Imviva Biotech Receives FDA IDE Authorization for clonoSEQ® Assay in TENACITY-01 Clinical Trial

June 30, 2026

Highly sensitive next-generation sequencing-based MRD testing will identify eligible patients with T-cell malignancies for trial enrollment and precisely evaluate treatment response

BOSTON, June 30, 2026 (GLOBE NEWSWIRE) -- Imviva Biotech, a clinical-stage biotechnology company developing next-generation allogeneic CAR-T cell therapies, today announced that the U.S. Food and Drug Administration (FDA) has granted authorization for its Investigational Device Exemption (IDE) application for the use of Adaptive Biotechnologies' clonoSEQ® assay in the TENACITY-01 clinical trial (NCT07070219). The TENACITY-01 trial evaluates CTD402, Imviva's investigational allogeneic anti-CD7 CAR-T cell therapy, for the treatment of relapsed/refractory (R/R) T-cell acute lymphoblastic leukemia/lymphoblastic lymphoma (T-ALL/LBL) and patients with T-ALL/LBL in first or second complete remission with minimal (or measurable) residual disease (MRD-positive).

Next-generation sequencing-based clonoSEQ provides highly sensitive, reliable detection of MRD—small amounts of cancer that remain after treatment but are often missed by standard methods and can lead to relapse. The relationship between MRD status and relapse risk is well-established, and a threshold of 0.01% (10-4) is widely used as a clinically actionable cutoff to define high-risk disease and guide treatment escalation in ALL (National Comprehensive Cancer Network). The use of clonoSEQ will serve a dual purpose in the TENACITY-01 trial—identifying patients with MRD levels of 0.1% or higher for enrollment eligibility and detecting and quantifying MRD in post-treatment bone marrow samples to support exploratory analyses.

IDE authorization signals that an assay is capable of being used in a highly regulated clinical development program where test results may be used for patient management. This IDE authorization enables the use of highly sensitive MRD assessment in the TENACITY-01 trial to identify eligible patients for enrollment and precisely evaluate treatment response.

Despite improvements in remission rates for newly diagnosed T-ALL/LBL, particularly in pediatric populations, high relapse rates remain a significant challenge. MRD status is one of the strongest independent predictors of relapse and survival in ALL, with studies showing 10-year event-free survival rates of approximately 77% versus 32% for MRD-negative versus MRD-positive pediatric patients (Berry et al., 2017).

“FDA authorization of our IDE is a significant step forward as we advance the TENACITY-01 clinical trial,” said Jan Davidson-Moncada, MD, PhD, Imviva Biotech Chief Medical Officer. “Integrating clonoSEQ will allow us to more accurately monitor MRD and evaluate the durability of CTD402. These insights can accelerate clinical decision-making and ultimately support improved patient outcomes by enabling earlier intervention and more personalized treatment strategies.”

"As the field moves increasingly toward MRD-guided treatment strategies, interventional clinical trials require MRD technologies that can deliver highly sensitive, standardized results across diverse clinical settings," said Mary Pat Lancelotta, Senior Vice President, MRD Biopharma at Adaptive Biotechnologies. "With its extensive clinical validation and broad use in hematologic malignancies, clonoSEQ is uniquely positioned to support these next-generation trial designs and help advance MRD-guided care for patients with T-ALL/LBL."

The ongoing global, single-arm, open-label TENACITY-01 trial is enrolling adolescents and adults (≥12 years) to evaluate the safety, efficacy, and cellular pharmacokinetics of CTD402. The current study will enroll up to 120 patients, divided between R/R and MRD-positive cohorts. All participants will receive a standard dose lymphodepletion (fludarabine/cyclophosphamide) and a flat dose of 400×10^6 CTD402 CAR-T cells.

For more information, visit www.imvivabio.com.

