

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: AS INDICATED ON THE AGENDA

DATE: AUGUST 24, 2017
11 A.M.

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

FILE NO. : 2017-18

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I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION	
1. CALL TO ORDER.	3
2. ROLL CALL.	3
3. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLIN 2: PARTNERING OPPORTUNITY FOR CLINICAL TRIAL STAGE PROJECTS.	4
CLOSED SESSION	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 CLIN 2: PARTNERING OPPORTUNITY FOR CLINICAL TRIAL STAGE PROJECTS (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
5. PUBLIC COMMENT.	NONE
6. ADJOURNMENT	11

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THURSDAY, AUGUST 24, 2017

11 A.M.

CHAIRMAN THOMAS: MORNING, EVERYBODY.

LIKE TO WELCOME EVERYBODY TO THE REGULARLY SCHEDULED MEETING OF THE ICOC AND THE APPLICATION REVIEW SUBCOMMITTEE. WE'LL PROCEED FIRST TO ROLL CALL.

MARIA, PLEASE WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: HERE.

MS. BONNEVILLE: SHERRY LANSING. KATHY LAPORTE.

MS. LAPORTE: HERE.

MS. BONNEVILLE: LAUREN MILLER. ADRIANA PADI LLA.

DR. PADI LLA: HERE.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: HERE.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: HERE.

MS. BONNEVILLE: ROBERT QUINT. AL ROWLETT.

1 MR. ROWLETT: HERE.

2 MS. BONNEVILLE: JEFF SHEEHY.

3 SUPERVISOR SHEEHY: HERE.

4 MS. BONNEVILLE: OS STEWARD. JONATHAN
5 THOMAS.

6 CHAIRMAN THOMAS: HERE.

7 MS. BONNEVILLE: ART TORRES.

8 MR. TORRES: HERE.

9 MS. BONNEVILLE: DIANE WINOKUR.

10 MS. WINOKUR: HERE.

11 MS. BONNEVILLE: ARE THERE ANY OTHER BOARD
12 MEMBERS ON THE LINE?

13 DR. DULIEGE: ANNE-MARIE DULIEGE. I JUST
14 JOINED.

15 MS. BONNEVILLE: THANK YOU, ANNE-MARIE.
16 DR. QUINT, ARE YOU ON THE LINE?

17 DR. QUINT: I AM.

18 MS. BONNEVILLE: GREAT. THANK YOU.

19 CHAIRMAN THOMAS: ON TO ITEM NO. 3, WHICH
20 IS CONSIDERATION OF THE APPLICATIONS SUBMITTED IN
21 RESPONSE TO CLIN2-PARTNERING OPPORTUNITY FOR
22 CLINICAL TRIAL STAGE PROJECTS. LIKE TO TURN THE
23 MEETING OVER TO SUPERVISOR SHEEHY.

24 SUPERVISOR SHEEHY: THANK YOU, CHAIRMAN
25 THOMAS.

1 SO THE FIRST ONE WE HAVE IS 10192, AND DO
2 WE HAVE A PRESENTATION ON THAT?

3 DR. SAMBRANO: I JUST HAVE THE GENERAL
4 REMINDER ON THE SCORING AND THE RFA. SO WE HAVE TWO
5 APPLICATIONS THAT ARE RESPONDING TO THE CLIN2
6 PROGRAM ANNOUNCEMENT FOR CLINICAL STAGE PROGRAMS.
7 THE SCORING THAT THE GRANTS WORKING GROUP USES TO
8 SCORE THESE APPLICATIONS IS THE SYSTEM OF 1, 2, AND
9 3 SO, AGAIN, JUST A REMINDER THAT A ONE MEANS THEY
10 HAVE EXCEPTIONAL MERIT AND WARRANT FUNDING; A 2
11 MEANS IT NEEDS IMPROVEMENT AND SHOULD COME BACK FOR
12 CHANGES; AND A SCORE OF 3 MEANS THAT IT'S
13 SUFFICIENTLY FLAWED THAT IT DOESN'T WARRANT FUNDING.

14 THE FIRST APPLICATION UNDER CONSIDERATION
15 IS CLIN2-10192, WHICH IS A PHASE 1-2 CLINICAL TRIAL
16 FOCUSED ON B-CELL CANCERS.

17 SO THIS IS A MONOCLONAL ANTIBODY THERAPY
18 THAT TARGETS CANCER STEM CELLS WHICH IS BEING
19 COMBINED WITH A SMALL MOLECULE DRUG THAT TOGETHER
20 THEY HOPE WILL LEAD TO COMPLETE REMISSION IN
21 PATIENTS WITH EITHER CHRONIC LYMPHOCYTIC LEUKEMIA OR
22 MANTLE CELL LYMPHOMA.

