April 6, 2026

SUBMITTED VIA CFTC PORTAL
Secretary of the Commission
Office of the Secretariat
U.S. Commodity Futures Trading Commission
Three Lafayette Centre
1155 21st Street, N.W.
Washington, D.C. 20581

Re: KalshiEX LLC – CFTC Regulation 40.2(a) Notification Regarding the Initial Listing of the "Will <manufacturer> <drug> report positive <stage> results in <group> in <time period>?" Contract

Dear Sir or Madam,

Pursuant to Section 5c(c) of the Commodity Exchange Act and Section 40.2(a) of the regulations of the Commodity Futures Trading Commission, KalshiEX LLC (Kalshi), a registered DCM, hereby notifies the Commission that it is self-certifying the "Will <manufacturer> <drug> report positive <stage> results in <group> in <time period>?" contract (Contract). The Contract will initially be listed after close-of-business on **April 7, 2026**; it is listed as the day after because of limitations of the Commission's online submission portal. The Exchange intends to list the contract on a custom basis. The Contract's terms and conditions (Appendix A) includes the following strike conditions:

- **<manufacturer>**
- **<drug>**
- **<stage>**
- **<time period>**
- **<date>**
- **<group>**

Along with this letter, Kalshi submits the following documents:

- A concise explanation and analysis of the Contract;
- Certification;
- Appendix A with the Contract's Terms and Conditions;
- Confidential Appendices with further information; and
- A request for FOIA confidential treatment.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Xavier Sottile
Head of Markets

KalshiEX LLC
xsottile@kalshi.com

KalshiEX LLC
Official Product Name: "Will <manufacturer> <drug> report positive <stage> results in <group> in <time period>?"
Rulebook: TRIALSTAGERESULTS
Summary: Clinical trial positive result in specified group
Kalshi Contract Category: Health/Science
Kalshi Internal Category: Health
April 6, 2026

CONCISE EXPLANATION AND ANALYSIS OF THE PRODUCT AND ITS COMPLIANCE WITH APPLICABLE PROVISIONS OF THE ACT, INCLUDING CORE PRINCIPLES AND THE COMMISSION'S REGULATIONS THEREUNDER

Pursuant to Commission Rule 40.2(a)(3)(v), the following is a concise explanation and analysis of the product and its compliance with the Act, including the relevant Core Principles (discussed in Appendix D), and the Commission's regulations thereunder.

I. Introduction

The "Will <manufacturer> <drug> report positive <stage> results in <group> in <time period>?" Contract is a contract relating to Health.

Further information about the Contract, including an analysis of its risk mitigation and price basing utility, as well as additional considerations related to the Contract, is included in Confidential Appendices C, D, and E.

Pursuant to Section 5c(c) of the Act and CFTC Regulations 40.2(a), the Exchange hereby certifies that the listing of the Contract complies with the Act and Commission regulations under the Act.

General Contract Terms and Conditions: The Contract operates similar to other event contracts that the Exchange lists for trading. The minimum price fluctuation is $0.01 (one cent). Price bands will apply so that Contracts may only be listed at values of at least $0.01 and at most $0.99. Further, the Contract is sized with a one-dollar notional value and has a minimum price fluctuation of $0.01 to enable Members to match the size of the contracts purchased to their economic risks. As outlined in Rule 5.16 of the Rulebook, trading shall be available at all times outside of any maintenance windows, which will be announced in advance by the Exchange. Members will be charged fees in accordance with Rule 3.13 of the Rulebook. Fees, if they are charged, are charged in such amounts as may be revised from time to time to be reflected on the Exchange's Website. A new Source Agency can be added via a Part 40 amendment. All instructions on how to access

the Underlying are non-binding and are provided for convenience only and are not part of the binding Terms and Conditions of the Contract. They may be clarified at any time. Furthermore, the Contract's payout structure is characterized by the payment of an absolute amount to the holder of one side of the option and no payment to the counterparty. During the time that trading on the Contract is open, Members are able to adjust their positions and trade freely. The Expiration Value and Market Outcome are determined at or after Market Close. The market is then settled by the Exchange, and the long position holders and short position holders are paid according to the Market Outcome. In this case, "long position holders" refers to Members who purchased the "Yes" side of the Contract and "short position holders" refers to Members who purchased the "No" side of the Contract. If the Market Outcome is "Yes," meaning that an event occurs that is encompassed within the Payout Criterion, then the long position holders are paid an absolute amount proportional to the size of their position and the short position holders receive no payment. If the Market Outcome is "No," then the short position holders are paid an absolute amount proportional to the size of their position and the long position holders receive no payment. Specification of the circumstances that would trigger a Market Outcome of "Yes" are included below in the section titled "Payout Criterion" in Appendix A.

