

BETH C. DRAIN, CA CSR NO. 7152

**PUBLIC COMMENT REGARDING
ROCKET PHARMACEUTICALS ACCESS AND AFFORDABILITY PLAN
FOR KRESLADI™
BEFORE THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
(CIRM)

ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT**

LOCATION: VIA ZOOM

DATE: SEPTEMBER 8, 2026
9 A.M.

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

FILE NO.: 2026-16

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I N D E X

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1 SEPTEMBER 8, 2026; 9 A.M.

2
3 MR. AGUIRRE-SACASA: GOOD MORNING, MEMBERS
4 OF THE PUBLIC. MY NAME IS RAFAEL AGUIRRE-SACASA, AND
5 I'M THE GENERAL COUNSEL AT CIRM, AND IT'S MY
6 DISTINCT PLEASURE TO HOLD A PUBLIC HEARING TODAY ON
7 THE SUBMISSION OF ROCKETS ACCESS PLAN FOR KRESLADI.
8 CIRM'S IP REGULATIONS REQUIRE THAT AN ACCESS PLAN BE
9 APPROVED FOLLOWING A PUBLIC HEARING THAT PROVIDES AN
10 OPPORTUNITY FOR PUBLIC COMMENT. THAT'S THE REASON
11 WE'RE HERE TODAY. TODAY'S MEETING PROVIDES THE
12 OPPORTUNITY FOR ORAL PUBLIC COMMENT AND CONCLUDES
13 CIRM'S SEVEN-BUSINESS-DAY PUBLIC COMMENT PERIOD.

14 THE IP REGULATIONS REQUIRE THAT A COMPANY
15 COMMERCIALIZING A CIRM-FUNDED DRUG SUBMIT A PLAN TO
16 PROVIDE ACCESS TO ELIGIBLE CALIFORNIANS WHO HAVE NO
17 OTHER MEANS TO PURCHASE THE DRUG. THE PLAN MUST BE
18 CONSISTENT WITH INDUSTRY STANDARDS AT THE TIME OF
19 COMMERCIALIZATION, TAKING INTO ACCOUNT THE SIZE OF
20 THE MARKET FOR THE DRUG AND THE RESOURCES OF THE
21 COMPANY ITSELF.

22 FOLLOWING FDA APPROVAL OF KRESLADI, ROCKET
23 REQUESTED AND RECEIVED AN EXTENSION OF THE INITIAL
24 ACCESS PLAN SUBMISSION DEADLINE AND SUBSEQUENTLY
25 SUBMITTED ITS PROPOSED ACCESS PLAN TO CIRM IN A

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1 TIMELY MANNER.

2 CIRM REVIEWED THE PLAN AGAINST ALL --
3 AGAINST THE REQUIREMENTS OF THE IP REGULATIONS,
4 CONSULTED WITH SUBJECT MATTER EXPERTS REGARDING --
5 SORRY -- RELEVANT INDUSTRY STANDARDS.

6 WE REVIEWED ROCKET'S CONFIDENTIALITY
7 REQUESTS AND SOUGHT ADDITIONAL INFORMATION AND
8 CLARIFICATION FROM ROCKET REGARDING CERTAIN ASPECTS
9 OF THE PLAN ITSELF. ON AUGUST 28TH CIRM POSTED THE
10 PUBLIC NOTICE AND THE NON-CONFIDENTIAL PORTIONS OF
11 ROCKET'S ACCESS PLAN ON ITS WEBSITE AND OPENED THE
12 SEVEN-BUSINESS-DAY PUBLIC COMMENT PERIOD, WHICH
13 CLOSES TODAY.

14 WRITTEN COMMENTS MAY BE SUBMITTED THROUGH
15 THE CLOSE OF THE COMMENT PERIOD AT 5 P.M. TODAY, AND
16 TODAY'S MEETING PROVIDES AN OPPORTUNITY FOR
17 INTERESTED MEMBERS OF THE PUBLIC TO PROVIDE ORAL
18 COMMENTS. FOLLOWING TODAY'S MEETING AND THE CLOSE OF
19 THE COMMENT PERIOD, CIRM WILL CONSIDER THE COMPLETE
20 RECORD, INCLUDING ROCKET'S ACCESS PLAN AND ANY
21 SUPPLEMENTAL INFORMATION, CIRM'S REVIEW AND ANALYSIS
22 THEREOF, AND ANY PUBLIC COMMENTS RECEIVED TODAY.

23 CIRM EXPECTS TO MAKE ITS DETERMINATION
24 WHETHER THE PLAN SATISFIES THE APPLICABLE IP
25 REQUIREMENTS WITHIN FIVE BUSINESS DAYS, BY SEPTEMBER

1 15TH.

