丹诺医药
TENNOR THERAPEUTICS

TenNor Therapeutics (Suzhou) Limited
丹諾醫藥(蘇州)股份有限公司
(A joint stock company incorporated in the People's Republic of China with limited liability)
(Stock code: 6872)

VOLUNTARY ANNOUNCEMENT POSITIVE RESULTS FROM A PHASE IIA PROOF-OF-CONCEPT CLINICAL TRIAL OF RIFAQUIZINONE (TNP-2092) FOR THE TREATMENT OF PROSTHETIC JOINT INFECTION AND INITIATION OF A MULTI-CENTER PHASE IIB CLINICAL TRIAL

This announcement is made by TenNor Therapeutics (Suzhou) Limited (the "**Company**") and its subsidiaries (the "**Group**") on a voluntary basis to keep the shareholders and potential investors of the Company informed of the latest business developments of the Group.

The board of directors (the "**Board**") of the Company is pleased to announce that positive top-line results were obtained from the Phase IIa proof-of-concept clinical trial of the Company's new drug candidate, rifaquizinone (TNP-2092), administered via intra-articular injection for the treatment of prosthetic joint infection ("**PJI**"). Rifaquizinone (TNP-2092) is the world's first new drug candidate developed specifically to target infections associated with implantable medical devices through a triple-targeting mechanism of action. Based on those proof-of-concept data, the Company has received approval for a multi-center Phase IIb clinical trial from the National Medical Products Administration of the PRC (the "**NMPA**") and the trial has recently been initiated.

Positive Results from a Phase IIa Proof-of-Concept Clinical Trial

The Phase IIa proof-of-concept clinical trial conducted in China evaluated the efficacy and safety of intra-articular injection of rifaquizinone (TNP-2092) without surgical debridement in patients with early postoperative, acute hematogenous, or chronic PJI.

According to the interim analysis as of 1 July 2026 (the "**Data Cutoff Date**"), the trial enrolled a total of 10 patients, of whom 7 were patients with confirmed Gram-positive bacterial infections by bacterial culture or next-generation gene sequencing and were included in the efficacy analysis set; 2 patients were excluded from the efficacy analysis due to negative culture results, and 1 newly enrolled patient at the Data Cutoff Date had no efficacy data available yet.

With respect to efficacy results, all 5 patients with early or acute PJI receiving intra-articular injections of rifaquizinone (TNP-2092) completed the 6-month follow-up visit, with a treatment success rate of 100%; among them, 4 patients completed the 12-month follow-up visit, also with a treatment success rate of 100%. Among the 2 patients with chronic PJI receiving intra-articular injection of rifaquizinone (TNP-2092), 1 of the 2 patients who completed the 6-month follow-up visit achieved treatment success, corresponding to a treatment success rate of 50%, while the 12-month follow-up visit data were not yet available as of the Data Cutoff Date.

With respect to safety results, a total of 9 patients were included in the safety analysis, and no treatment-emergent adverse events or serious adverse events related to rifaquizinone (TNP-2092) were reported. For the remaining one patient still in follow-up visit, no treatment-emergent adverse events or serious adverse events related to rifaquizinone (TNP-2092) were reported as of the Data Cutoff Date.

The above results demonstrate the favorable efficacy and excellent safety profile of intra-articular injection of rifaquizinone (TNP-2092), supporting the accelerated clinical development of this novel non-surgical treatment option for PJI.

Initiation of a Multi-center Phase IIb Clinical Trial

Based on the positive data from the Phase IIa proof-of-concept clinical trial above, the Company has received approval for a multi-center Phase IIb clinical trial from the NMPA and the trial has recently been initiated.

About PJI

PJI is a serious complication following joint replacement surgery that can transform an initially successful operation into a crisis for both the healthcare system and patients. In the United States, there are approximately 45,000 new cases of PJI each year, while there are approximately 22,000 cases in China, with the incidence showing a rapid upward trend. However, the treatment of PJI faces significant challenges as the formation of bacterial biofilms substantially reduces the efficacy of conventional antimicrobial agents. Treatment regimens that rely solely on antimicrobial agents without surgical intervention are not recommended in clinical practice due to their extremely high failure rates.

