REVIEW ARTICLE

Introducing a Novel Once-weekly Dipeptidyl Peptidase 4 Inhibitor: Trelagliptin in India

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Abstract

India faces a growing burden of type 2 diabetes mellitus (T2DM), necessitating innovative treatments that improve glycemic control, reduce glycemic variability (GV), and enhance patient adherence. Dipeptidyl peptidase 4 (DPP-4) inhibitors are established antidiabetic agents; however, once- or twice-daily dosing often limits long-term compliance. Trelagliptin, a novel once-weekly DPP-4 inhibitor, addresses this issue with an extended half-life and superior molecular stability, enabling sustained DPP-4 inhibition and significant GV reduction. Improved glycemic control with trelagliptin can potentially lower the risk of macrovascular and microvascular complications associated with T2DM. Trelagliptin, developed and launched in India by Zuventus Healthcare Limited under the brand name Trelaglip®, offers prolonged efficacy and high selectivity in inhibiting the DPP-4 enzyme, helping minimize side effects. Development began with in-house active pharmaceutical ingredient (API) synthesis, followed by successful formulation and stability studies. A bioequivalence study confirmed pharmacokinetic equivalence with the reference product by Takeda, Japan. In a randomized phase 3 clinical trial involving patients with glycated hemoglobin (HbA1c) ≥8%, trelagliptin showed greater HbA1c reduction (−1.25%) as compared to vildagliptin (−1.15%) and a similar safety profile. Mild adverse events occurred in 6.67% of trelagliptin users compared to 9.17% with vildagliptin. This article outlines the development and regulatory journey leading to trelagliptin's first approval in India by the Central Drugs Standard Control Organization (CDSCO) in December 2024. Phase 4 real-world evidence studies are currently ongoing in India to assess long-term safety and efficacy.

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Introduction

Type 2 diabetes mellitus (T2DM) represents a significant and growing public health challenge in India, with over 77 million adults currently affected.[1] Rapid urbanization, sedentary lifestyles, and dietary changes have contributed to this alarming rise, earning India the unfortunate title of the "diabetes capital of the world." Managing this chronic condition requires effective, accessible, and patient-friendly therapeutic options to control blood glucose levels and mitigate complications such as cardiovascular disease, neuropathy, and retinopathy.[2] Additionally, managing glycemic variability (GV)—the fluctuations in blood glucose levels—is essential, as it is now well established that GV induces oxidative stress, inflammation, and endothelial dysfunction, contributing to macrovascular and microvascular complications.[3]

To address these challenges, therapies with extended dosing intervals have been developed. For instance, several glucagon-like peptide-1 receptor agonists (GLP-1RAs), such as dulaglutide and semaglutide, are now available as once-weekly injectable formulations. While GLP-1RAs offer potent glucose-lowering effects and promote weight loss, they require subcutaneous injection and, besides being painful, are often associated with gastrointestinal side effects like nausea and vomiting.[4] In contrast, DPP-4 inhibitors—which work by inhibiting the DPP-4 enzyme to preserve endogenous incretin hormones—are orally administered and exceptionally well tolerated. Though they are generally weight neutral and offer more modest HbA1c reductions compared to GLP-1RAs, DPP-4 inhibitors have a clear edge in tolerability, with a low risk of gastrointestinal upset and an excellent overall safety profile.[5]

Among the pharmacological options available, DPP-4 inhibitors have become a cornerstone in T2DM therapy due to their glucose-dependent mechanism of action, low risk of hypoglycemia, and favorable side effect profile. However, a major limitation of most DPP-4 inhibitors is the need for daily dosing, which can undermine adherence, particularly for individuals managing complex treatment regimens.[6]

Poor adherence to long-term therapy is a major challenge in managing T2DM, especially in low- and middle-income countries like India.[7] Adherence often declines sharply after the first 6 months of treatment, leading to poor glycemic control, increased risk of complications, and higher healthcare costs. Therefore, effective T2DM management must go beyond pharmacological efficacy to prioritize strategies that improve adherence—particularly in reducing the burden of multiple daily dosing.[8]

Against this backdrop, the introduction of trelagliptin, marketed in India as Trelaglip® by Zuventus Healthcare Limited, a once-weekly oral DPP-4 inhibitor, marks a transformative shift in diabetes management.[9] Trelaglip® offers an effective, safe, and more convenient therapeutic option that addresses both clinical efficacy and the practical needs of patients. Available in 100, 50, and 25 mg doses, Trelaglip® reduces dosing frequency, enhancing treatment adherence and potentially improving long-term glycemic outcomes—particularly in populations with limited access to healthcare or a high treatment burden. A comprehensive understanding of trelagliptin's pharmacological profile and therapeutic advantages is therefore essential to appreciate its role in advancing diabetes care.

