## INDEX

<table>
<thead>
<tr>
<th>ITEM DESCRIPTION</th>
<th>PAGE NO.</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPEN SESSION:</td>
<td></td>
</tr>
<tr>
<td>1. CALL TO ORDER</td>
<td>3</td>
</tr>
<tr>
<td>2. ROLL CALL</td>
<td>3</td>
</tr>
<tr>
<td>3. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLIN1:</td>
<td>5</td>
</tr>
<tr>
<td>PARTNERING OPPORTUNITY FOR LATE STAGE PRECLINICAL PROJECTS</td>
<td></td>
</tr>
<tr>
<td>4. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO THE PARTNERING OPPORTUNITY FOR TRANSLATIONAL RESEARCH PROJECTS</td>
<td>11</td>
</tr>
<tr>
<td>CLOSED SESSION</td>
<td>NONE</td>
</tr>
<tr>
<td>5. 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 CLIN1: PARTNERING OPPORTUNITY FOR LATE STAGE PRECLINICAL PROJECTS AND THE PARTNERING OPPORTUNITY FOR TRANSLATIONAL RESEARCH PROJECTS</td>
<td></td>
</tr>
<tr>
<td>6. PUBLIC COMMENT</td>
<td>NONE</td>
</tr>
<tr>
<td>7. ADJOURNEMENT</td>
<td>26</td>
</tr>
</tbody>
</table>
CHAIRMAN THOMAS: I'D LIKE TO WELCOME EVERYBODY -- THIS IS J.T. -- TO THE REGULAR MEETING OF THE ICOC AND THE APPLICATION REVIEW SUBCOMMITTEE FOR MARCH 2017. WE ARE BROADCASTING TO YOU FROM THE CITY OF HOPE WHERE WE'RE IN THE PROCESS TODAY OF A MOST INFORMATIVE AND INTERESTING ALPHA CLINIC SYMPOSIUM THAT THE CITY OF HOPE IS HOSTING FOR OUR ALPHA CLINIC NETWORK.

AND WE HAVE FOLKS HERE FROM MEMBERS OF THE PUBLIC. WOULD LIKE TO HAVE MARIA CALL THE ROLL.

MS. BONNEVILLE: GEORGE BLUMENTHAL. DAVID BRENNER. KEN BURTIS. DEBORAH DEAS. ANNE-MARIE DULIEGE. HOWARD FEDEROFF. JUDY GASSON. SAM HAWGOOD. DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: STEVE JUELSGAARD.

DR. JUELSGAARD: HERE.

MS. BONNEVILLE: SHERRY LANSING. KATHY LAPORTE.

MS. LAPORTE: HERE.

MS. BONNEVILLE: BERT LUBIN. SHLOMO MELMED. LAUREN MILLER.
MS. MILLER: HERE.
MS. BONNEVILLE: LLOYD MINOR. ADRIANA PADILLA.
DR. PADILLA: HERE.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: HERE.
MS. BONNEVILLE: FRANCISCO PRIETO. CARMEN PULIAFITO. ROBERT QUINT.
DR. QUINT: HERE.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: HERE.
MS. BONNEVILLE: JEFF SHEEHY.
SUPERVISOR SHEEHY: HERE.
MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: HERE.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: HERE.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: HERE.
MS. BONNEVILLE: KRISTINA VUORI. DIANE WINOKUR.
CHAIRMAN THOMAS: THANK YOU, MARIA.
MS. WINOKUR: THIS IS DIANE WINOKUR.
MS. BONNEVILLE: THANK YOU, DIANE.
CHAIRMAN THOMAS: WE'RE GOING TO MOVE TO

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ITEM 3 IN THE AGENDA, WHICH IS CONSIDERATION OF
APPLICATIONS SUBMITTED IN RESPONSE TO CLIN1:
PARTNERING OPPORTUNITY FOR LATE STAGE PRECLINICAL
PROJECTS. AT THIS POINT I WILL TURN THE MEETING
OVER TO SUPERVISOR SHEEHY.

SUPERVISOR SHEEHY: THANK YOU, CHAIRMAN
THOMAS. DR. SAMBRANO, DO YOU HAVE A PRESENTATION?

DR. SAMBRANO: YES, I DO.

SUPERVISOR SHEEHY: GREAT. THANK YOU.

DR. SAMBRANO: GOOD MORNING, EVERYONE.