Currently, all available treatment options for patients require surgical intervention, yet treatment outcomes remain suboptimal: for early postoperative or acute hematogenous PJI, guidelines recommend debridement, antibiotics, and implant retention (DAIR) procedures, but reported failure rates exceed 30%; for chronic PJI, a two-stage revision arthroplasty is required, which involves multiple surgeries, prolonged hospitalization and several months of functional loss postoperatively, with failure rates still exceeding 10%. The economic burden of PJI is extremely heavy, with treatment costs in the United States exceeding US$390,000 per patient. Meanwhile, the continued growth in joint replacement surgeries further intensifies the clinical challenge, driving a rapid increase in PJI incidence; it is estimated that by 2035, the number of new PJI cases globally will reach 425,800 per year, of which China is projected to account for 86,500 cases.

About Rifaquizinone (TNP-2092)

Rifaquizinone (TNP-2092) is the world's first new drug candidate developed specifically to target biofilm infections associated with implantable medical devices through a triple-targeting mechanism of action. Through its unique triple-targeting synergistic mechanism of action by simultaneously inhibiting bacterial RNA polymerase, DNA gyrase and DNA topoisomerase IV. Rifaquizinone (TNP-2092) not only demonstrates potent bactericidal activity against drug-resistant pathogens (including methicillin-resistant S. aureus and quinolone-resistant S. aureus), but also reduces the resistance frequency to an extremely low level ($<10^{-12}$).

In the preclinical study, rifaquizinone (TNP-2092) has demonstrated strong *in vitro* and *in vivo* biofilm bactericidal activity, and its efficacy is superior to that of current standard-of-care antibiotics. The Company has successfully completed six Phase I and Phase II clinical trials in the U.S. and China, and the intravenous administration of rifaquizinone (TNP-2092) has demonstrated favorable safety and excellent efficacy profile in the treatment of acute bacterial skin and skin structure infections.

The transformative potential of rifaquizinone (TNP-2092) has been highly recognized by regulatory authorities. Rifaquizinone (TNP-2092) has been granted Qualified Infectious Disease Product, Fast Track, and Orphan Drug designations by the United States Food and Drug Administration. In addition, rifaquizinone (TNP-2092) has also received the outstanding award at the National Disruptive Technology Innovation Competition in China (全國顛覆性技術創新大賽優勝獎).

About the Company

The Company is a near-commercial stage biotechnology company dedicated to the discovery, development and commercialization of differentiated therapies to address unmet medical needs in disease areas associated with bacterial infections and bacterial metabolism. Relying on its proprietary multi-targeting conjugate molecule technology platform, the Company aims to deliver therapeutic solutions to overcome the limitations of conventional treatments and improve patient outcomes.

As at the date of this announcement, the Company had established a drug research and development pipeline comprising eight innovative programs, including two core products, namely: rifasutenizol (TNP-2198), a multi-targeting conjugated new molecular entity ("**NME**") candidate for the treatment of *Helicobacter pylori* infection when used in combination with amoxicillin and a proton pump inhibitor, as well as monotherapy for bacterial vaginosis and *Clostridioides difficile* infection; and rifaquizinone (TNP-2092) injection, a triple-targeting NME candidate for the treatment of acute bacterial skin and skin structure infection and implant-associated bacterial infections (such as PJI, left ventricular assist device infection and catheter-related bloodstream infection).

We may not be able to ultimately develop and market rifaquizinone (TNP-2092) successfully. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By order of the Board
TenNor Therapeutics (Suzhou) Limited
Dr. Ma Zhenkun
Chairman of the Board, Executive Director,
Chief Executive Officer and General Manager

Hong Kong, 7 September 2026

As at the date of this announcement, the Board comprises: (i) Dr. Ma Zhenkun as an executive Director; (ii) Dr. Song Gaoguang as a non-executive Director; and (iii) Mr. Lee Wai Kong, Albert, Dr. Ni Lin and Dr. Li Leping as independent non-executive Directors.