23 AND SO THEIR GOAL IS TO COMPLETE WHAT
24 THEY'RE CALLING A PHASE 1B-2A CLINICAL TRIAL TO
25 ASSESS SAFETY AND EFFICACY OF THIS COMBINATION

1 THERAPY IN PATIENTS. THE PROPOSED ACTIVITIES
2 INCLUDE MANUFACTURING OF THE MONOCLONAL ANTIBODY TO
3 SUPPLY THE TRIAL AS WELL AS THE CONDUCT OF THE TRIAL
4 ITSELF. THE FUNDS REQUESTED ARE 18.3 MILLION. THEY
5 ARE PROVIDING A CO-FUNDING AMOUNT OF ABOUT 13.3.

6 ON THIS APPLICATION, AS USUAL, WE CONDUCT
7 A BUDGET, AN INITIAL BUDGET REVIEW WHICH IT PASSED.
8 AND WHEN WE TOOK IT TO THE GRANTS WORKING GROUP FOR
9 THE SCIENTIFIC REVIEW, THEY UNANIMOUSLY SCORED THIS
10 A 1. CIRM CONCURS WITH THAT RECOMMENDATION IN THE
11 AWARD AMOUNT OF 18.3 MILLION. MR. SHEEHY.

12 SUPERVISOR SHEEHY: SO DO I HAVE A MOTION
13 TO ACCEPT THE CIRM TEAM'S RECOMMENDATION?

14 MR. TORRES: SO MOVED.

15 SUPERVISOR SHEEHY: MOVED BY SENATOR
16 TORRES. DO I HAVE A SECOND.

17 DR. HIGGINS: SECOND.

18 SUPERVISOR SHEEHY: SECOND BY DAVID
19 HIGGINS.

20 IS THERE ANY DISCUSSION? IS THERE ANY
21 PUBLIC COMMENT AT ANY OF THE SITES? CAN WE CALL THE
22 ROLL PLEASE.

23 MS. BONNEVILLE: DAVID HIGGINS.

24 DR. HIGGINS: YES.

25 MS. BONNEVILLE: STEVE JUELGAARD.

1 MR. JUELSGAARD: YES.
2 MS. BONNEVILLE: KATHY LAPORTE.
3 MS. LAPORTE: YES.
4 MS. BONNEVILLE: ADRIANA PADI LLA.
5 DR. PADI LLA: YES.
6 MS. BONNEVILLE: JOE PANETTA.
7 MR. PANETTA: YES.
8 MS. BONNEVILLE: FRANCISCO PRIETO.
9 DR. PRIETO: AYE.
10 MS. BONNEVILLE: ROBERT QUINT.
11 DR. QUINT: YES.
12 MS. BONNEVILLE: AL ROWLETT.
13 MR. ROWLETT: YES.
14 MS. BONNEVILLE: JEFF SHEEHY.
15 SUPERVISOR SHEEHY: YES.
16 MS. BONNEVILLE: JONATHAN THOMAS.
17 CHAIRMAN THOMAS: YES.
18 MS. BONNEVILLE: ART TORRES.
19 MR. TORRES: AYE.
20 MS. BONNEVILLE: DIANE WINOKUR.
21 MS. WINOKUR: YES.
22 MS. BONNEVILLE: MOTION CARRIES.
23 SUPERVISOR SHEEHY: GREAT. THANK YOU.
24 SO, DR. SAMBRANO, CAN WE GO TO THE SECOND
25 APPLICATION?

1 DR. SAMBRANO: THANK YOU, MR. SHEEHY.

2 THE NEXT APPLICATION IS CLIN2-1038. THIS
3 IS A CLINICAL TRIAL FOR IMPROVING BONE MARROW
4 ENGRAFTMENT.

5 SO THE THERAPY HERE IS CORD BLOOD THAT IS
6 COMBINED WITH ENDOTHELIAL CELLS IN ORDER TO EXPAND
7 THE CORD BLOOD CELLS AND INTRODUCE THEM TO PATIENTS
8 WHO HAVE RECEIVED MYELOABLATION CONDITIONING. IN
9 PARTICULAR, THIS TRIAL IS FOR PATIENTS WHO HAVE BEEN
10 GOING THROUGH THE MYELOABLATION IN RESPONSE TO ACUTE
11 LYMPHOBLASTIC LEUKEMIA, AML, OR MYELODI SPLASIA.