2 AT THIS POINT, WE'LL TURN IT OVER TO
3 PUBLIC COMMENTS.

4 CLAUDETTE, DO WE HAVE ANYBODY ONLINE?

5 MS. MANDAC: THERE'S NO ONE YET ONLINE, AND
6 OUR APOLOGIES, BUT WE ARE EXPERIENCING SOME
7 TECHNICAL DIFFICULTIES WITH THE LIVESTREAM. SO
8 PEOPLE SHOULD JOIN US ON ZOOM FOR ANY PUBLIC
9 COMMENT, OR YOU CAN ALSO COME TO OUR OFFICE, WHICH
10 IS OPEN AT 601 GATEWAY. INSTRUCTIONS ARE AVAILABLE
11 HERE FOR HOW TO JOIN US FOR PUBLIC ORAL COMMENT.

12 MR. AGUIRRE-SACASA: THANK YOU VERY MUCH.
13 AND, AGAIN, THIS IS FOR ORAL COMMENTS. IF YOU WANT
14 TO SUBMIT A WRITTEN COMMENT, PLEASE DO SO.

15 (PAUSE IN PROCEEDINGS.)

16 MS. MANDAC: I DO SEE THAT WE HAVE FOLKS
17 THAT HAVE JOINED THE ZOOM. AS A REMINDER, IF YOU DID
18 WANT TO RAISE YOUR HAND AS A PERSON ON THE PHONE,
19 YOU WILL NEED TO PRESS STAR 9, AND THEN WHEN CALLED
20 UPON, YOU'LL PRESS STAR 6. AND EVERYONE HAS THREE
21 MINUTES. FOR THOSE ON THE VIDEO, YOU'LL JUST NEED TO
22 RAISE YOUR ZOOM HAND AS WELL AND LET US KNOW.

23 MR. AGUIRRE-SACASA: AND WE THANK YOU FOR
24 JOINING, OF COURSE.

25 (PAUSE IN PROCEEDINGS.)

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1 MR. AGUIRRE-SACASA: HI, GOOD MORNING,
2 EVERYONE. THIS IS JUST A REMINDER THAT WE ARE
3 HOLDING THE PUBLIC COMMENT PERIOD FOR THE ROCKET
4 PHARMACEUTICALS ACCESS PLAN FOR KRESLADI. IF YOU ARE
5 INTERESTED IN MAKING ANY PUBLIC COMMENTS, PLEASE
6 FOLLOW THE INSTRUCTIONS ON SCREEN. WE'LL BE HERE
7 UNTIL 9:30 THIS MORNING. THANK YOU VERY MUCH.

8 (WAITING FOR REQUESTS TO SPEAK.)

9 MR. AGUIRRE-SACASA: HI, FOLKS. GOOD
10 MORNING. ONE FINAL REMINDER HERE, THAT WE'RE
11 DISCUSSING THE ROCKET PHARMACEUTICAL ACCESS PLAN.
12 TODAY IS THE FINAL DAY OF THE SEVEN PUBLIC -- 7-DAY
13 PUBLIC COMMENT PERIOD. WE WILL BE HERE UNTIL 9:30.
14 IF YOU WANT TO PROVIDE ORAL COMMENTS ON THE ACCESS
15 PLAN, AND IF YOU PREFER TO SUBMIT WRITTEN COMMENTS,
16 WE'LL ACCEPT THOSE UNTIL 5 P.M. TODAY.

17 THANK YOU VERY MUCH.

18 MR. AGUIRRE-SACASA: OKAY, FOLKS. AT THIS
19 POINT, WE'RE GOING TO CONCLUDE THE PUBLIC COMMENT
20 PERIOD, ORAL COMMENT -- ORAL PUBLIC COMMENT PERIOD
21 FOR THE ROCKET ACCESS PLAN FOR KRESLADI.

22 AS I'VE MENTIONED MULTIPLE TIMES TODAY, IF
23 YOU WOULD LIKE TO SUBMIT A WRITTEN COMMENT, THEY CAN
24 BE SUBMITTED THROUGH THE CLOSE OF THE COMMENT PERIOD
25 TODAY UNTIL 5 O'CLOCK.

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1 WE'D LIKE TO THANK THOSE OF YOU WHO
2 JOINED, AND WE APPRECIATE YOUR SUPPORT. THANK YOU
3 VERY MUCH.

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN
AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT
THE FOREGOING TRANSCRIPT OF THE VIRTUAL ORAL
COMMENTS REGARDING KRESLADI ON BEHALF OF THE
INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN
THIS MATTER HELD ON SEPTEMBER 8, 2026, WAS HELD AS
HEREIN APPEARS AND THAT THIS IS THE ORIGINAL
TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT
APPEAR IN THIS TRANSCRIPT WERE FORMATTED AND EDITED
BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE
AND ACCURATE RECORD OF THE PROCEEDING.

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