

# VRG Therapeutics Advances VRG-145, a Synergistic Oral Combination for Migraine Prophylaxis, to Final Preclinical Stage

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[Therapeutics](#) (VRG Tx), a leading biotechnology research and development company, discovered a strong synergistic effect between two drugs for the preventive treatment of migraine. This novel synergy has been proven in vivo in two different animal models of migraine, showing 5-10x potentiation of the pain alleviating effect compared to that of individual components.

The discovery paved the way for the development of a first-in-class oral small-molecule combination therapy called VRG-145 – selected from the Combi-X project – for the preventive treatment of migraine. The two components of VRG-145 are drugs marketed for 20+ years as long-term treatments for other indications with favorable and well-established safety profiles. Hence, an accelerated development path and reduced development costs are expected compared to the development of entirely new chemical entities.

VRG-145 has entered late-stage preclinical development and is expected to reach the clinical phase by early 2025. VRG Tx is looking for a strategic partner to participate in the clinical development of this asset.

About migraine: According to the WHO, migraine is one of the 10 most disabling diseases, affecting more than 1 billion people worldwide. The current treatment options are limited, as



just 50% of patients achieve up to 50% improvement. Current therapies have either moderate efficacy, low tolerability due to side effects, or a high propensity for therapeutic resistance. As such, there is a great need for the development of more efficacious drugs.

About VRG-145: VRG-145 is a novel, first-in-class pharmacotherapy with mechanisms different from those of currently used drugs, like antiepileptics, beta-blockers, calcium antagonists, a few antidepressants, and CGRP-blocking drugs.

The priority patent applications, filed in the US in March 2024, on the basis of which PCT applications are planned, cover combinations of two drug classes: NMDA receptor antagonists and compounds with inhibitory actions on the renin-angiotensin system. VRG-145 has been selected from the following list of potential candidates: as the first active ingredient, an angiotensin-converting-enzyme (ACE) inhibitor, such as trandolapril, benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, perindopril, quinapril, ramipril, zofenopril; or an angiotensin receptor blocker (ARBs), such as candesartan, azilsartan, telmisartan, valsartan, eprosartan, irbesartan, losartan, and olmesartan; and as the second active ingredient, an NMDA antagonist, such as memantine and dextromethorphan, which all might be considered as components of useful combinations for treating migraine.

Remarkable in-vivo Proof of Concept (PoC) results: In PoC studies, VRG-145 exhibited 5-10x potentiation of the pain alleviating effect compared to that of individual components, no pharmacokinetic interaction, and no positive interaction for potential cardiovascular or CNS side effects at higher doses, thus providing an improved therapeutic margin with high effectiveness at perfectly tolerated lower doses as compared to its individual components. It promises high clinical efficacy by significantly reducing the frequency and severity of migraine attacks in partially or fully-resistant patients administering current drug therapies like CGRP antagonists or anti-CGRP mAbs but not getting sufficient relief.

With its increased therapeutic margin, once-daily oral administration, low manufacturing cost, and favorable safety profile, VRG-145 has the potential to become the next-generation market leader in migraine prophylaxis and dominate the ca. \$6 billion global preventive migraine market.

VRG Tx is looking for a strategic partner to advance this asset to clinical development.

About VRG Tx: VRG Therapeutics is an original biopharmaceutical R&D company headquartered in Budapest, Hungary. It leverages its unique technologies to create cures for diseases through novel mechanisms of action that conventional biopharmaceutical approaches cannot. VRG Tx's miniprotein-based portfolio addresses major unmet clinical needs in autoimmune diseases, inflammation, and oncological indications, while also incubating two assets with promising applications, one in migraine prophylaxis (VRG-145) and another one as a CNS medication.

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