THIS IS AN APPLICATION THAT WE ARE BRINGING FOR YOUR
CONSIDERATION THAT WAS REVIEWED IN JANUARY. IT WAS
RESPONDING TO THE CLIN1, CLINICAL PROGRAM FOR
IND-ENABLELING WORK. THE APPLICANT APPEALED THAT, IT
HAS NOW BEEN RESOLVED, AND SO WE’RE BRINGING THIS
FOR YOUR CONSIDERATION TODAY.

A REMINDER OF A COUPLE OF NOTES IN THE
PROCESS. WHEN WE CONDUCT THE GWG REVIEW, WE HAVE
ALL MEMBERS OF THE GWG VOTE ON WHETHER THEY FELT
THAT THE REVIEW WAS CONDUCTED IN A SCIENTIFIC
RIGOROUS WAY, THAT THERE WAS SUFFICIENT TIME ALLOWED
FOR ALL VIEWPOINTS TO BE HEARD, AND THAT THE SCORES
REFLECT THE RECOMMENDATION OF THE GWG. OUR PATIENT
ADVOCATE MEMBERS WHO ARE ALSO MEMBERS OF THIS BOARD
ALSO VOTE ON WHETHER THEY FEEL THE REVIEW IS CARRIED
OUT IN A FAIR MANNER AND WAS FREE FROM UNDUE BIAS.

IN THIS CASE, AS WAS FOR ALL THE APPLICATIONS REVIEWED DURING THIS CYCLE, THE VOTE WAS UNANIMOUS IN FAVOR OF BOTH STATEMENTS THAT WERE CONSIDERED ON THAT DAY.

A REMINDER OF THE SCORING SYSTEM FOR THESE APPLICATIONS. THESE ARE SCORED ON A 1-2-3 BASIS. A SCORE OF 1 MEANS THAT THEY HAVE EXCEPTIONAL MERIT AND WARRANT FUNDING; SCORE OF 2 MEANS THE APPLICATION NEEDS IMPROVEMENT, BUT CAN BE SUBMITTED TO ADDRESS THE AREAS FOR IMPROVEMENT; AND A SCORE OF 3 MEANS THAT THE APPLICATION IS SUFFICIENTLY FLAWED THAT IT DOESN'T WARRANT FUNDING AND THIS PROJECT SHOULD NOT BE SUBMITTED FOR SIX MONTHS.

THE APPLICATION THAT IS BEING CONSIDERED IS CLIN1-09759. THIS IS A PRECLINICAL DEVELOPMENT PROJECT FOR A CELL THERAPY TO TREAT PARKINSON'S DISEASE. THE THERAPY IS A HUMAN EMBRYONIC STEM CELL-DERIVED NEUROPROGENITOR CELL THAT EXPRESSES MEF2C, A TRANSCRIPTION FACTOR. IT IS FOR PATIENTS WITH MODERATE TO SEVERE PARKINSON'S DISEASE.

THE GOAL OF THE PROJECT IS TO COMPLETE PRECLINICAL ACTIVITIES THAT WILL ENABLE THEM TO FILE AN IND FOR TESTING THE CELL THERAPY PRODUCT IN THE CLINIC. SOME OF THE MAJOR PROPOSED ACTIVITIES
INCLUDE MANUFACTURING THE PRODUCT, SOME PRECLINICAL
DOSE RESPONSE EFFICACY, TOXICITY AND SAFETY STUDIES,
AND, OF COURSE, TO PREPARE AND FILE THE IND.
THE REQUESTED AMOUNT IS 4.8 MILLION FOR
THIS APPLICATION.
THE APPLICATION UNDERWENT A BUDGET REVIEW
FOR THE ACTIVITIES THAT WERE PROPOSED AND THE COSTS
THAT WERE ASSOCIATED WITH THAT. IT PASSED THAT.
HOWEVER, AT THE GWG REVIEW, REVIEWERS SCORED THIS A
3, WHICH MEANS THEY DO NOT FEEL IT WARRANTS FUNDING,
AND THE VOTE ON THIS WAS UNANIMOUS, THIRTEEN MEMBERS
OF THE GWG ALL SCORING A SCORE OF 3. THE CIRM TEAM
ALSO, IN REVIEWING AND ASSESSING THE PROCESS OF THE
REVIEW, AGREES WITH THE DO NOT FUND RECOMMENDATION
IN THIS CASE. MR. SHEEHY.
SUPERVISOR SHEEHY: THANK YOU, DR.
SAMBRANO. DO I HAVE A MOTION TO EITHER FUND OR NOT
FUND THIS APPLICATION?
CHAIRMAN THOMAS: I MOVE THAT WE NOT FUND.
SUPERVISOR SHEEHY: DO I HAVE A SECOND?
MS. LAPORTE: I SECOND THAT.
SUPERVISOR SHEEHY: DO WE HAVE ANY
DISCUSSION? DO WE HAVE ANY PUBLIC COMMENT? I THINK
THERE'S INDIVIDUALS IN LOS ANGELES, MEMBERS OF THE
PUBLIC.
CHAIRMAN THOMAS: NO PUBLIC COMMENT HERE, JEFF.

