Obsidian Therapeutics to Present Updated Amsoki-cel Efficacy and Pooled Safety Data in Advanced Melanoma at SITC 2026 Annual Meeting

November 6, 2026

- *Amsoki-cel ORR was 67% at RP2D (n=10/15), including 2 CRs and 8 PRs; 5 responses remain ongoing, including both CRs and 2 PRs with 100% SOD reduction (one of which deepened since the abstract data cutoff)*
- *Amsoki-cel mPFS was 8.3 months and mDOR was not reached at median 14.3-month study follow up; 33% of patients (5/15) remained in deep, ongoing response at 12 months post-infusion*
- *In pooled safety set (n=37), amsoki-cel demonstrated a consistent, favorable safety profile: no DLTs, TRM, ICANS or ICU transfers*
- *Topline data from registration-enabling cohort of Phase 1/2 Agni-01 study in advanced melanoma expected by year-end 2027*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 6, 2026-- Obsidian Therapeutics, Inc. (Nasdaq: OBX), a clinical-stage biopharmaceutical company harnessing novel protein-regulation technology to develop engineered tumor-infiltrating lymphocyte (TIL) cell therapies, today announced positive updated results in patients with immune-checkpoint inhibitor (ICI)-resistant advanced melanoma from the Phase 1 single-center first-in-human (FIH) study and the Phase 1/2 Agni-01 multicenter study of amsokigene autoleucel (amsoki-cel, formerly OBX-115). These data will be presented in a poster presentation on Saturday, November 7, 2026, at the Society for Immunotherapy of Cancer (SITC) 2026 Annual Meeting, taking place in Phoenix, AZ.

Amsoki-cel is a novel engineered TIL cell therapy armored with pharmacologically regulatable membrane-bound IL15 and designed to deliver an improved, patient-centric treatment regimen. Amsoki-cel has the potential to reduce treatment burden through the option for less-invasive core needle biopsy (CNB) tumor tissue procurement, exclusively low-dose lymphodepletion (LD) compatible with outpatient administration, and elimination of IL2 from the treatment regimen.

Updated efficacy 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 amsoki-cel in adult patients with advanced melanoma that has progressed following treatment with ICI. Efficacy results from the September 25, 2026, data cutoff include 15 patients treated at the recommended phase 2 dose (RP2D). Additional data to be presented include pooled safety data across 37 patients from the Phase 1 FIH single-center study (NCT05470283) and the Phase 1/2 Agni-01 multicenter study (NCT06060613) as of a May 5, 2026 data cutoff.

Updated amsoki-cel data demonstrate strong efficacy and response durability, with 33% of all patients treated at RP2D still in response at month 12 post-infusion

- Study conducted in high unmet-need patients with melanoma, including a majority (93%) who previously received doublet ICI, and 73% with disease progression after anti–PD-1 + anti–CTLA-4 doublet therapy
- 67% objective response rate (ORR) (per RECIST v1.1), including 2 confirmed complete responses (CR) and 8 confirmed partial responses (PR)
- Durable clinical benefit, including 5 of 10 responses ongoing as of the median 14.3-month study follow-up
    - Since the May 5, 2026 abstract data cutoff, 1 PR deepened to 100% reduction in the sum of diameters (SOD) of target lesions at 6 months post-infusion, for a total of 2 PRs with 100% SOD reduction and 2 CRs, all of which are ongoing
    - At 12-month landmark post-infusion, 33% of all treated patients (5/15) remained in deep, ongoing response with SOD reduction of 72% (1 patient) to 100% (4 patients)
- Median progression-free survival (mPFS) was 8.3 months and median duration of response (mDOR) was not reached

Amsoki-cel demonstrates a consistent, favorable safety profile across the pooled safety population

- No dose-limiting toxicities (DLT), treatment-related mortality (TRM), immune effector cell-associated neurotoxicity syndrome (ICANS) or ICU transfers
- Majority of non-hematologic treatment-emergent adverse events (TEAEs) occurring in ≥30% of patients were Grade 2 or less; one reported Grade 3 cytokine release syndrome (CRS)
- Tumor tissue acquired using CNB (10 patients, 27%) or surgical resection (27 patients, 73%)

The poster presentation is available in the Publications section of the Obsidian Therapeutics website.

