Obsidian Therapeutics Announces First Patient Enrolled in the Registration-enabling Cohort of Phase 1/2 Agni-01 Study Evaluating Amsoki-cel (OBX-115) in Advanced Melanoma

August 5, 2026

- *Following discussions with FDA, Company has decided to pursue a single-arm trial design intended to support future BLA submission*
- *Initiation of registration-enabling cohort follows positive Phase 1/2 results demonstrating a 67% ORR at RP2D (n=10/15), including 2 complete responses, in patients with difficult-to-treat advanced melanoma*
- *Topline data from registration-enabling cohort expected by year-end 2027*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 5, 2026-- Obsidian Therapeutics, Inc. (“Obsidian”) (Nasdaq: OBX), a clinical-stage biopharmaceutical company harnessing novel protein-regulation technology to develop engineered tumor-infiltrating lymphocyte (TIL) cell therapies, today announced the first patient has been enrolled in the registration-enabling cohort of the Phase 1/2 Agni-01 multicenter study of amsokigene autoleucel (amsoki-cel, formerly OBX-115), an engineered TIL cell therapy armored with pharmacologically regulatable membrane-bound IL15 (mbIL15), in patients with immune checkpoint inhibitor (ICI)-resistant advanced or metastatic melanoma.

“We have obtained alignment with the FDA across key trial design and manufacturing considerations, including drug potency assay, to proceed with the registration-enabling cohort in support of the single-arm accelerated approval pathway for amsoki-cel in advanced melanoma. Enrolling the first patient in this cohort is an important step toward bringing a patient-centric TIL treatment regimen to patients with difficult-to-treat ICI-resistant advanced melanoma,” said Parameswaran Hari, M.D., M.S., Chief Medical Officer of Obsidian. “We believe amsoki-cel has the potential to serve a broad patient population given its IL2-free regimen, option for less-invasive core needle biopsy tumor tissue procurement, and exclusively low-dose lymphodepletion compatible with outpatient administration. We anticipate reporting topline data from the registration-enabling cohort by year-end 2027.”

The single-arm registration-enabling cohort is part of the ongoing Agni-01 study (NCT06060613), which is a multicenter Phase 1/2 study, and designed to further evaluate the safety and efficacy of amsoki-cel at the recommended phase 2 dose (RP2D) in patients with ICI-resistant advanced melanoma. The primary endpoint is objective response rate (ORR) as measured per Response Evaluation Criteria in Solid Tumors (RECIST v1.1) by blinded independent central radiologist review (BICR). Enrollment is anticipated to be completed by end of Q1 2027.

Initiation of the registration-enabling cohort follows positive Phase 1/2 results from the Agni-01 study, where amsoki-cel demonstrated strong efficacy with a 67% ORR at the RP2D (n=10/15), including two complete responses in a patient population with high unmet need, difficult-to-treat advanced melanoma. Amsoki-cel has also delivered a consistent, favorable safety profile with low-dose lymphodepletion and no IL2 in the treatment regimen. There were no reported dose-limiting toxicities, treatment-related mortality, immune effector cell-associated neurotoxicity syndrome or ICU transfers.

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 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.

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).

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, and expectations regarding 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 Registration Statement on Form S-4 filed with the SEC on July 2, 2026 (SEC file No. 333-295249). 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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Source: Obsidian Therapeutics, Inc.