. HE HAS PUT IN THE TIME. HE HAS DONE HIS CHORES. TWENTY YEARS AGO HE WON THE BEST CARTILAGE BASIC SCIENCE AWARD FROM THE

INTERNATIONAL CARTILAGE REPAIR SOCIETY AND HAS STOOD OUT IN THIS FIELD EVER SINCE. I URGE THE PASSAGE OF APPLICATION NO. DISC2-12610. THANK YOU. DON C. REED."

THANK YOU.

MS. BONNEVILLE: THANK YOU, DR. D'LIMA. RAVI, IF YOU'D LIKE TO GO NEXT, YOU HAVE THREE MINUTES.

MR. PAMNANI: HI, EVERYONE. CAN YOU HEAR ME?

MS. BONNEVILLE: YES. RAVI, GO AHEAD. YOU'RE UNMUTED NOW. GO AHEAD.

MR. PAMNANI: OKAY. THANK YOU SO MUCH. THANK YOU FOR THE OPPORTUNITY TO SPEAK, MEMBERS OF THE BOARD. MY NAME IS RAVI PAMNANI, CEO OF INTACT THERAPEUTICS. OUR COMPANY'S APPLICATION DISC2-12532 FOCUSES ON THE DEVELOPMENT OF A FIRST-IN-CLASS STEM CELL TARGETING THERAPY FOR ORAL MUCOSITIS, AN EXCRUCIATINGLY PAINFUL YET COMMON COMPLICATION OF CANCER TREATMENT.

I WOULD LIKE TO THANK DR. MARTIN, A GASTROENTEROLOGIST AT UCLA AND A PREVIOUS CIRM AWARD RECIPIENT WHO SPOKE ABOUT HIS EXPERIENCES WITH ORAL MUCOSITIS EARLIER IN THE SESSION.

ORAL MUCOSITIS AFFECTS OVER 500,000 CANCER

PATIENTS PER YEAR AND IS SIGNIFICANTLY UNDERREPORTED DUE TO A LACK OF EFFECTIVE THERAPIES. WE ARE DEVELOPING A NOVEL MOUTHWASH FORMULATION LEVERAGING TECHNOLOGY FROM STANFORD UNIVERSITY. THE FORMULATION DELIVERS A REGENERATIVE PROTEIN WHICH RESTORES THE INJURED ORAL MUCOSA BY STIMULATING NATIVE STEM CELLS. THEY EVEN PROTECT THE MUCOSA AGAINST INITIAL INJURY. LOCAL APPLICATION AS A MOUTHWASH MAY ALSO REDUCE POTENTIAL SYSTEMIC SIDE EFFECTS.

WE ARE REALLY VERY EXCITED ABOUT DEVELOPING THIS TECHNOLOGY, AND WE LOOK FORWARD TO FURTHER FEEDBACK IN COLLABORATION WITH CIRM. THANK YOU FOR YOUR ATTENTION.

CHAIRMAN THOMAS: THANK YOU. MARIA, ARE THERE ANY OTHER PUBLIC COMMENTS AT THIS POINT?

MS. BONNEVILLE: NOT THAT I SEE, NO.

CHAIRMAN THOMAS: OKAY. WE HAVE A MOTION ON THE TABLE AND A SECOND, WHICH IS TO NOT FUND THE BALANCE OF THE APPLICATIONS IN TIER II WHILE ENCOURAGING THEM TO REAPPLY WHICH THEY WILL HAVE THE OPPORTUNITY TO IN VERY SHORT ORDER. MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: DAN BERNAL.

MR. BERNAL: AYE.

MS. BONNEVILLE: MARK FISCHER-COLBRIE.
DR. FISCHER-COLBRIE: AYE.
MS. BONNEVILLE: FRED FISHER.
DR. FISHER: AYE.
MS. BONNEVILLE: DAVID HIGGINS.
DR. HIGGINS: YES.
MS. BONNEVILLE: STEVE JUELSGAARD.
MR. JUELSGAARD: YES.
MS. BONNEVILLE: RICH LAJARA.
MR. LAJARA: AYE.
MS. BONNEVILLE: DAVE MARTIN.
DR. MARTIN: YES.
MS. BONNEVILLE: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: AYE.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: THE MOTION CARRIES.
CHAIRMAN THOMAS: THANK YOU, MARIA. LAST BUT NOT LEAST ON THIS PARTICULAR AGENDA TOPIC, DO WE

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HAVE A MOTION TO APPROVE ALL GRANTS LISTED IN TIER I?

DR. MARTIN: SO MOVED. DAVE MARTIN.

CHAIRMAN THOMAS: THANK YOU, DAVE. IS THERE A SECOND?

DR. FISHER: SECOND.