Trelagliptin: A Novel Once-weekly Dipeptidyl Peptidase 4 Inhibitor

Trelagliptin is a novel, orally active, and highly selective dipeptidyl peptidase 4 (DPP-4) inhibitor developed for the management of T2DM. It has the molecular formula $C_{18}H_{20}FN_5O_2$, and its chemical structure is depicted in Figure 1.

As a member of the DPP-4 inhibitor class, trelagliptin enhances the activity of incretin hormones, such as glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP). These hormones are essential for maintaining glucose homeostasis, as they stimulate insulin secretion and suppress glucagon release in a glucose-dependent manner. By inhibiting

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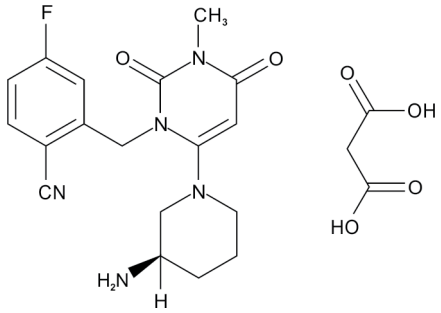


Fig. 1: Chemical structure of trelagliptin

the DPP-4 enzyme, trelagliptin prevents the degradation of GLP-1 and GIP, thereby improving glycemic control while minimizing the risk of hypoglycemia—a common concern with many other antidiabetic therapies.[10] DPP-4 inhibitors, including trelagliptin, have been shown to reduce GV by enhancing GLP-1 activity. This contributes to more stable blood glucose levels throughout the day. Meta-analyses have also demonstrated that these agents significantly reduce the mean amplitude of glycemic excursions (MAGE) compared to other antidiabetic drugs, further underscoring their role in managing GV.[11]

A defining feature of trelagliptin is its once-weekly dosing schedule, enabled by a prolonged elimination half-life of approximately 54.3 hours. This extended pharmacological activity stems from its advanced molecular design, which was achieved using structure-based drug design techniques to optimize both binding affinity and enzyme selectivity.[9] The drug exhibits a dissociation half-life of about 30 minutes, significantly longer than that of other DPP-4 inhibitors such as vildagliptin (<2 minutes) and sitagliptin (~3.5 minutes). This slower dissociation rate underlies its sustained DPP-4 inhibition throughout the dosing interval.[9] In a 12-week monotherapy study, a 100 mg once-weekly dose maintained a mean DPP-4 inhibition of 77.4% even 7 days after the final dose, compared to just 2.4% in the placebo group—demonstrating potent and durable efficacy.[12]

Trelagliptin also exhibits exceptional molecular specificity, with IC_{50} values exceeding 100,000 nmol/L for structurally related enzymes such as DPP-2, DPP-8, DPP-9, prolyl endopeptidase (PEP), and fibroblast activation protein alpha (FAPα). This >10,000-fold selectivity for DPP-4 minimizes side effects, supporting its favorable safety and tolerability profile.[10]

Clinical trials have affirmed trelagliptin's safety and tolerability, showing a low incidence of adverse effects, comparable to daily DPP-4 inhibitors. This combination of efficacy, safety, and convenience positions trelagliptin as a transformative option in the pharmacological management of T2DM—particularly valuable in improving adherence and long-term glycemic control.[13–15]

By offering an effective, safe, and more convenient therapeutic option, trelagliptin addresses both the clinical and practical needs of patients with T2DM. Its introduction in India represents a significant advancement in diabetes care, providing a solution that aligns with the country's growing need for innovative and patient-centric treatments. The development and introduction of this therapy in the Indian market began with the capability and capacity to synthesize its active pharmaceutical ingredient (API) by Zuventus Healthcare Limited—marking the first step in Indian advancement.