SUPERVISOR SHEEHY: GREAT. THANK YOU.

THEN, MARIA, CAN WE HAVE A VOTE?

MS. BONNEVILLE: YES.

ANNE-MARIE DULIEGE. DAVID HIGGINS.

DR. HIGGINS: CAN I SUBMIT MY VOTE WITH COMMENTARY, OR DO I HAVE TO DO THAT OUTSIDE? VERY BRIEF COMMENT, IS THAT POSSIBLE?

MR. TORRES: I SUGGEST WE SUSPEND THE ROLL CALL AND LET DAVID SPEAK, THEN PROCEED.

DR. HIGGINS: I'M SORRY FOR THAT. SO THIS IS DAVID HIGGINS AT CITY OF HOPE. I THINK IT PROBABLY GOES WITHOUT SAYING THAT I HAVE A VESTED INTEREST IN THIS AREA OF RESEARCH AND THIS AREA OF FUNDING FOR CIRM. AND I ALSO WANT TO POINT OUT THAT THE APPLICANT IS A WORLD-CLASS SCIENTIST THAT HAS A LONG CAREER OF TOPNOTCH SCIENCE AND CARE FOR PATIENTS. AND THAT IS NOT IN QUESTION.

I THINK IT ALSO GOES WITHOUT SAYING THAT CIRM'S BEST INTEREST IS TO FUND THE LARGEST NUMBER OF THE BEST PROPOSALS THAT WE CAN FIND IN ORDER TO GET NEW THERAPIES AND EVEN CURES FOR DISEASES, INCLUDING PARKINSON'S. SO IT'S IN OUR BEST INTEREST TO FIND AND FUND THE BEST OF THE BEST. AND IT'S MY
HOPE IN THIS PARTICULAR CASE THAT THE APPLICANTS WILL CIRCLE BACK AROUND WITH CIRM, LOOK AT THE GWG'S COMMENTS, AND REVIEW WHAT NEEDS TO BE DONE, AND I HOPE TO SEE A RESUBMISSION FROM THEM IN THE FUTURE. THAT'S ALL I'M GOING TO SAY.

SUPERVISOR SHEEHY: THANK YOU. DO WE HAVE ANY OTHER BOARD COMMENT? AGAIN, DO WE HAVE ANY PUBLIC COMMENT? MS. BONNEVILLE, COULD YOU CALL THE ROLL PLEASE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DAVID HIGGINS.

DR. HIGGINS: NO.

DR. JUELSGAARD: COULD SOMEBODY REPEAT THE MOTION JUST SO WE'RE CLEAR WHAT WE'RE VOTING ON?

SUPERVISOR SHEEHY: SURE. LET'S START OVER FROM THE TOP. THE MOTION IS TO NOT FUND APPLICATION 09759. THE MOTION WAS MADE BY CHAIRMAN THOMAS AND SECONDED BY KATHY LAPORTE.

SO WE'VE TAKEN BOARD COMMENT AND PUBLIC COMMENT. SO AT THIS POINT WE SHALL CALL THE ROLL.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DAVID HIGGINS.

DR. HIGGINS: PARDON MY CONFUSION. I VOTE YES.

MS. BONNEVILLE: STEVE JUELSGAARD.
DR. JUELSGAARD:  YES.
MS. BONNEVILLE:  KATHY LAPORTE.
MS. LAPORTE:  YES.
MS. BONNEVILLE:  LAUREN MILLER.
MS. MILLER:  YES.
MS. BONNEVILLE:  ADRIANA PADILLA.
DR. PADILLA:  YES.
MS. BONNEVILLE:  JOE PANETTA.
MR. PANETTA:  YES.
MS. BONNEVILLE:  FRANCISCO PRIETO.
DR. PRIETO:  AYE.
MS. BONNEVILLE:  ROBERT QUINT.
DR. QUINT:  YES.
MS. BONNEVILLE:  AL ROWLETT.
MR. ROWLETT:  YES.
MS. BONNEVILLE:  JEFF SHEEHY.
SUPERVISOR SHEEHY:  YES.
MS. BONNEVILLE:  JONATHAN THOMAS.
CHAIRMAN THOMAS:  YES.
MS. BONNEVILLE:  ART TORRES.
MR. TORRES:  AYE.
MS. BONNEVILLE:  DIANE WINOKUR.
MS. WINOKUR:  YES.
MS. BONNEVILLE:  THANK YOU. THE MOTION CARRIES.
SUPERVISOR SHEEHY: THANK YOU.