About CTD402

CTD402 is an investigational ‘ready-at-point of care’ allogeneic anti-CD7 CAR-T cell therapy designed for T-cell mediated disease. The product candidate incorporates T-cell receptor (TCR) and HLA class II knockout, along with Imviva's proprietary ANSWER™ inhibitory ligands to enhance resistance to host immune rejection. The robustness of CTD402's manufacturing process, showing product consistency across multiple donors and production lots, promises to deliver an 'off-the-shelf' allogeneic platform with the critical advantage of immediate availability, eliminating manufacturing delays that can be life-threatening for patients with rapidly progressive disease.

A global Phase 1b/2 clinical trial (TENACITY-01) evaluating CTD402 for the treatment of relapsed/refractory T-ALL/LBL patients is enrolling patients (NCT07070219). The U.S. Food and Drug Administration has granted Rare Pediatric Disease Designation (RPDD), and Regenerative Medicine Advanced Therapy (RMAT) designation to CTD402 for the treatment of relapsed or refractory T-cell acute lymphoblastic leukemia (T-ALL).

About Imviva Biotech

Imviva Biotech is a clinical-stage biotechnology company dedicated to developing innovative allogeneic CAR-T cell therapies for patients with cancer and autoimmune diseases. The company's proprietary platform incorporates advanced cell engineering technologies to create off-the-shelf cellular immunotherapies. Imviva's pipeline includes programs in both oncology and autoimmune indications.

About clonoSEQ

clonoSEQ® is the first and only FDA-cleared in vitro diagnostic (IVD) test for detecting and tracking minimal (or measurable) residual disease (MRD) in patients with multiple myeloma (MM) or B-cell acute lymphoblastic leukemia (B-ALL) using bone marrow, and in patients with chronic lymphocytic leukemia (CLL) using blood or bone marrow. clonoSEQ is also available in diffuse large B-cell lymphoma (DLBCL), mantle cell lymphoma (MCL), T-cell acute lymphoblastic leukemia (T-ALL), and other lymphoid cancers and specimen types as a CLIA-validated laboratory developed test (LDT).

clonoSEQ is covered by Medicare for MM, CLL, ALL, DLBCL and MCL.

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To review the FDA-cleared uses of clonoSEQ, visit clonoSEQ.com/technical-summary.

About Adaptive Biotechnologies

Adaptive Biotechnologies (“we” or “our”) is a commercial-stage biotechnology company focused on harnessing the inherent biology of the adaptive immune system to transform the diagnosis and treatment of disease. We believe the adaptive immune system is nature’s most finely tuned diagnostic and therapeutic for most diseases, but the inability to decode it has prevented the medical community from fully leveraging its capabilities. Our proprietary immune medicine platform reveals and translates the massive genetics of the adaptive immune system with scale, precision and speed. We apply our platform to partner with biopharmaceutical companies, inform drug development, and develop clinical diagnostics across our two business areas: Minimal Residual Disease (MRD) and Immune Medicine. Our commercial products and clinical pipeline enable the diagnosis, monitoring, and treatment of diseases such as cancer, autoimmune disorders, and infectious diseases. Our goal is to develop and commercialize immune-driven clinical products tailored to each individual patient.

Forward-Looking Statements

This press release contains forward-looking statements that are based on management’s beliefs and assumptions and on information currently available to management. All statements contained in this release other than statements of historical fact are forward-looking statements, including statements regarding our ability to develop, commercialize and achieve market acceptance of our current and planned products and services, our research and development efforts, and other matters regarding our business strategies, use of capital, results of operations and financial position, and plans and objectives for future operations.

In some cases, you can identify forward-looking statements by the words “may,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “ongoing” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. These risks, uncertainties and other factors are described under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in the documents we file with the Securities and Exchange Commission from time to time. We caution you that forward-looking statements are based on a combination of facts and factors currently known by us and our projections regarding the future, about which we cannot be certain. As a result, the forward-looking statements may not prove to be accurate. The forward-looking statements in this press release represent our views as of the date hereof. We undertake no obligation to update any forward-looking statements for any reason, except as required by law.

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