How the Journey Began

Development of Trelagliptin Active Pharmaceutical Ingredient

The journey to introduce trelagliptin in India began with a significant challenge: the unavailability of a domestically available API. Recognizing the strategic importance of self-sufficiency and uninterrupted supply, Zuventus Healthcare Limited initiated the development of the trelagliptin API in-house. This initiative went beyond technical formulation—it represented a decisive shift toward reducing dependency on imports and strengthening India's pharmaceutical manufacturing capabilities. The animal toxicology studies were done on the API and were found to be safe.

A dedicated research and development (R&D) team at Zuventus worked rigorously to establish a robust and scalable synthesis process for the API. Through multiple rounds of process optimization and stringent quality testing, the team ensured the compound met all regulatory and pharmacopoeial standards. Comprehensive analytical assessments were performed to validate the API's purity, potency, and batch-to-batch consistency. Following these efforts, the finalized API dossier was submitted to the Central Drugs Standard Control Organization (CDSCO). The subsequent approval under (API Approval Number: Bulk-ND-52/2024) marked a pivotal milestone in the product's development timeline, enabling progression toward formulation and clinical evaluation.

From Formulation to Stability

Following API approval, the focus shifted to formulation development. The goal was to formulate a dosage form that matches the internationally available formulation from Takeda, so that all the available clinical literature for the standardized international formulation is applicable to this new formulation. This required careful selection of excipients, optimization of the manufacturing process, and rigorous stability testing. Formulation development is both an art and a science. Zuventus's R&D team faced challenges such as maintaining the drug's bioavailability and preventing degradation over time.

A comprehensive series of stability studies—both accelerated (6 months) and long-term (24 months)—were conducted to evaluate the formulation's stability under various simulated climatic conditions representative of India's storage and distribution environments. These studies were carried out under controlled temperature and relative humidity (RH) conditions, specifically 30 ± 2°C for long-term and 40 ± 2°C for accelerated testing, with a consistent RH of 75 ± 5%.

The results validated that the Trelaglip® formulation retained its potency, release profile, and purity, with no significant degradation or formation of impurities over the testing period. These outcomes confirmed the formulation's stability and viability for mass production and wide distribution across India's varied climatic zones. This successful formulation stabilization served as the foundation for the next phase—bioequivalence studies, marking a crucial advancement toward clinical evaluation and regulatory submission.

Bioequivalence Study

To ensure that Zuventus's Trelaglip® could be brought to market in India, it was essential to establish its bioequivalence to the reference listed drug (RLD) Zafatek® developed by Takeda. Bioequivalence confirmed that the test formulation delivers the active ingredient into the bloodstream at a rate and extent comparable to the RLD, ensuring equivalent therapeutic outcomes. This step was critical in the regulatory approval process overseen by the CDSCO.

Zuventus initiated the bioequivalence study following review and approval of the study protocol by the Subject Expert Committee (SEC) on Endocrinology and Metabolism. Zuventus obtained permission from the CDSCO to import the RLD from Japan (Import Permission No.: ND/CT-17/41/2022, dated 15th December 2022) and conduct the bioequivalence study (BENOC No.: BE/ND/30/2022, dated 15th December 2022). The study was prospectively registered with the Clinical Trials Registry–India (CTRI/2023/01/048758, dated 5th January 2023). The study was conducted in 32 healthy volunteers, comparing Zuventus's formulation (T) to the reference drug (R) in accordance with international guidelines. Blood samples were collected at multiple time intervals to evaluate key pharmacokinetic parameters. The pharmacokinetic parameters are summarized in

Table 1, and the mean plasma concentration vs. time profile of trelagliptin is shown in Figure 2.

The similarity in AUC_{0-72} values and Cmax, along with statistical analysis confirming that the 90% confidence intervals for both parameters (as shown in Table 2) fell within the regulatory bioequivalence range of 80.00–125.00%, demonstrates bioequivalence.

This successful outcome affirmed that Zuventus's formulation met the necessary standards for therapeutic equivalence, marking a pivotal milestone. This achievement paved the way for the subsequent phase 3 clinical trial in India and eventual marketing permission.

Clinical Development: Designing and Executing of the Trial

Following the successful demonstration of bioequivalence, Zuventus moved forward to the next phase by proposing a clinical trial to the SEC under the CDSCO. The SEC suggested several amendments to the protocol to enhance safety monitoring, which were incorporated as follows: inclusion of provisions for safety monitoring for pancreatitis; specification of an eGFR threshold below which patients would be excluded; exclusion of patients with a previous history of pancreatitis.

