



Obsidian Therapeutics to Present Phase 2 Clinical Data for OBX-115 in Advanced Melanoma in Oral Presentation at 2026 ASCO Annual Meeting

May 21, 2026

- *OBX-115 ORR was 67% at RP2D (n=10/15), including 2 complete responses, in patients with difficult-to-treat advanced melanoma*
- *OBX-115 safety profile remains consistent: no DLTs, no ICANS, no ICU transfers, and no TRM*
- *OBX-115 is an investigational IL2-sparing engineered TIL cell therapy compatible with minimally invasive core needle biopsy and outpatient-enabled low-dose LD, with the potential to broaden the population of patients eligible for cell therapy*

CAMBRIDGE, Mass., May 21, 2026 – Obsidian Therapeutics, Inc., a clinical-stage biopharmaceutical company harnessing novel protein-regulation technology to develop engineered tumor-infiltrating lymphocyte (TIL) cell therapies, today announced positive Phase 2 results in patients with advanced melanoma from the Phase 1/2 Agni-01 multicenter study of OBX-115. These data will be presented in an oral presentation by Allison S. Betof, M.D., Ph.D., FASCO, associate professor of medicine (oncology), Stanford School of Medicine, on Monday, June 1, 2026, at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL.

OBX-115 is a novel engineered TIL cell therapy armored with pharmacologically regulatable membrane-bound IL15 and designed to deliver an improved, patient-centric treatment regimen. With its potentially reduced treatment burden driven by option for less-invasive core needle biopsy tumor tissue procurement, exclusively low-dose lymphodepletion (LD) compatible with outpatient administration and elimination of IL2 in the treatment regimen, OBX-115, if approved, has the potential to become a meaningful therapeutic option and expand the cell therapy eligible population of patients with advanced or metastatic melanoma.

Oral Presentation Title: OBX-115 engineered tumor-infiltrating lymphocyte (TIL) cell therapy with regulatable membrane-bound IL15 (mbIL15) in patients with advanced melanoma that has progressed on/after immune checkpoint inhibitors (ICI): Phase 2 results

Session Title: Oral Abstract Session – Melanoma/Skin Cancers

Abstract: #9507

Location: Grand Ballroom S100bc

Session Date and Time: June 1, 8:00AM-11:00AM CT

Presentation Time: 10:12 AM-10:24 AM CT

Data to be presented are from the single-arm open-label Phase 1/2 Agni-01 multicenter study ([NCT06060613](#)) assessing the safety and efficacy of OBX-115 in adult patients with advanced melanoma that has progressed following treatment with ICI. Results from the January 22, 2026 data cutoff include 15 patients treated at the recommended phase 2 dose (RP2D), with n=6 from Phase 1 and n=9 from Phase 2.

OBX-115 demonstrated strong efficacy with a 67% objective response rate (ORR) in a difficult-to-treat advanced melanoma patient population

- Study conducted in high unmet need melanoma patients, including a majority (93%) who were previously treated with doublet ICI
 - 73% of patients had progression after anti-PD-1 + anti-CTLA-4 doublet therapy, a group with particularly low response rates to subsequent therapy
- 67% ORR (per RECIST v1.1), including 2 confirmed complete responses (CR) and 8 confirmed partial responses (PR) (compared to 1 CR and 9 PRs in abstract text)
- Durable clinical benefit, including 8 of 10 responses ongoing as of the median 4.3 month study follow-up

OBX-115 continues to deliver consistent, favorable safety profile; treatment regimen with low-dose lymphodepletion and no IL2

- All patients received low-dose LD, including 4 in the outpatient setting
- No dose-limiting toxicities (DLT), treatment-related mortality (TRM), immune effector cell-associated neurotoxicity syndrome (ICANS) or ICU transfers
- Majority of treatment-emergent adverse effects (TEAEs) occurring in ≥20% of patients were Grade 2 or less

Dr. Betof commented, “These data highlight OBX-115’s promising safety and efficacy profile, demonstrating the potential for durable benefit with low rates of major safety signals, including no DLTs, ICU transfer or TRM. The notable reduction in patient treatment burden relative to other therapies, driven by attributes such as core needle biopsy tumor tissue procurement and treatment regimen with outpatient-compatible low-dose lymphodepletion and without IL2, could be very beneficial and broaden the

number of cell therapy eligible patients.”

“Results from the Agni-01 study, including the 67% ORR, with 80% of responses ongoing as of the median 4.3 month study follow up, further emphasize OBX-115’s potential in advanced melanoma. We are highly encouraged by the anticipated benefit demonstrated in patients with difficult-to-treat advanced melanoma, including patients with disease progression following anti-PD-1 combination exposure,” said Parameswaran Hari, M.D., M.S., Chief Medical Officer of Obsidian. “We have been in discussions with the FDA, and after reaching alignment on key design elements including eligibility criteria, clinical trial endpoints and drug product potency assay, plan to pursue a single-arm accelerated approval pathway. We look forward to continuing to advance OBX-115 through the clinic and plan to begin treating patients in the registration-enabling cohort of our multicenter study in mid-2026.”

Obsidian is also investigating OBX-115 in patients with non-small cell lung cancer (NSCLC) in the Agni-01 trial. NSCLC Phase 1 data are expected in the first half of 2027.

