ForPatients
by Roche

Bladder Cancer

Safety and Pharmacology Study of Atezolizumab Alone and in Combination With Bacille Calmette-Guérin (BCG) in High-Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) Participants

Trial Status	Trial Runs In	Trial Identifier
Terminated	1 Countries	NCT02792192 WO29635

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This Phase Ib/II study is designed to assess the safety, tolerability, pharmacokinetics, immunogenicity, patient reported outcomes (PROs), and preliminary anti-tumor activity of atezolizumab administered by intravenous (IV) infusion alone and in combination with intravesical BCG in high-risk NMIBC participants. The study will be conducted in following cohorts: Cohort 1A, Cohort 1B, Cohort 2, and Cohort 3. Atezolizumab will be administered at a fixed dose of 1200 milligrams (mg) every 3 weeks (q3w) for a maximum of 96 weeks. BCG will be administered to evaluate dose-limiting toxicities (DLTs), maximum tolerated dose (MTD), or maximum administered dose (MAD). De-escalation will be allowed for up to three dose levels of BCG (full dose [50 mg], 66 percent [%] of a full dose, and 33% of a full dose [Cohort 1B only]). After the MTD or MAD is determined for Cohort 1B, this dose will be used for all subsequent participants enrolled into Cohorts 1B, 2, and 3, unless the MTD is determined to be 33% of a full BCG dose. If MTD is determined to be 33% of a full BCG dose, then, no participants will be enrolled into Cohorts 2 and 3 until an assessment of the safety and activity of the combination of atezolizumab plus 33% of a full BCG dose is completed.

Hoffmann-La Roche
Sponsor

Phase 1/Phase 2
Phase

NCT02792192 WO29635
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>= 18 Years	No