After submission of these amendments, Zuventus received a No Objection Certificate (CT NOC No. CT/ND/58/2022) to proceed with the clinical study. The trial was subsequently registered with the Clinical Trials Registry of India on 9th January 2023 (Reg. No.: CTRI/2023/01/048826).

The trial was a randomized, controlled, noninferiority study comparing once-weekly trelagliptin to twice-daily vildagliptin in patients with T2DM, aiming to assess efficacy and safety over 16 weeks. Results were robust in patients with HbA1c ≥ 8%, with the trelagliptin group showing a greater mean HbA1c reduction (–1.25%) compared to vildagliptin (–1.15%) (p = 0.7629). The mean difference was 0.11% (95% CI: –0.28 to 0.50; p = 0.5899), with the upper confidence limit below the 0.5% margin, confirming noninferiority. Approximately 48.57% of trelagliptin patients and 47.57% of vildagliptin patients achieved HbA1c <7% (p = 0.8850), indicating comparable efficacy, while secondary endpoints showed no significant differences in fasting glucose (Δ1.11; 95% CI: –16.79 to 19.02, p = 0.9025), postprandial glucose (Δ3.33; 95% CI: –30.55 to 23.88, p = 0.8093), fasting serum insulin (Δ5.22; 95% CI: –15.01 to 25.45, p = 0.6113), glucagon (Δ0.72; 95% CI: –96.34 to 94.90, p = 0.9882), C-peptide (Δ0.36; 95% CI: –0.31 to 1.03, p = 0.2912), and GLP-1 levels (Δ–0.02; 95% CI: –0.06 to 0.02, p = 0.3995). The change in glycemic parameters from baseline to week 16 is shown in Figure 3.

Safety data revealed that both drugs were well tolerated, with adverse events occurring in 6.67% of trelagliptin patients and 9.17% of vildagliptin patients, all mild and resolving without complications, and no serious adverse events reported, reinforcing trelagliptin's favorable safety profile.

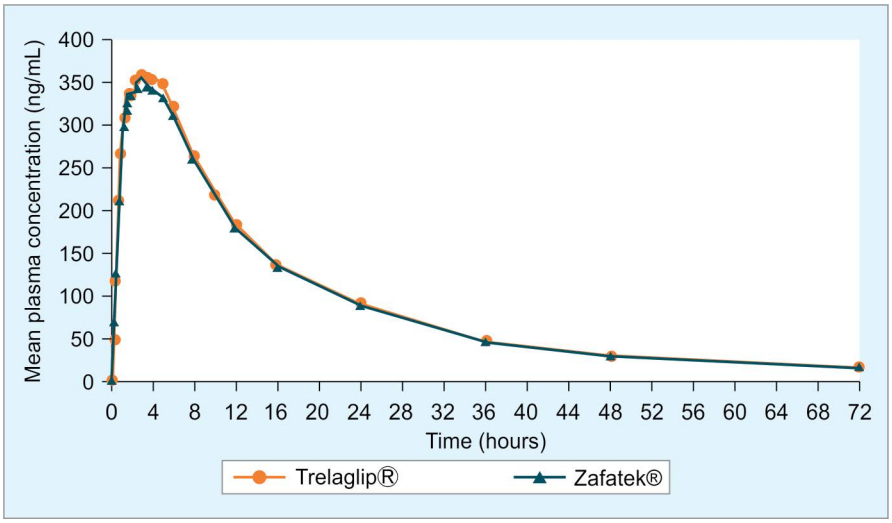


Fig. 2: Trelagliptin mean plasma concentration vs time

Table 1: Pharmacokinetic parameters of test and reference product

Parameter	*Arithmetic mean ± SD (%CV), N = 31*	
	Trelaglip® (T)	*Zafatek® (R)*
C_{max} (ng/mL)	437.55 ± 120.449 (27.53)	429.03 ± 174.309 (40.63)
AUC_{0-72} (ng × hour/mL)	6710.97 ± 797.947 (11.89)	6558.39 ± 795.249 (12.13)
T_{max} (hour)[a]	3.50 (0.33–6.00)	3.00 (0.33–6.00)

