LEN generics – can we go faster?



LEN generics may submit for regulatory approval around the same time as CAB generics (Q3-4 2026), primarily because CAB (actual) LEN (actual) LEN has been licensed even before regulatory submission/approval, is already moving towards tech transfer to generic CAB (estimated) LEN (estimated) manufacturers (as of O4 2024) and because BE timelines are expected to be much shorter for LEN than for CAB. Year 0 Year 1 Year 2 Year 3 Year 4 Year 5 Year 6 Year 7 Starts July 2020 Phase 3 results Starts June 2024 FDA: US Food and Drug Administration API: Active Pharmaceutical Ingredient June 2025 Driginator VL: Voluntary License FDA approval MPP: Medicines Patent Pool SRA: Stringent Regulatory Authority **Direct VI s to** Sublicense to PQ: Pregualification VI to MPP 3 generics License signed 6 generics BE: Bioequivalence with generics Licensees access 6 months 6 months complete tech pack from originator 9 months 1 year **API development** Generic manufacturers 9 months 1 year Prototype development 6 months 6 months Dossier batch 18 months minimum 6 months **Pivotal** bioequivalence 3 months 3 months Dossier submission Earliest SRA/WHO PQ filing 2nd half 2026 Earliest SRA/WHO PQ filing 2nd half 2026

This graphic aims to exhibit average timelines, but it is important to acknowledge that each generic manufacturer will move at different timelines and that unanticipated delays can happen at any step of the processes shown above. This graphic therefore aims to estimate timelines but should be used as a guideline rather than taken as 100% definitive.