DR. STEWARD: AM I IN CONFLICT ON THIS ONE?

MS. BONNEVILLE: YES.

DR. STEWARD: OKAY. THANK YOU.

SUPERVISOR SHEEHY: SO ITEM 4, CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO THE PARTNERING OPPORTUNITY FOR TRANSLATIONAL RESEARCH PROJECTS.

DR. SAMBRANO: THANK YOU, MR. SHEEHY.

SO WE'RE BRINGING FOR YOUR CONSIDERATION APPLICATIONS RESPONDING TO THE TRANSLATIONAL RESEARCH PROGRAM. THIS IS AN OPPORTUNITY THAT IS AVAILABLE NOW THREE TIMES A YEAR OR EVERY FOUR MONTHS. AND THE DEADLINE -- BECAUSE IT'S ABOUT EVERY FOUR MONTHS, THE DEADLINES COME TOO LATE AFTER THE BOARD MEETING THAT CONSIDERS THESE APPLICATIONS. SO THE NEXT DEADLINE IS COMING UP APRIL 5TH. THAT'S JUST A NOTE TO BE AWARE OF.

THE OBJECTIVE OF THIS PROGRAM, AS YOU KNOW, IS TO SUPPORT PROMISING STEM CELL-BASED PROJECTS THAT WILL ACCELERATE COMPLETION OF THOSE TRANSLATIONAL STAGE ACTIVITIES THAT WILL ALLOW PROJECTS TO ADVANCE TO CLINICAL STUDY OR IN THE CASE OF TOOLS TO BE COMMERCIALIZED FOR BROAD END USE.
THERE ARE A VARIETY OF PRODUCTS THAT CAN COME IN UNDER A TRAN AWARD: A THERAPEUTIC, A DIAGNOSTIC, A MEDICAL DEVICE OR A TOOL. THE PROGRAM ALLOWS FOR DIFFERENT -- OR BECAUSE THE TRAN ACTIVITIES DIFFER FOR EACH OF THESE PRODUCT TYPES, THERE ARE DIFFERENT FUNDING CAPS FOR THESE PROGRAMS AS WELL AS A TIME THAT'S ALLOWED TO COMPLETE THOSE ACTIVITIES. FOR A TOOL A CAP OF ONE MILLION UP TO A THERAPEUTIC WHICH ALLOWS TWO TO FOUR MILLION, DEPENDING ON WHETHER IT'S A CELL THERAPY OR SMALL MOLECULE. THERE ARE DIFFERENCES THERE AND SOME DIFFERENCES IN THE APPLICATION.

HOWEVER, IN GENERAL, WHAT WE'RE LOOKING FOR ARE PRODUCTS THAT ARE AT THE STAGE WHERE THEY'VE DEMONSTRATED A PROOF OF CONCEPT. FOR A THERAPEUTIC IT MEANS THAT THEY'VE IDENTIFIED A SINGLE THERAPEUTIC CANDIDATE WITH DISEASE MODIFYING ACTIVITY; OR FOR SOMETHING LIKE A TOOL OR A DEVICE, THAT THEY HAVE A PROTOTYPE DEVELOPED IN ORDER TO DEMONSTRATE THE PROOF OF CONCEPT. SO THAT'S THE STAGE OF READINESS THAT WE ARE LOOKING FOR FOR PROJECTS THAT ARE COMING IN.

THE TRANSLATION ACTIVITIES THAT THEY CONDUCT OVER THE APPROXIMATE TWO YEARS OF THE AWARD SHOULD LEAD THEM TO COMPLETING A PRE-IND MEETING OR
A PRESUBMISSION MEETING WITH THE FDA, DEPENDING ON THE PRODUCT TYPE; OR IF IT'S A TOOL, TO TRANSFER IT TO MANUFACTURING FOR COMMERCIALIZATION OF THAT PRODUCT.