About OBX-115

Obsidian’s lead investigational cytoTIL15™ program, OBX-115, is a novel engineered tumor-derived autologous T cell immunotherapy (tumor-infiltrating lymphocyte [TIL] cell therapy) armored with pharmacologically regulatable membrane-bound IL15 (mBL15). OBX-115 has the potential, if approved, to become a meaningful therapeutic option for patients with advanced or metastatic melanoma and other solid tumors by leveraging the expected benefits of mBL15 and Obsidian’s proprietary, differentiated manufacturing process designed to enhance persistence, antitumor activity, and clinical safety of TIL cell therapy. Obsidian is investigating OBX-115 in the phase 1/2 Agni-01 multicenter trial in patients with advanced solid tumors ([NCT06060613](https://clinicaltrials.gov/ct2/show/study/NCT06060613)).

About Obsidian Therapeutics

Obsidian Therapeutics, Inc. is a clinical-stage biopharmaceutical company harnessing novel protein-regulation technology to develop engineered TIL cell therapies for the treatment of patients with solid tumors. Obsidian’s proprietary cytoDRIVE® technology is designed to precisely regulate the timing and level of protein function by using FDA-approved small-molecule drugs. Obsidian is headquartered in Cambridge, MA. For more information, please visit www.obsidiantx.com.

Additional Information and Where to Find It

In connection with the proposed transactions between Obsidian and Galera Therapeutics, Inc. (“Galera”), Galera and the newly formed company formed in connection therewith will file relevant materials with the SEC. The newly formed company has filed a registration statement on Form S-4 that includes information statement and prospectus relating to the proposed transaction, which constitutes an information statement of Galera and a prospectus of the newly formed company (the “Prospectus”). Galera and the newly formed company may also file other documents with the SEC regarding the proposed transaction. This press release is not a substitute for the Prospectus or any other document which Galera or the newly formed company may file with the SEC or send to stockholders of Galera or Obsidian in connection with the proposed transaction. The Prospectus will be mailed to stockholders of Galera. INVESTORS AND SECURITYHOLDERS OF GALERA ARE URGED TO READ THE REGISTRATION STATEMENT AND THE PROSPECTUS AND ALL OTHER DOCUMENTS FILED OR THAT WILL BE FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT GALERA, OBSIDIAN AND THE PROPOSED TRANSACTION. Investors and security holders may obtain free copies of the registration statement and the Prospectus (when available) and other documents filed with the SEC by Galera or the newly formed company through the website maintained by the SEC at www.sec.gov. Copies of the documents filed with the SEC by Galera will be available free of charge on Galera’s website at www.galeratx.com.

No Offer or Solicitation

This press release is for informational purposes only and not intended to and does not constitute an offer to subscribe for, buy or sell, or the solicitation of an offer to subscribe for, buy or sell, or an invitation to subscribe for, buy or sell, any securities of Galera, Obsidian or the newly formed company, or the solicitation of any vote or approval in any jurisdiction pursuant to or in connection with the proposed transaction or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended, and otherwise in accordance with applicable law.

Participants in the Solicitation

This press release is not a solicitation of a proxy from any security holder of Galera or Obsidian. However, Galera and Obsidian and each of their respective directors and executive officers may be considered participants in the solicitation of proxies in connection with the proposed transaction. Information about the directors and executive officers of Galera may be found in its Annual Report on Form 10-K for the year ended December 31, 2025, which was filed with the SEC on March 19, 2026 and its proxy statement for its 2026 annual meeting of stockholders, which was filed with the SEC on April 10, 2026. Other information regarding the participants in the proxy solicitations and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in Prospectus and other relevant materials to be filed with the SEC when they become available.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements concerning future clinical development activities, potential milestone payments, the merger transaction and completion of the concurrent private placement financing, the expected effects, perceived benefits or opportunities and related timing with respect thereto and expectations regarding or plans for the combined company's pipeline.

These forward-looking statements relate to Galera, Obsidian and the newly formed company (together, "us" or "we"), our business prospects and our results of operations and are subject to certain risks and uncertainties posed by many factors and events that could cause our actual business, prospects and results of operations to differ materially from those anticipated by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those described under the heading "Risk Factors" included in Galera's Annual Report on Form 10-K for the year ended December 31, 2025 and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2026. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "aim," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. We undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that might subsequently arise, except as required by applicable law.

These forward-looking statements are based upon our current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation: statements about the synergies or benefits of the proposed transaction, including future financial and operating results, plans, objectives, expectations and intentions; the anticipated timing of closing of the proposed transaction and the private placement financing; negative effects of the announcement or consummation of the proposed transaction on the market price of our capital stock and our operating results; risks relating to the value of shares of the newly formed company to be issued in the proposed transaction; risks related to the ability to obtain approval of the Galera stockholders; changes in capital resource requirements; risks related to our inability to obtain sufficient additional capital to continue to advance our product candidates; our and our collaborators' ability to execute clinical programs for our product candidates; timing, progress, enrollment or results of clinical trials with our product candidates; our ability to obtain and maintain intellectual property rights and regulatory exclusivities; and our ability to establish a market for our product candidates if the combined company receives regulatory approval therefor.

Inquiries:

Caroline Code

VP Corporate Development and Investor Relations

ccode@obsidiantx.com