CERTIFICATIONS PURSUANT TO SECTION 5c OF THE COMMODITY EXCHANGE ACT, 7 U.S.C. § 7A-2 AND COMMODITY FUTURES TRADING COMMISSION RULE 40.2, 17 C.F.R. § 40.2

Based on the above analysis, the Exchange certifies that:

- ❏ The Contract complies with the Act and Commission regulations thereunder.
- ❏ This submission (other than those appendices for which confidential treatment has been requested) has been concurrently posted on the Exchange's website at https://kalshi.com/regulatory/filings.

Should you have any questions concerning the above, please contact the exchange at ProductFilings@kalshi.com.

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By: Xavier Sottile
Title: Head of Markets
Date: April 6, 2026

Attachments:

Appendix A - Contract Terms and Conditions
Appendix B - Trading Prohibitions
Appendix C (Confidential) - Further Considerations
Appendix D (Confidential) - Source Agency
Appendix E (Confidential) - Compliance with Core Principles

APPENDIX A – CONTRACT TERMS AND CONDITIONS

Official Product Name: "Will <manufacturer> <drug> report positive <stage> results in <group> in <time period>?"
Rulebook: TRIALSTAGERESULTS

TRIALSTAGERESULTS

Scope: These rules shall apply to this contract.

Underlying: The Underlying for this Contract is the <stage> trial results reported by or on behalf of <manufacturer> for <drug> in <group> in <time period>, as documented by the Source Agency. Revisions to the Underlying made after Expiration will not be accounted for in determining the Expiration Value.

Source Agency: The Source Agencies are, in hierarchical order, <manufacturer>'s official press releases, investor relations communications, and regulatory filings (including but not limited to SEC filings, EMA submissions, and PMDA submissions); the U.S. Food and Drug Administration (FDA); the European Medicines Agency (EMA); the U.S. National Library of Medicine's ClinicalTrials.gov database; peer-reviewed publications in which <manufacturer> or its agents are an authoring or sponsoring party; The New England Journal of Medicine, The Lancet, JAMA, and Nature Medicine; the Associated Press, Reuters, Bloomberg News, The Wall Street Journal, The Financial Times, STAT News, BioPharma Dive, and Fierce Biotech.

Type: The type of Contract is an Event Contract.

Issuance: After the initial Contract, Contract iterations will be listed on an as-needed basis at the discretion of the Exchange and corresponding to the risk management needs of Members.

<manufacturer>: <manufacturer> refers to a specific pharmaceutical, biotechnology, or life sciences company or entity specified by the Exchange. <manufacturer> may refer to:

- A specific named company identified by its legal name or its widely recognized trade name or ticker symbol (e.g., "Pfizer," "PFE," "Moderna");
- A subsidiary, joint venture, or co-development partner, provided that the Contract listing explicitly identifies the entity at that level of specificity;
- Multiple companies using AND logic (all must report) or OR logic (any one suffices), as specified by the Exchange;
- A company that has undergone a name change, rebranding, merger, or acquisition since the listing of the Contract, provided the successor entity is the most natural continuation of the originally identified company. Any such determination will be announced by the Exchange.

The identity of <manufacturer> shall remain consistent throughout the life of the Contract. Corporate restructuring, spin-offs, or licensing transfers do not create a new <manufacturer> unless the Exchange determines, in its sole discretion, that the relevant development program has been materially transferred to an entity that is not the natural successor of the original

<manufacturer>, in which case the Exchange will announce any applicable adjustment pursuant to Rule 7.1.