THE SCORING SYSTEM THAT WE UTILIZE IN THE TRAN IS DIFFERENT FROM THE CLINICAL PROGRAM. HERE WE USE A RANGE OF 1 TO 100, WITH A SCORE OF 85 TO 100 BEING RECOMMENDED FOR A FUNDING TIER, AND ANYTHING BELOW 85 IS NOT RECOMMENDED FOR FUNDING. AND WE UTILIZE THE MEDIAN IN ORDER TO ASSIGN THE FINAL INDIVIDUAL SCORE, THE MEDIAN FROM ALL THE INDIVIDUAL GWG MEMBERS THAT SCORE.
THE RECOMMENDATIONS THAT CAME OUT OF THIS PARTICULAR CYCLE FOR TRAN APPLICATIONS ARE AS FOLLOWS. THERE ARE TWO APPLICATIONS THAT WERE RECOMMENDED THAT ARE IN THE TOP TIER THAT TOTAL TO AN AMOUNT OF ABOUT FOUR MILLION. THERE ARE, BECAUSE THIS IS THE FIRST CYCLE THIS YEAR, PLENTY OF FUNDS AVAILABLE TO COVER THE AMOUNT OF THOSE TWO APPLICATIONS. OF COURSE, JUST A NOTE THAT THE FINAL AWARD AMOUNT WOULD NOT EXCEED THE AMOUNT SHOWN BECAUSE WE DO GO THROUGH AN ASSESSMENT OF ALLOWABLE COSTS AND ACTIVITIES, AND IN SOME CASES THAT AMOUNT MAY BE REDUCED.

AS PREVIOUSLY NOTED, THE GWG VOTE ON THE REVIEW PROCESS. WE CONDUCT THAT HERE TOO. AND, AGAIN, ON THIS REVIEW, IT WAS A UNANIMOUS VOTE.

AND THEN, FINALLY, I'M GOING TO GIVE YOU A VERY BRIEF OVERVIEW OF THE TWO APPLICATIONS THAT WERE RECOMMENDED SO YOU HAVE A SENSE OF WHAT IT IS THAT WE ARE BRINGING TO FUND.

SO THE FIRST APPLICATION IS TRAN4-09884. THE TITLE IS "A NOVEL ROBUST AND COMPREHENSIVE PREDICTIVE TOOL USING HUMAN DISEASE-SPECIFIED INDUCED PLURIPOTENT STEM CELLS FOR CLINICAL DRUG SCREENING." THIS IS IN THE TOOL CATEGORY, OBVIOUSLY. THE GOAL HERE IS TO ADDRESS THE
CHALLENGE FOR DRUG DEVELOPERS, THAT MANY DRUG DEVELOPERS FIND THAT DRUGS ARE EITHER WITHDRAWN FROM THE MARKET OR FROM LATE STAGE DEVELOPMENT DUE TO UNPREDICTABLE CARDIOTOXICITY ONCE THESE DRUGS ACTUALLY GET TO PATIENTS OR TO CLINICAL TRIALS. AND THIS, THE APPLICANT FEELS, IS DUE LARGELY TO INEFFECTIVE SCREENING ASSAYS.

SO WHAT THEY PROPOSE TO DO HERE IS TO CREATE AN ASSAY THAT WOULD CIRCUMVENT THIS AND PREVENT THE COSTS AND THE EFFORT IN TAKING SUCH DRUGS THROUGH THAT DEVELOPMENT PROCESS. SO THEY HAVE CREATED AN INDUCED PLURIPOTENT STEM CELL-DERIVED CARDIOMYOCYTE SCREENING PLATFORM. THEY TAKE IPS CELLS FROM HEALTHY SUBJECTS AS WELL AS THOSE THAT HAVE COMMON HEREDITARY CARDIAC DISORDERS IN ORDER TO CREATE THAT SCREENING PLATFORM FOR SMALL MOLECULE DRUGS IN ORDER TO PREDICT WHETHER THESE COULD HAVE CARDIOTOXIC EFFECTS.

THIS APPLICATION SCORED A 90. THIRTEEN OUT OF 13 OF THE GWG REVIEWERS SCORED IT IN THE TOP TIER. AND JUST VERY BRIEFLY, THIS IS AN APPLICATION THAT THE REVIEWERS REALLY LOVED. THIS IS THE SECOND TIME THIS CAME AROUND, AND IT HAD A HIGH SCORE. IT HAD SOME ADMINISTRATIVE ISSUES THAT BROUGHT IT BACK THROUGH THE GWG. BUT EVEN AFTER THE SECOND REVIEW,
IT WAS CLEAR THAT THIS IS A STRONG PROPOSAL. IT WAS FELT THAT THE NEED TO DEVELOP THE TOOL THAT THEY PROPOSE COULD HAVE A GREAT IMPACT IN THE RESEARCH COMMUNITY AND IN DRUG DEVELOPMENT. THEY FEEL THE TEAM IS OUTSTANDING AND THAT THEY HAVE A COMPREHENSIVE STRATEGY FOR DEVELOPING THIS TOOL.

