4TEEN4 Receives U.S. FDA Fast Track Designation for Invobenitug in Cardiogenic Shock

Hennigsdorf/Berlin, July 16, 2026 – 4TEEN4 Pharmaceuticals GmbH today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to invobenitug (formerly known as procizumab), for the treatment of cardiogenic shock (CS). Invobenitug is 4TEEN4's lead investigational monoclonal antibody targeting circulating dipeptidyl peptidase 3 (cDPP3). It is currently being evaluated in PROCARD 2a (NCT06832722), a multicenter, randomized, placebo-controlled, double-blind Phase 1b/2a trial assessing its safety, tolerability, pharmacokinetics, and exploratory efficacy in patients with CS and elevated cDPP3 concentrations.

"Fast Track designation represents an important milestone for 4TEEN4 as we continue to advance invobenitug through clinical development," said **Dr. Andreas Bergmann, CEO of 4TEEN4 Pharmaceuticals**. "The designation recognizes both the significant unmet medical need in cardiogenic shock and the potential of invobenitug as a targeted therapeutic approach. Building on encouraging preclinical findings and favorable safety and tolerability data from our Phase 1 study in healthy volunteers, we look forward to collaborating closely with the FDA as we advance the program."

Cardiogenic shock is a rapidly progressive, life-threatening syndrome that occurs when the body is unable to maintain sufficient circulation to support essential organ function. cDPP3, a key driver of shock, degrades angiotensin II, inducing dysregulation of the renin-angiotensin-aldosterone system (RAAS) that can lead to organ failure and death. By inhibiting cDPP3, invobenitug is intended to restore RAAS signaling, stabilize cardiovascular function and improve outcomes in patients with shock.

"Cardiogenic shock remains one of the most challenging conditions in acute cardiovascular medicine, with mortality rates exceeding 50% and no approved therapies that target the underlying biology," commented **Alexandre Mebazaa, MD, PhD, Professor of Medicine at Université Paris Cité in France and Principal Investigator for the ongoing PROCARD 2a study**. "Rather than simply treating the downstream consequences of shock, our goal is to intervene at its biological root by neutralizing cDPP3 in patients most likely to benefit. This designation marks an important step towards establishing one of the first targeted therapeutic approaches for cardiogenic shock."

Fast Track Designation is intended to facilitate the development and expedite the regulatory review of investigational therapies for serious conditions that have the potential to address an unmet medical need. The designation provides opportunities for more frequent interactions with the FDA throughout development, as well as potential eligibility for Rolling Review, Accelerated Approval, and Priority Review, where applicable.

About Cardiogenic Shock

Cardiogenic shock is a severe and life-threatening condition in which the circulatory system fails to deliver sufficient oxygen to meet the body's metabolic demands, leading to organ dysfunction and high mortality. It can result from a variety of causes, including sepsis, trauma, burns, major surgery, and cardiac events, and accounts for approximately one in three admissions to intensive care units.[1]

Cardiogenic shock is the second most common form of circulatory failure. It is most often triggered by acute myocardial infarction or acute decompensated heart failure. Despite advances in supportive care, cardiogenic shock remains a major unmet medical need associated with substantial morbidity and

[1] Van Lier, D. & Pickkers, P. Circulating biomarkers to assess cardiovascular function in critically ill. Curr. Opin. Crit. Care 27, 261–268 (2021).

mortality rates exceeding 50%.[2,3] No approved pharmacologic therapy specifically targets the molecular mechanisms of cardiogenic shock.

About Invobenitug

Invobenitug (formerly known as procizumab) is a humanized monoclonal antibody designed to selectively target circulating dipeptidyl peptidase 3 (cDPP3). Under physiological conditions, DPP3 is an intracellular enzyme. However, when released into the circulation, typically as a result of cellular injury, it degrades angiotensin peptides, resulting in dysregulation of the renin-angiotensin-aldosterone system (RAAS). The loss of RAAS control can lead to shock, broad organ failure, and ultimately death. By inhibiting cDPP3 activity, invobenitug restores RAAS balance and stabilizes cardiovascular function. The therapeutic potential of invobenitug has been demonstrated in preclinical and clinical settings, where it effectively normalized cardiovascular parameters, reversed organ dysfunction, and increased survival. Invobenitug also exhibited a favorable safety and tolerability profile in a completed Phase 1 study in healthy volunteers. Invobenitug is currently being evaluated in the Phase 1b/2a PROCARD 2a clinical trial.

About 4TEEN4

4TEEN4 is a clinical-stage biotechnology company developing invobenitug (formerly known as procizumab) as a potential biomarker-guided therapy for patients with cardiogenic shock associated with elevated cDPP3. 4TEEN4's mission is to reverse life-threatening shock and restore organ function with invobenitug. This highly specific, first-in-class antibody blocks circulating DPP3, the key pathological driver of mortality in shock. Based on highly encouraging results across preclinical models and initial use in patients, invobenitug is now in a Phase 1b/2a study evaluating its potential as a treatment for shock caused by acute cardiovascular and septic events. By targeting the root cause, 4TEEN4 aims to move shock treatment beyond supportive care and improve survival in critically ill patients.

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[2] van Diepen, S. et al. Contemporary Management of Cardiogenic Shock: A Scientific Statement from the American Heart Association. Circulation 136, e232-e268 (2017).
[3] Arrigo, M. et al. Current and future trial design in refractory cardiogenic shock. Eur. J. Heart Fail. 25, 609–615 (2023).