<drug>: <drug> refers to a specific pharmaceutical compound, biologic, therapeutic, vaccine, medical device subject to clinical evaluation, or combination product, as specified by the Exchange. <drug> may be identified by:

- Its International Nonproprietary Name (INN) or generic name (e.g., "lecanemab");
- Its proprietary or brand name (e.g., "Leqembi");
- Its development code, trial identifier, or internal compound designation (e.g., "BNT111"), where a common name has not yet been established;
- A class or category of compound, where specified by the Exchange with sufficient precision to allow unambiguous identification.

Where <drug> has been renamed, rebranded, or reformulated in a manner that does not materially alter the therapeutic compound or its primary mechanism of action under investigation, the Contract shall continue to track the same compound under its updated designation, as announced by the Exchange. A reformulation that changes the active ingredient, route of administration, or primary indication in a manner material to the <stage> under evaluation may be treated as a distinct compound at the Exchange's discretion, and any such determination will be announced to Members.

<stage>: <stage> refers to a defined phase or milestone of clinical development as specified by the Exchange. <stage> may refer, but is not limited, to:

- A specific clinical trial phase as defined by the FDA, EMA, or equivalent regulatory body: Phase 1 (safety and dosing), Phase 2 (efficacy and side effects), Phase 3 (confirmatory efficacy and safety), or Phase 4 (post-marketing surveillance);
- A combined or seamless trial design, such as Phase 1/2 or Phase 2/3, in which case results from the combined trial as a whole shall satisfy <stage> unless the Exchange specifies a sub-phase;
- An adaptive trial stage, interim analysis, or pre-specified primary endpoint readout designated by the Exchange;
- A regulatory review milestone, such as a New Drug Application (NDA), Biologics License Application (BLA), or Marketing Authorization Application (MAA) submission or approval, where the Exchange explicitly designates such a milestone as <stage>;
- An expedited designation pathway outcome, including but not limited to Breakthrough Therapy Designation, Fast Track Designation, Accelerated Approval, Priority Review, or Orphan Drug Designation, where explicitly specified by the Exchange as <stage>.

Where the clinical development program of <drug> is restructured such that the designated <stage> no longer corresponds to a discrete readout (e.g., a Phase 2 is merged into a Phase 3 and

no standalone Phase 2 results are reported), the Exchange will determine the most appropriate resolution approach pursuant to Rule 7.1 and will announce any such determination to Members.

<group>: <group> refers to a specific patient population, cohort, or subpopulation within the clinical development program of <drug> as specified by the Exchange. <group> may be defined by:

- A biomarker or genomic characteristic (e.g., "EGFR-mutant patients," "PD-L1 expression ≥ 50%");
- A demographic characteristic (e.g., "pediatric patients," "patients aged 65 and older");
- A disease characteristic (e.g., "moderate-to-severe," "treatment-naïve," "second-line");
- A treatment assignment within a multi-arm trial (e.g., "combination therapy arm");
- A geographic, regulatory, or jurisdictional cohort (e.g., "Japanese patient population");
- The overall trial population, in which case <group> shall be interpreted as "all enrolled patients" and no subgroup restriction applies; or
- "Any," in which case positive results in any pre-specified subgroup or the overall population shall satisfy the Payout Criterion.

For the purposes of this Contract, <group> shall refer only to a **pre-specified** subgroup, defined as one explicitly identified in the trial protocol, statistical analysis plan, or registration on ClinicalTrials.gov or an equivalent registry prior to the unblinding of trial data, unless the Exchange explicitly designates a post-hoc subgroup in the Contract listing and labels it as such. Results reported for a post-hoc subgroup not explicitly designated by the Exchange shall not satisfy the Payout Criterion, regardless of their statistical or clinical characterization by <manufacturer>. Where <group> is the overall trial population, the pre-specified subgroup requirement does not apply and the primary endpoint of the overall trial governs resolution.

