

Glossary of terms

Carrierwave technology

Carrierwave is a technology acquired as part of the acquisition of New River Pharmaceuticals ('NRP') and is used in VYVANSE. Since its acquisition, Shire scientists have significantly improved the understanding and breadth of this technology. It potentially allows Shire to develop new chemical entities ('NCE's), but with less risk as the products will be based on the understanding of known products which we seek to improve.

CNS

Central Nervous System

Hyperphosphataemia

Chronic Kidney Disease disrupts the delicate interplay between the body's levels of calcium, parathyroid hormone ('PTH'), and vitamin D, leading to hyperphosphataemia. Over time, hyperphosphataemia can ultimately lead to calcification in the heart, lung, and some arteries.¹ Accumulating evidence shows that hyperphosphataemia contributes to cardiovascular disease, which accounts for almost half of all deaths among dialysis patients.² Studies have shown that cardiovascular mortality in dialysis patients aged 25–34 years is more than five times greater than that in people aged 65–74 in the general population.³

FDA

US Food and Drug Administration

GDP

Gross Domestic Product

Phase 1

Oral therapies usually conducted in healthy human volunteers to determine if a drug candidate is safe for the more extensive testing.

Phase 2

Clinical trials conducted in patients with relevant disease to assess the safety and efficacy of the trust candidate.

Phase 3

Clinical trials conducted in the target patient population to comprehensively assess the safety and efficacy of the drug candidate.

¹ Norris KC. Toward a new treatment paradigm for hyperphosphataemia in chronic renal disease. *Dial Transplant* 1998; 27 (12): 767–773

² Block G, Port FK. Re-evaluation of risks associated with hyperphosphataemia and hyperparathyroidism in dialysis patients: recommendations for a change in management. *Am J Kidney Dis* 2000; 35 (6): 1226–1237

³ Foley R et al. Clinical epidemiology of cardiovascular disease in chronic renal disease. *Am J Kidney Dis* 1998; 32 (5) Suppl 3:112–119