THERE WAS A CONCERN THAT REALLY RELATED TO THE MANUFACTURING AND DISTRIBUTION OF THIS PRODUCT, THAT THIS PLAN FOR DOING SO WAS NOT ADEQUATELY ADDRESSED IN THE APPLICATION. IT WASN'T A MAJOR CONCERN TO THEM AND SOMETHING THAT THEY FELT THAT THEY COULD ACCOMPLISH. THAT'S THE FIRST APPLICATION.

SHALL WE PAUSE AND CONSIDER IT OR SHOULD I GO THROUGH BOTH OF THEM?

SUPERVISOR SHEEHY: SINCE WE ONLY HAVE TWO IN THE FUNDABLE CATEGORY, LET'S DEAL WITH THOSE FIRST, AND WE'LL TAKE THEM ONE AT THAT TIME. IS THERE A MOTION TO FUND THIS APPLICATION?

CHAIRMAN THOMAS: SO MOVED.

SUPERVISOR SHEEHY: IS THERE A SECOND?

DR. PRIETO: SECOND.

SUPERVISOR SHEEHY: SECOND BY DR. PRIETO.

ANY BOARD COMMENT? ANY PUBLIC COMMENT? MARIA, COULD YOU CALL THE ROLL PLEASE.
MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

DR. JUELSGAARD: YES.

MS. BONNEVILLE: SHERRY LANSING. KATHY LAPORTE.

MS. LAPORTE: YES.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: YES.

MS. BONNEVILLE: ADRIANA PADILLA.

DR. PADILLA: YES.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: YES.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: AYE.

MS. BONNEVILLE: ROBERT QUINT.

DR. QUINT: YES.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: YES.

MS. BONNEVILLE: JEFF SHEEHY.

SUPERVISOR SHEEHY: YES.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: YES.

MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: AYE.

MS. BONNEVILLE: DIANE WINOKUR.

MS. WINOKUR: YES.

MS. BONNEVILLE: MOTION CARRIES.

SUPERVISOR SHEEHY: THANK YOU. THE SECOND ONE PLEASE, DR. SAMBRANO.

DR. SAMBRANO: THE SECOND APPLICATION IN THE TOP TIER IS TRAN1-09814. THIS IS ENTITLED "PREDICTABLE PRO-REGENERATIVE SCAFFOLD FOR TREATING SYMPTOMATIC PERIPHERAL ARTERY DISEASE." THIS IS A THERAPY CANDIDATE. THE IDEA HERE IS TO TAKE WHAT IS A SCAFFOLD MATERIAL FROM PORCINE MUSCLE WHERE THEY TAKE THE EXTRACELLULAR MATRIX COMPONENTS AND COMBINE THEM INTO A HYDROGEL THAT'S INJECTABLE THAT CAN BE INTRODUCED INTO THE PATIENT MUSCLE THAT IS SUFFERING IN THE LIMB FROM PERIPHERAL ARTERY DISEASE.

THE GOAL IS THAT WHEN THIS HYDROGEL IS INJECTED, THAT IT GENERATES A SERIES OF RECRUITMENT OF BLOOD VESSELS AND DIFFERENTIATION OF MUSCLE STEM CELLS IN ORDER TO IMPROVE BLOOD FLOW AND THE MUSCLE FUNCTION.

THIS APPLICATION ALSO, LIKE THE FIRST, RECEIVED A 90. FOURTEEN OUT OF 14 MEMBERS OF THE
GRANTS WORKING GROUP SCORED IT IN THE TOP TIER.

REVIEWERS, BRIEFLY, FELT THAT WAS AN APPLICATION THAT PRESENTED A VERY STRONG PLAN. THEY HAVE GOOD PRECLINICAL DATA, AND THE PRECLINICAL STUDIES SHOWED INCREASED VASCULAR PERFUSION, INCREASED MUSCLE DEVELOPMENT AS A STRONG PROOF OF CONCEPT, AS WELL AS SAFETY. THIS IS AN APPLICATION THAT WAS RESUBMITTED, AND THE GWG MEMBERS FELT THE APPLICANT PROVIDED VERY GOOD RESPONSES TO THE PREVIOUS CONCERNS THAT THEY HAD.

THE ONE RECOMMENDATION, PERHAPS, AS OPPOSED TO MAYBE A CONCERN, THAT THE REVIEWERS FELT THAT THE APPLICANT SHOULD HAVE A PRE-IND MEETING WITH THE FDA SOONER RATHER THAN LATER IN ORDER TO MAKE SURE THAT THEY ALIGN THEIR IND PLAN PROPERLY AND CAN ENSURE THEY HAVE A GOOD PLAN GOING FORWARD FOR THIS PROJECT.