<time period>: <time period> refers to a specific range of time as specified by the Exchange. This may be defined by exact dates (e.g., "between January 1, 2026, and December 31, 2026"), relative markers (e.g., "before July 1, 2027"), an event (e.g., "at the 2026 ASCO Annual Meeting"), or broader intervals (e.g., "Q1–Q2 2027," "calendar year 2026"). "Between" is inclusive of both endpoints, while "before" and "after" exclude the specified date unless stated otherwise. <time period> may also refer to "Any" or "None," to multiple dates (even if non-consecutive), or to a singular and discrete date or time.

Payout Criterion: The Payout Criterion for the Contract encompasses the Expiration Values that <manufacturer> reports positive <stage> results for <drug> in <group> in <time period>.

For the purposes of this Contract, **"reports positive <stage> results in <group>"** means that <manufacturer>, or an authorized agent acting on its behalf, publicly discloses results from <stage> of the clinical development program of <drug> in which the **primary endpoint(s)** applicable to <group>, as pre-specified in the trial protocol or registration on ClinicalTrials.gov

or equivalent registry, are met with statistical significance at the level pre-specified by the trial protocol (or, if no significance threshold is pre-specified, at $p < 0.05$).

Additional clarification(s):

- **Primary endpoint requirement:** Results shall be considered "positive" only if the pre-specified primary endpoint(s) applicable to <group> are met. Favorable secondary endpoint results alone, in the absence of a met primary endpoint, shall not constitute a "positive" result for purposes of this Contract. Where a trial designates co-primary endpoints applicable to <group>, all co-primary endpoints must be met unless the Exchange specifies otherwise in the Contract listing.
- **Pre-specified subgroup requirement:** Where <group> is a subpopulation other than the overall trial population, the subgroup must have been pre-specified in the trial protocol, statistical analysis plan, or trial registry prior to unblinding. A statistically favorable result within <group> that arises from a post-hoc analysis not designated by the Exchange shall not satisfy the Payout Criterion. Where <group> is the overall trial population, this requirement does not apply and the primary endpoint of the overall trial governs.
- **Statistical significance within <group>:** Where <group> is a subpopulation, statistical significance must be demonstrated within <group> itself at the pre-specified threshold. A result that is statistically significant in the overall population but not within <group>, or that achieves nominal significance within <group> only in the context of a hierarchical testing procedure that was not met at a prior step, shall not satisfy the Payout Criterion unless the trial protocol explicitly designates the <group> analysis as a primary or co-primary endpoint with its own significance threshold.
- **Disclosure timing:** Results must be publicly disclosed within <time period> to satisfy the Payout Criterion. Disclosure may take the form of a press release, regulatory filing, a presentation at a medical or scientific conference that is accessible to the public or conference attendees and is accompanied by a corresponding press release, abstract, or regulatory filing by <manufacturer>, or peer-reviewed publication, provided that the disclosing party is <manufacturer> or an authorized representative. Leaks, analyst reports, or third-party speculation not confirmed by <manufacturer> shall not constitute disclosure.
- **Interim analyses:** A pre-specified interim analysis that meets the primary endpoint applicable to <group> at its designated interim stopping boundary (e.g., as determined by an independent Data Safety Monitoring Board or equivalent body recommending early stopping for efficacy) shall qualify as a "positive <stage> result in <group>," provided that this outcome is publicly confirmed by <manufacturer> within <time period>. An interim analysis that is favorable but does not reach the pre-specified stopping boundary shall not qualify. A trial stopped early for futility or safety shall resolve "No."