CV, coefficient of variance; SD, standard deviation; [a]T_{max}, median (range)

Approval by Central Drugs Standard Control Organization

Following the clinical trial, Zuventus submitted a comprehensive dossier to the CDSCO, encompassing preclinical, bioequivalence, and clinical data. On 13th November 2024, the SEC committee granted permission to manufacture and market trelagliptin in 100 mg, 50 mg, and 25 mg strengths. Subsequently, on 26th December 2024, the CDSCO approved trelagliptin (Approval Number: MF-ND-53/2024) for the treatment of T2DM in India. This milestone marked the approval of the country's first once-weekly DPP-4 inhibitor, highlighting its potential to streamline diabetes care. The clinical development journey of trelagliptin in India is illustrated in Figure 4.

When should Therapy with Trelagliptin be Initiated?

Initiation of Trelagliptin Therapy as per the International Diabetes Management Guidelines

According to diabetes management guidelines, subsequent to dietary and lifestyle modifications, treatment should begin with metformin. If blood glucose levels are not adequately controlled with

Table 2: Ratio analysis and 90% confidence intervals

	Geometric LS mean (N = 31)						
	Trelaglip®	*Zafatek®*	*T/R ratio (%)*	*ISCV (%)*	*Power (%)*	*90% CI*	*Conclusion*
LnC_{max} (ng/mL)	422.78	404.38	104.55	23.04	98.05	94.77–115.34	Bioequivalent
$LnAUC_{0-72}$ (ng × hour/mL)	6662.06	6511.66	102.31	4.25	99.99	100.45–104.20	Bioequivalent

CI, confidence interval; ISCV, intrasubject coefficient of variance; LS, least square

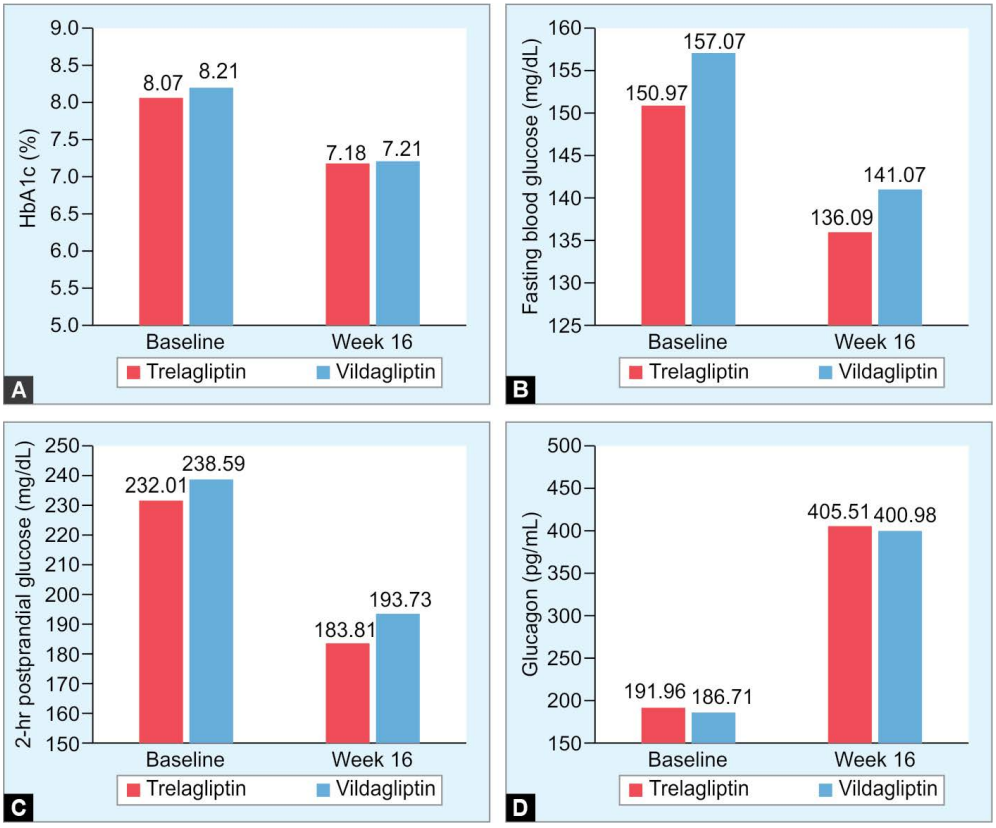
metformin monotherapy, a DPP-4 inhibitor or another class of antidiabetic agents should be added. Since metformin is typically administered once or twice daily, the patient can continue with the same dosage regimen, and trelagliptin can be added as a once-weekly dose to complement the existing treatment. The recommended approach for incorporating trelagliptin into therapy is outlined in Figure 5.[16]