AND THEN THE SECOND CONCERN WAS TO FOCUS IN ON CRITICAL LIMB ISCHEMIA AS OPPOSED TO THE PATIENT POPULATION WHICH THEY ARE LARGELY TARGETING WHICH IS A PATIENT POPULATION THAT IS CALLED INDUCED CLAUDICATION. IT IS A PATIENT POPULATION THAT EXPERIENCES PAIN IN RESPONSE TO EXERCISE. SO IT IS A TYPE OF PERIPHERAL ARTERY DISEASE. THEY FELT THAT THE GREATEST NEED IS IN CLI AND WOULD LIKE TO SEE
THE APPLICANTS MOVE INTO THAT ARENA.

SUPERVISOR SHEEHY: THANK YOU, DR.

SAMBRANO.

CAN I GET A MOTION TO EITHER FUND OR NOT?

I GUESS A MOTION TO FUND WOULD BE APPROPRIATE.

DR. QUINT: SO MOVED.

MS. LAPORTE: SECOND.

SUPERVISOR SHEEHY: ARE THERE ANY BOARD COMMENTS? ANY PUBLIC COMMENT?

DR. JUELSGAARD: JUST A QUICK QUESTION. I NOTED IN THE COMMENTS UNDER CONCERNS THERE'S TALK ABOUT A LEAD PRODUCT IN DEVELOPMENT. IT SOUNDS AS IF THEY'VE GOT SOMETHING ELSE GOING ON IN ADDITION TO OR BESIDES THIS; IS THAT RIGHT?

DR. SAMBRANO: THEY HAVE SOMETHING ELSE THAT HAS BEEN IN THE CLINIC. AND SO PART OF THE CONCERN THAT THE REVIEWERS EXPRESSED DURING THE FIRST ONE IS THAT THEY WANTED TO HAVE A HEAD-TO-HEAD COMPARISON WITH AN ANALOGOUS PRODUCT THAT THEY HAVE.

THIS IS AN IMPROVEMENT ON THAT PRODUCT. SO, YES, THERE IS ANOTHER THAT THEY HAVE DEVELOPED THAT IS SIMILAR.

DR. JUELSGAARD: ALL RIGHT. THANKS.

SUPERVISOR SHEEHY: ANY OTHER BOARD COMMENT? MARIA, COULD YOU CALL THE ROLL PLEASE.
MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

DR. JUELSGAARD: YES.

MS. BONNEVILLE: KATHY LAPORTE.

MS. LAPORTE: YES.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: YES.

MS. BONNEVILLE: ADRIANA PADILLA.

DR. PADILLA: YES.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: YES.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: AYE.

MS. BONNEVILLE: ROBERT QUINT.

DR. QUINT: YES.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: YES.

MS. BONNEVILLE: JEFF SHEEHY.

SUPERVISOR SHEEHY: YES.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: YES.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.
SO NOW WE HAVE REMAINING ITEMS. ARE THERE ANY OTHER OF THE REMAINING ITEMS THAT ANYONE WOULD LIKE TO MOVE INTO THE FUNDABLE CATEGORY?

THEN COULD I GET A MOTION TO NOT FUND THE REMAINING ITEMS?

MR. ROWLETT: SO MOVED.

DR. JUELSGAARD: SECOND.

SUPERVISOR SHEEHY: ANY BOARD COMMENT?

ANY PUBLIC COMMENT?

CHAIRMAN THOMAS: YES. WE HAVE DR. CHIU HERE AT CITY OF HOPE WHO WOULD LIKE TO GIVE PUBLIC COMMENT.

DR. CHIU: SO IT'S IN THE NATURE OF A QUESTION. CAN EVERYBODY HEAR ME?

MS. BONNEVILLE: YES.

DR. CHIU: ACCORDING TO DR. SAMBRANO'S CHART, THERE ARE NINE APPLICATIONS THAT HAD A SCORE OF 1 TO 84; BUT IN THE PRINTOUT, I NOTICED SIX IN THE GRAY ZONE. AND AM I MISREADING SOMETHING? WERE
THERE ONLY SIX THAT WERE SCORED 1 TO 84 OR WERE THERE NINE?

DR. SAMBRANO: THERE WERE 11 APPLICATIONS THAT WERE REVIEWED. TWO WERE RECOMMENDED, NINE WERE NOT, AND THE ONES THAT ARE NOT SHOWN ON THE SPREADSHEET WITHDREW BEFORE THE BOARD MEETING.