CHAIRMAN THOMAS: THANK YOU, FRED. MOVED AND SECONDED. QUESTIONS OR COMMENTS BY MEMBERS OF THE BOARD? HEARING NONE, MARIA, DO WE HAVE ANY PUBLIC COMMENTS ON TIER I GRANTS?

MS. BONNEVILLE: I DO NOT SEE ANY.

CHAIRMAN THOMAS: THANK YOU. WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: YES. AND IF BOARD MEMBERS COULD PLEASE RESPOND YES OR NO EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT WHEN YOUR NAME IS CALLED.

DAN BERNAL.

MR. BERNAL: AYE.

MS. BONNEVILLE: YSABEL DURON.

MS. DURON: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. BONNEVILLE: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: YES.

MS. BONNEVILLE: FRED FISHER.

DR. FISHER: YES.
MS. BONNEVILLE: ELENA FLOWERS. DAVID HIGGINS.
DR. HIGGINS: YES.
MS. BONNEVILLE: STEVE JUELSGAARD.
MR. JUELSGAARD: YES.
MS. BONNEVILLE: RICH LAJARA.
MR. LAJARA: YES.
MS. BONNEVILLE: DAVE MARTIN.
DR. MARTIN: YES.
MS. BONNEVILLE: CHRIS MIASKOWSKI.
DR. MIASKOWSKI: YES.
MS. BONNEVILLE: EXCEPT.
DR. MIASKOWSKI: EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.
MS. BONNEVILLE: THANK YOU.
LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: AYE.
MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: AYE EXCEPT FOR THOSE WITH WHICH I AM CONFLICTED.

MS. BONNEVILLE: KAROL WATSON.

DR. WATSON: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. BONNEVILLE: THANK YOU VERY MUCH. THE MOTION CARRIES.

CHAIRMAN THOMAS: THANK YOU, MARIA. THAT CONCLUDES THE ACTION ITEMS ON TODAY'S AGENDA. DO WE HAVE ANY PUBLIC COMMENT ON ANY TOPICS OF ANY KIND ANYONE WOULD LIKE TO SAY SOMETHING ABOUT? MARIA, HEARING NONE? I BELIEVE THAT THEN BRINGS US TO THE END OF THE MEETING. THANK YOU, EVERYBODY, AS ALWAYS, FOR YOUR ATTENTION. AND WE WILL SEE YOU, MARIA, NEXT WHEN?

MS. BONNEVILLE: SEPTEMBER. I WAS JUST LOOKING THROUGH THE DATES. I BELIEVE IT IS -- GOSH. YOU KNOW, I DON'T SEE IT ON MY CALENDAR, SO I CAN'T TELL YOU THE EXACT DATE, BUT I WILL SEND THAT OUT TO YOU.

DR. GUILLEN: IT'S THURSDAY, SEPTEMBER 23E, EVERYONE. THURSDAY, SEPTEMBER 23D.

MS. BONNEVILLE: WELL, THERE YOU GO.

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THANK YOU, DOUG.

CHAIRMAN THOMAS: THANKS, DOUG. OKAY. THANK YOU.

MR. ROWLETT: MR. CHAIRMAN, IF I COULD MAKE A QUICK COMMENT.

CHAIRMAN THOMAS: CERTAINLY, AL.

MR. ROWLETT: GIL, I WANTED TO EXPRESS THAT YOU ARE -- I KNOW YOU'VE DONE IT IN THE PAST, BUT TODAY, WHEN YOU PROVIDED US WITH AN UNDERSTANDING OF WHERE THE APPLICATIONS FIT IN THE CIRM PORTFOLIO, IT WAS VERY HELPFUL.

DR. SAMBRANO: THANK YOU.

CHAIRMAN THOMAS: THANK YOU. STEVE, AL, OR GIL, DO YOU HAVE ANY PARTICULAR COMMENTS ON ANY SUPPORTING ISSUES YOU'D LIKE TO MAKE AS WE HEAD INTO SEPTEMBER?

MR. TORRES: ALL RIGHT. I'M LEAVING. GOODBYE.

CHAIRMAN THOMAS: YOU CAN COMMENT TOO, ART.

MR. JUELSGAARD: I THINK WE ARE ALL QUITE HAPPY WITH WHERE THINGS STAND.

MR. ROWLETT: AYE.

CHAIRMAN THOMAS: ALL RIGHT. THANK YOU FOR YOUR COMMENTS.

MS. BONNEVILLE: THANK YOU SO MUCH.

CHAIRMAN THOMAS: THANKS, EVERYBODY. BYE-BYE.

MS. BONNEVILLE: BYE, EVERYONE.

(THE MEETING WAS THEN CONCLUDED AT 11:16 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 ZOOM PROCEEDINGS BEFORE THE APPLICATION REVIEW SUBCOMMITTEE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON AUGUST 24, 2021, 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.

BETH C. DRAIN, CA CSR 7152
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