Adjunct to Insulin Therapy in Patients with Inadequate Glycemic Control

Trelagliptin may also be considered in patients with T2DM who are unable to achieve sufficient glycemic control with insulin therapy alone.[15] Studies are available where trelagliptin was added to sulfonylureas, biguanides, thiazolidinediones, and alpha-glucosidase inhibitors.[13]

Patients Unable or Unwilling to Regularly Monitor Blood Glucose

Trelagliptin's once-weekly dosing schedule significantly reduces the need for frequent blood glucose monitoring. This makes it a practical choice for patients who are unable or unwilling to perform regular self-monitoring of blood glucose (SMBG). Such convenience supports better adherence in real-world



Figs 3A to D: Change in glycemic control parameters from baseline to week 16; (A) HbA1c; (B) Fasting blood glucose; (C) 2-hour postprandial glucose; (D) Glucagon

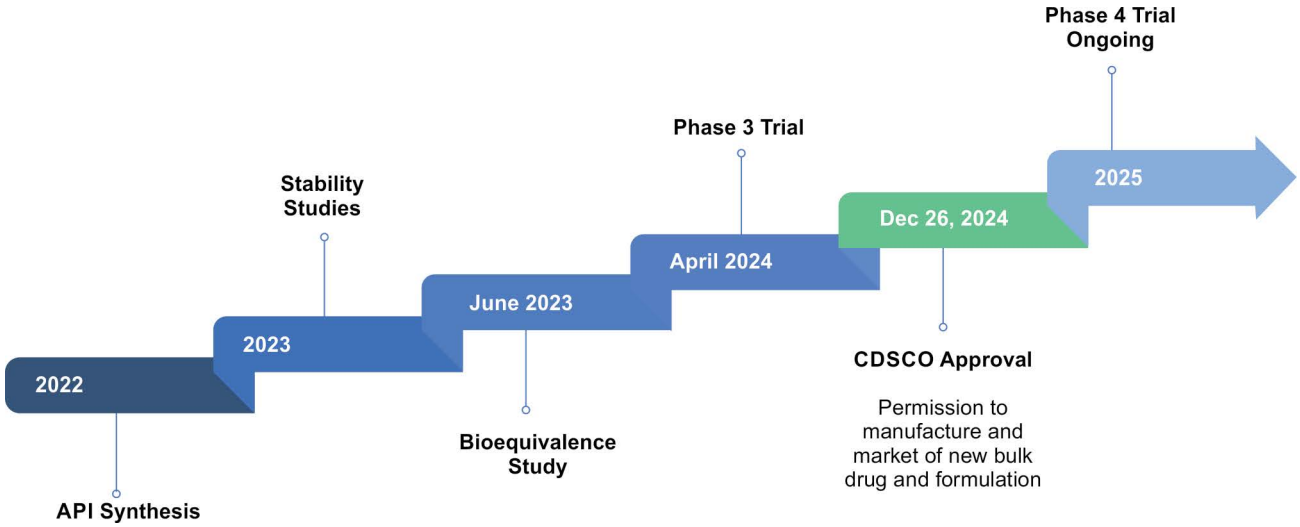


Fig. 4: Clinical development of trelagliptin in India

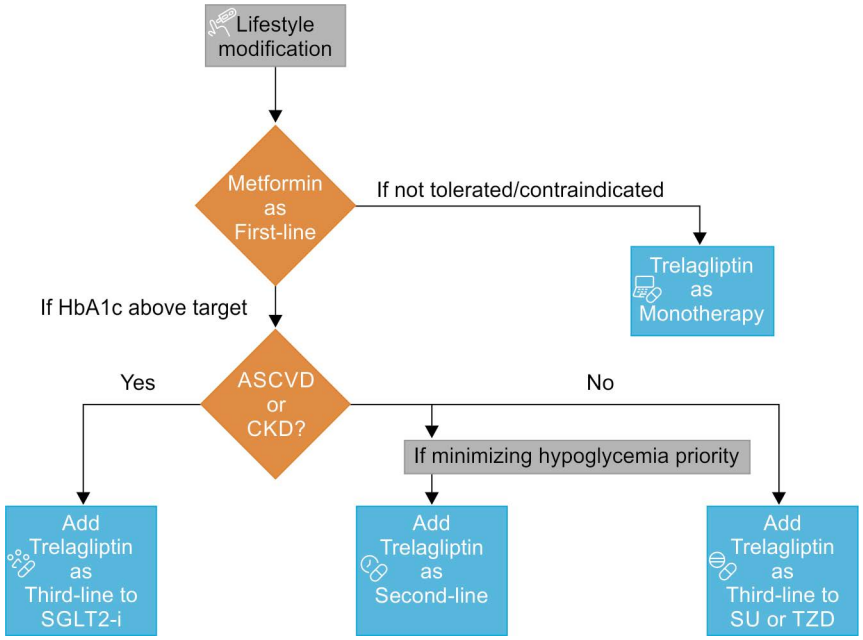


Fig. 5: Treatment algorithm for T2DM with trelagliptin; ASCVD, atherosclerotic cardiovascular disease; CKD, chronic kidney disease; DPP-4 inhibitor, dipeptidyl peptidase 4 inhibitor; SGLT2-I, sodium–glucose cotransporter-2 inhibitor; sulfonylurea; TZD, thiazolidinedione

scenarios, especially for individuals with barriers to frequent testing.[17]

Geriatric Patients with Dementia or Those Requiring Nursing Care

In elderly patients with dementia or those requiring nursing care, simplifying treatment regimens can substantially reduce the caregiving burden. Trelagliptin's weekly administration helps decrease the number of daily medications, offering relief to family members and caregivers. It thus represents a valuable therapeutic option in the geriatric population, where polypharmacy and adherence challenges are common.[18]

Primary Care and Rural Healthcare Settings

Trelagliptin once-weekly therapy may especially be useful in primary and rural health settings, as minimal counselling and monitoring are required to use it effectively.[18]

Global Availability and Clinical Development