“These updated data, including promising efficacy, durability, and safety, in patients with ICI-resistant advanced melanoma continue to underscore amsoki-cel’s potential as a meaningful treatment option for patients,” said lead author and presenter, Rodabe Amaria, M.D., professor of Melanoma Medical Oncology at The University of Texas MD Anderson Cancer Center. “The less burdensome treatment approach, including option for minimally invasive CNB tumor tissue procurement, low-dose

lymphodepletion compatible with outpatient administration and no IL2, has the potential to make TIL therapy more accessible, while still delivering durable clinical benefit."

"The updated results from the Agni-01 study, including a mPFS of 8.3 months and mDOR that has not yet been reached at median study follow-up of 14.3 months, further reinforce amsoki-cel's potential in patients with ICI-resistant advanced melanoma. We are particularly encouraged by the durability, including 33% of all patients treated at RP2D with ongoing responses at the one-year mark, and continued deepening of responses over time," said Parameswaran Hari, M.D., M.S., Chief Medical Officer of Obsidian. "Enrollment in the registration-enabling cohort of our multicenter study is ongoing and expected to complete by the end of the first quarter of 2027. We look forward to reporting topline data by year-end 2027."

Obsidian also published results summarizing safety and efficacy data (May 5, 2026 data cutoff) from the FIH and ongoing Agni-01 studies in *Nature Medicine* on Tuesday, November 3, 2026. The publication, "Regulatable Membrane-Bound IL-15 Engineered TIL Cell Therapy for Immune Checkpoint Inhibitor-Resistant Advanced Melanoma: Pooled Analysis of Phase 1 and 1/2 Trials," is available online here.

Obsidian is also investigating amsoki-cel 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 Amsokigene Autoleucel (amsoki-cel, formerly OBX-115)

Obsidian leverages its cytoDRiVE® platform to develop engineered TIL cell therapies. Obsidian's lead investigational TIL program, amsoki-cel, is a novel engineered tumor-derived autologous T cell immunotherapy (tumor-infiltrating lymphocyte [TIL] cell therapy) armored with pharmacologically regulatable membrane-bound IL15 (mbIL15). Amsoki-cel has the potential, if approved, to become a meaningful therapeutic option for patients with advanced (unresectable or metastatic) melanoma and other solid tumors by leveraging the expected benefits of mbIL15 and Obsidian's proprietary, differentiated manufacturing process designed to enhance persistence, antitumor activity, and clinical safety of TIL cell therapy. Obsidian is investigating amsoki-cel in the Phase 1/2 Agni-01 multicenter trial in patients with advanced solid tumors (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 has offices in Cambridge and Bedford, MA. For more information, please visit www.obsidiantx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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. Such statements include, but are not limited to, implied and express statements concerning beliefs and expectations regarding: future clinical development activities, therapeutic potential, clinical benefits and safety of Obsidian's product candidates; potential indications and patient populations for amsoki-cel, if approved; the timing of enrollment in, completion of and reporting of data from clinical trials, including the Agni-01 study; and the timing, progress, objectives or plans for Obsidian's development of its clinical pipeline and interactions with regulatory agencies.

These forward-looking statements relate to Obsidian, its business, prospects and results of operations, and are subject to certain risks and uncertainties posed by many factors and events that could cause Obsidian's actual business, prospects and results of operations to differ materially from those anticipated by such forward-looking statements. 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: Obsidian's ability to advance amsoki-cel through clinical development, and to obtain regulatory approval of amsoki-cel; the results of preclinical studies, or clinical studies not being predictive of future results in connection with future studies; the initiation, timing, progress and results of clinical trials; Obsidian's ability to fund its development activities and achieve development goals; Obsidian's dependence on third parties to conduct clinical trials and manufacture amsoki-cel; Obsidian's ability to attract, hire and retain key personnel, and protect its intellectual property; Obsidian's financial condition and need for substantial additional funds in order to complete development activities and commercialize amsoki-cel, if approved; regulatory developments and approval processes of the U.S. Food and Drug Administration and comparable foreign regulatory authorities; Obsidian's competitors and industry; and other risks and uncertainties described under the heading "Risk Factors" included in the Quarterly Report on Form 10-Q for the quarter ended June 30, 2026. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. These forward-looking statements are based upon Obsidian's current expectations and involve assumptions that may never materialize or may prove to be incorrect. 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.

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