12 THE GOAL IS TO COMPLETE A PHASE 1B
13 CLINICAL TRIAL AND ASSESS THE SAFETY AND EFFICACY OF
14 THIS COMBINATION CELL THERAPY IN PATIENTS. THE
15 PROPOSED ACTIVITIES INCLUDE THE PATIENT RECRUITMENT
16 AND ENROLLMENT, AN INTERIM ANALYSIS OF THAT INITIAL
17 COHORT, AND CONDUCT OF THE TRIAL ITSELF. THE FUNDS
18 REQUESTED ARE 5 MILLION. THE APPLICANTS ARE
19 PROVIDING ABOUT 2.7 MILLION IN CO-FUNDING.

20 THIS APPLICATION ALSO PASSED INITIAL
21 BUDGET REVIEW, AND THE GRANTS WORKING GROUP
22 UNANIMOUSLY GAVE A SCORE OF 1. THE CIRM TEAM
23 RECOMMENDATION CONCURS WITH THE GRANTS WORKING GROUP
24 RECOMMENDATION OF FUNDING THIS APPLICATION FOR 5
25 MILLION. MR. SHEEHY.

1 SUPERVISOR SHEEHY: THANK YOU. DO I HAVE
2 A MOTION TO ACCEPT THE CIRM TEAM RECOMMENDATION?

3 MR. TORRES: SO MOVED.

4 DR. DULIEGE: SECOND.

5 SUPERVISOR SHEEHY: SENATOR TORRES AND DR.
6 DULIEGE, I THINK, IS THE SECOND. GREAT.

7 IS THERE ANY DISCUSSION? ANY PUBLIC
8 COMMENT AT ANY OF THE SITES? COULD WE CALL THE ROLL
9 PLEASE.

10 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

11 DR. DULIEGE: YES.

12 MS. BONNEVILLE: DAVID HIGGINS. STEVE
13 JUELGAARD.

14 MR. JUELGAARD: YES.

15 MS. BONNEVILLE: KATHY LAPORTE.

16 MS. LAPORTE: YES.

17 MS. BONNEVILLE: ADRIANA PADI LLA.

18 DR. PADI LLA: YES.

19 MS. BONNEVILLE: JOE PANETTA.

20 MR. PANETTA: YES.

21 MS. BONNEVILLE: FRANCISCO PRIETO.

22 DR. PRIETO: AYE.

23 MS. BONNEVILLE: ROBERT QUINT.

24 DR. QUINT: YES.

25 MS. BONNEVILLE: AL ROWLETT.

1 MR. ROWLETT: YES.
2 MS. BONNEVILLE: JEFF SHEEHY.
3 SUPERVISOR SHEEHY: YES.
4 MS. BONNEVILLE: JONATHAN THOMAS.
5 CHAIRMAN THOMAS: YES.
6 MS. BONNEVILLE: ART TORRES.
7 MR. TORRES: AYE.
8 MS. BONNEVILLE: DIANE WINOKUR.
9 MS. WINOKUR: YES.
10 MS. BONNEVILLE: DAVID HIGGINS, ARE YOU ON
11 THE LINE?
12 DR. HIGGINS: YES, I AM.
13 MS. BONNEVILLE: WHAT IS YOUR VOTE ON
14 THIS?
15 DR. HIGGINS: YES.
16 MS. BONNEVILLE: THE MOTION CARRIES.
17 SUPERVISOR SHEEHY: THANK YOU. THANK YOU,
18 EVERYONE. I TURN IT BACK TO CHAIRMAN THOMAS.
19 CHAIRMAN THOMAS: THANK YOU, SUPERVISOR.
20 GO TO ITEM 5 NOW. IS THERE ANY PUBLIC
21 COMMENT AT ANY OF THE SITES ON ANY ISSUES? HEARING
22 NONE, DO I ENTERTAIN A MOTION TO ADJOURN?
23 SUPERVISOR SHEEHY: SO MOVED.
24 CHAIRMAN THOMAS: MOVED BY SUPERVISOR
25 SHEEHY. SECONDED BY?

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MR. ROWLETT: SECOND.

CHAIRMAN THOMAS: THANK YOU, AL.

ALL THOSE IN FAVOR PLEASE SAY AYE. THANK
YOU, FOLKS. WE STAND ADJOURNED.

(THE MEETING WAS THEN CONCLUDED AT
11:12 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 TELEPHONIC PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE AND THE APPLICATION REVIEW SUBCOMMITTEE IN THE MATTER OF ITS REGULAR MEETING HELD ON AUGUST 24, 2017, 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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