DR. CHIU: THANK YOU. AND A SECOND FOLLOW-UP QUICK QUESTION. THESE ARE THE ONES THAT WERE REVIEWED, THE TOTAL NINE PLUS TWO THAT YOU INDICATED. HOW MANY PROPOSALS CAME IN OUT OF WHICH THESE 11 WERE SELECTED FOR REVIEW?

DR. SAMBRANO: SO ALL OF THE ELEVEN APPLICATIONS THAT WERE REVIEWED WERE ALL THE ELIGIBLE APPLICATIONS THAT WERE RECEIVED.

DR. CHIU: POSITIVELY SELECTED, RIGHT?

DR. SAMBRANO: THERE WAS NO POSITIVE SELECTION.

DR. CHIU: THERE WAS NO POSITIVE SELECTION. THESE ARE ALL THAT MET ELIGIBILITY?

DR. SAMBRANO: CORRECT.

DR. CHIU: JUST CLARIFY FOR ME, IF YOU DON'T MIND, ARE TRAN PROPOSALS POSITIVELY SELECTED OR JUST BY ELIGIBILITY?

DR. SAMBRANO: IT DEPENDS ON HOW MANY PROPOSALS ARE RECEIVED. IF THERE ARE MORE PROPOSALS
THAN CAN BE TAKEN TO A SINGLE OR THROUGH A SINGLE
CYCLE OF THE GWG, THEN THEY UNDERGO POSITIVE
SELECTION. BUT SO FAR IN ALL THE TRAN CYCLES THAT
WE'VE HAD, WE HAVE RECEIVED A NUMBER OF APPLICATIONS
THAT MEANS WE DON'T HAVE TO CONDUCT A POSITIVE
SELECTION. THEY HAVE ALL BEEN UNDER THE AMOUNT THAT
WE CAN MANAGE.

DR. CHIU: OKAY. THANK YOU VERY MUCH.
SUPervisor SHEEHY: DO WE HAVE ANY OTHER
PUBLIC COMMENT? MARIA, COULD YOU CALL THE ROLL
PLEASE.
MR. HARRISON: JUST A REMINDER TO MEMBERS
WHO MAY HAVE AN INTEREST IN AN APPLICATION THAT
FALLS WITHIN THE TIERS, TO VOTE YES OR NO WITH
RESPECT TO THOSE APPLICATIONS IN WHICH YOU HAVE A
CONFLICT.
DR. JUELsgAARD: JEFF, COULD YOU REPEAT
THE MOTION SO WE'RE JUST CLEAR ON WHAT WE'RE VOTING
ON?
SUPERVISOR SHEEHY: THE MOTION IS TO NOT
FUND ANY OF THE REMAINING APPLICATIONS, WHICH I
THINK THERE'S SIX ON THIS PAGE.
MS. BONNEVILLE: ANNE-MARIE DULIEGE.
DAVID HIGGINS.
DR. HIGGINS: YES.
MS. BONNEVILLE: STEVE JUELSGAARD.
DR. JUELSGAARD: YES.
MS. BONNEVILLE: SHERRY LANSING. KATHY LAPORTE.
MS. LAPORTE: YES.
MS. BONNEVILLE: LAUREN MILLER.
MS. MILLER: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: FRANCISCO PRIETO.
DR. PRIETO: AYE.
MS. BONNEVILLE: ROBERT QUINT.
DR. QUINT: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: JEFF SHEEHY.
SUPERVISOR SHEEHY: YES.
MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: YES.
MR. HARRISON: EXCEPT FOR THOSE WITH WHICH YOU HAVE A CONFLICT.
DR. STEWARD: EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT. MY APOLOGIES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: EXCEPT FOR THOSE WITH
WHICH YOU HAVE A CONFLICT.
CHAIRMAN THOMAS: EXCEPT FOR THOSE WITH
WHICH I HAVE A CONFLICT.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: YES.
MS. BONNEVILLE: THANK YOU. THE MOTION
CARRIES.
SUPERVISOR SHEEHY: I THINK THAT'S IT FOR
BUSINESS TODAY. IT'S BACK TO YOU IF YOU WANT TO
CLOSE OUT THE MEETING, CHAIRMAN THOMAS.
CHAIRMAN THOMAS: THANK YOU, SUPERVISOR
SHEEHY.
LAST THING ON THE AGENDA IS GENERAL PUBLIC
COMMENT ON ANY ITEMS OF INTEREST. HEARING NONE, WE
STAND ADJOURNED. HAVE A GOOD DAY, EVERYBODY.
(THE MEETING WAS THEN CONCLUDED AT
11:37 A.M.)
REPORTER'S CERTIFICATE


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