- **Accelerated approval and surrogate endpoints:** Where <stage> explicitly encompasses an accelerated approval pathway based on a surrogate or intermediate endpoint, the meeting of that surrogate endpoint per the applicable regulatory standard within <group> shall be deemed sufficient to constitute a "positive" result, provided this is specified in the Contract listing.
- **Regulatory action as positive result:** Where the Exchange designates <stage> as an NDA/BLA/MAA approval or equivalent, the formal approval decision by the relevant regulatory authority (FDA, EMA, PMDA, or other body specified by the Exchange) within <time period> for an indication encompassing <group> shall constitute the Payout Criterion. A Complete Response Letter (CRL), Refuse to File letter, or equivalent rejection shall resolve the Contract "No." An approval limited to a narrower label than <group> as specified in the Contract listing shall resolve "No" unless the Exchange determines that the approved population is the natural and substantive equivalent of <group>, which will be announced to Members. An approval for a label that is broader than or otherwise encompasses <group> shall resolve "Yes."
- **Advisory committee recommendations:** For the avoidance of doubt, advisory committee recommendations, panel votes, or regulatory staff review documents do not constitute regulatory approval. Only the formal issuance of an approval letter, marketing authorization, or equivalent regulatory action by the designated authority shall satisfy the Payout Criterion where <stage> is defined as a regulatory approval milestone.
- **Partial, topline, and full data disclosures:** Topline results disclosed by <manufacturer> that unambiguously characterize the primary endpoint applicable to <group> as met shall be sufficient to satisfy the Payout Criterion, even if complete study data, statistical analysis plans, or peer-reviewed publications are not yet available at the time of disclosure. A statement that results are "mixed," "inconclusive," or that "further analysis is required" shall not constitute a positive result unless and until a subsequent unambiguous confirmation is made within <time period>.
- **Manufacturer co-development and licensing arrangements:** Where <drug> is being co-developed under a partnership, collaboration, or licensing agreement, and the reporting entity is a partner, licensee, or co-developer rather than <manufacturer> itself, results publicly attributed to the program shall qualify as being reported by <manufacturer> provided that <manufacturer> is a named party to the relevant development agreement and does not publicly disavow the reported results within <time period>.
- **Program discontinuation:** If <manufacturer> publicly announces the permanent discontinuation, abandonment, or out-licensing of the <drug> development program for <stage> prior to the expiration of <time period>, and no results have been reported, the Contract shall resolve "No." A temporary clinical hold imposed by a regulatory agency does not constitute abandonment unless <manufacturer> subsequently withdraws the program.

- **Data integrity and retractions:** If results that initially satisfied the Payout Criterion are publicly retracted, withdrawn, or materially corrected by <manufacturer> prior to the Expiration Date such that the primary endpoint applicable to <group> is no longer met, the Contract shall resolve "No." Retractions or corrections published after the Expiration Date shall not affect resolution.
- **Multiple trials for the same stage:** If <manufacturer> is running more than one trial of <drug> that falls within the designated <stage> and includes <group>, positive results from any one such trial within <group> shall satisfy the Payout Criterion unless the Contract listing specifies a particular trial by name, NCT identifier, or other distinguishing characteristic.
- **Combination therapies:** Where <drug> is studied as part of a combination regimen and the trial's primary endpoint applicable to <group> pertains to the combination, the results shall be attributed to <drug> for purposes of this Contract, provided <drug> is a named component of the combination as specified in the Contract listing.
- Where <drug> is removed from a combination regimen via protocol amendment prior to the primary endpoint readout, subsequent results from the amended combination shall not be attributed to <drug>.

The following **ARE** encompassed by the Payout Criterion:

- A press release or SEC filing from <manufacturer> stating that the pre-specified primary endpoint applicable to <group> of a <stage> trial of <drug> was met with statistical significance, published within <time period>.
- An independent DSMB recommendation to stop the trial early for efficacy within <group>, publicly confirmed by <manufacturer> within <time period>.
- A formal regulatory approval of <drug> by the designated authority within <time period> for an indication that encompasses <group>, where <stage> is defined as an approval milestone.
- Topline data disclosed at a medical conference within <time period> by <manufacturer> or its authorized representative confirming the primary endpoint applicable to <group> was met.
- Where <group> is "Any," positive results meeting the primary endpoint in any pre-specified subgroup or the overall population, disclosed within <time period>.

The following are **NOT** encompassed by the Payout Criterion:

- Secondary or exploratory endpoint results alone, in the absence of a met primary endpoint applicable to <group>.
- Results that meet the primary endpoint in the overall trial population but not within <group>, where <group> is a defined subpopulation with its own pre-specified endpoint.