Trelagliptin, a once-weekly DPP-4 inhibitor, has demonstrated promising efficacy and growing international reach. In India, phase I and III trials have been completed, and phase IV studies are currently underway. The drug is marketed under various names globally: Trelaglip® (India, Zuventus Healthcare), Zafatek (Japan and China, Takeda Pharmaceuticals), Wedica and Triliptin (Bangladesh), Truli-1 (Kenya), Trelaget (Pakistan), and TRELA (Myanmar and Cambodia).

Although Takeda Pharmaceuticals, the original developer, discontinued further development in the US and EU in 2014 due to high regulatory costs, trelagliptin has continued to expand its footprint across Asia and other emerging markets as a convenient, once-weekly oral therapy for T2DM.[9]

Looking Ahead: Phase 4 and Real-world Evidence

Zuventus is now initiating phase 4 studies of Trelaglip® 100 mg in patients with normal and mild renal function, 50 mg in moderate renal stage, and 25 mg in severe and end-stage renal stage patients to generate real-world evidence on trelagliptin. These postmarketing studies will include a larger and more diverse patient population, focusing on long-term safety, efficacy, and the identification of rare adverse events. Additionally, these studies will evaluate Trelaglip®'s effect on GV in real-world settings, patient adherence, real-life clinical outcomes, and the durability of glycemic control over time. The findings are expected to inform clinical practice and may support the expansion of trelagliptin's therapeutic indications, ensuring it continues to meet the evolving needs of Indian patients.

Conclusion

The introduction of once-weekly trelagliptin in India marks a significant advancement in diabetes care. Through domestic API development, successful demonstration of bioequivalence with the global standard, and a robust clinical trial confirming noninferiority, Zuventus Healthcare Limited has taken key steps toward improving treatment options for type 2 diabetes.

As phase 4 studies commence and real-world evidence begins to emerge, trelagliptin is well positioned to become a transformative option in the diabetes treatment landscape—simplifying therapy, improving adherence, and enhancing long-term outcomes for patients across the country. As India's first once-weekly DPP-4 inhibitor, Trelaglip® not only enhances current therapeutic options but also sets a new standard in diabetes care—with its full potential just beginning to unfold.

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