- Post-hoc subgroup analyses not explicitly designated as <group> by the Exchange, regardless of their statistical or clinical characterization by <manufacturer> or third parties.
- Analyst estimates, third-party reports, or media speculation not confirmed by <manufacturer>.
- Interim results that are favorable within <group> but do not reach the pre-specified interim stopping boundary.
- A trial stopped for safety, futility, or enrollment difficulties.
- Results publicly disclosed outside of <time period>, even if the underlying trial completed within <time period>.
- Preclinical, animal model, or in vitro results, regardless of how favorable.
- Phase 1 safety data alone (absent an explicit efficacy signal designated as the primary endpoint by the trial protocol), where <stage> is defined as Phase 2 or later.
- A regulatory submission (e.g., NDA filing) where <stage> is defined as regulatory approval, unless the approval itself is granted within <time period>.
- A regulatory approval for an indication that does not encompass <group> as specified in the Contract listing.

Minimum Tick: The Minimum Tick size for the Contract shall be $0.01.

Position Accountability Level: The Position Accountability Level for the Contract shall be $25,000 per strike, per Member.

Last Trading Date: The Last Trading Date of the Contract will be the Expiration Date. The Last Trading Time will be the Expiration time.

Settlement Date: The Settlement Date of the Contract shall be no later than the day after the Expiration Date, unless the Market Outcome is under review pursuant to Rule 7.1.

Expiration Date: The latest Expiration Date of the Contract shall be one week after the final day of <time period>. If an event described in the Payout Criterion occurs, expiration will be moved to an earlier date and time in accordance with Rule 7.2.

Expiration time: The Expiration time of the Contract shall be 10:00 AM ET.

Settlement Value: The Settlement Value for this Contract is $1.00.

Expiration Value: The Expiration Value is the value of the Underlying as documented by the Source Agency on the Expiration Date at the Expiration time.

Contingencies: Before Settlement, Kalshi may, at its sole discretion, initiate the Market Outcome Review Process pursuant to Rule 7.1 of the Rulebook. If an Expiration Value cannot be

determined on the Expiration Date, Kalshi has the right to determine payouts pursuant to Rule 7.1 in the Rulebook.

APPENDIX B – TRADING PROHIBITIONS

In addition to the general prohibition against trading on material nonpublic information, the Exchange will institute additional prohibitions for trading the contract. Persons under 18 years of age are not permitted to create Kalshi accounts. The following individuals will be prohibited from trading:

- Officers, directors, employees, contractors, and consultants of <manufacturer>, including its subsidiaries, affiliates, joint venture partners, co-development partners, and licensees involved in the clinical development program of <drug>.
- Members of any Data Safety Monitoring Board (DSMB), independent data monitoring committee, clinical endpoint adjudication committee, or equivalent independent oversight body with access to unblinded trial data for <drug>.
- Principal investigators, sub-investigators, clinical research coordinators, and site staff at clinical trial sites enrolling or treating patients in the relevant <stage> trial(s) of <drug>, to the extent they have access to unblinded or aggregated efficacy data.
- Employees, contractors, and consultants of contract research organizations (CROs), central laboratories, biostatistical firms, and data management vendors engaged by <manufacturer> to conduct, analyze, or monitor the relevant trial(s).
- Officers, directors, employees, and review staff of the FDA, EMA, PMDA, or other regulatory authority with access to non-public submissions, review documents, inspection findings, or advisory communications relating to <drug> in <stage>.
- Members of FDA advisory committees, EMA scientific committees (e.g., CHMP), or equivalent regulatory panels convened to evaluate <drug>, from the time of their appointment to such panel through resolution of the Contract.
- Officers, directors, and employees of institutional review boards (IRBs) or ethics committees reviewing safety or efficacy data for the relevant trial(s) of <drug>.
- Employees of investment banks, consultants, or financial advisors engaged by <manufacturer> or its partners to advise on transactions, financing, or strategic decisions materially related to the <drug> development program, to the extent such persons possess non-public clinical data or knowledge of announcement timing.
- Persons who have entered into confidentiality, consulting, or expert-network agreements with <manufacturer> or its agents that provide access to non-public clinical trial data, timelines, or results for <drug>.
- Immediate family members (spouses, domestic partners, parents, children, and siblings) and household members of any of the above.
- Any person who has obtained material non-public information regarding the timing, content, or outcome of the <stage> results for <drug> in <group> through any means, including but not limited to inadvertent disclosure, misappropriation, or breach of confidentiality obligations.