

A Study of RO5217790 (HPV Targeted Immunotherapy) in Patients With High Grade Cervical Intraepithelial Neoplasia Associated With High Risk HPV Infection.

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This is a randomized, double blind, placebo controlled, parallel group multicenter study in women with biopsy confirmed Grade 2 or Grade 3 cervical intraepithelial neoplasia (CIN). Two hundred patients will be enrolled and randomized in a 2: 1 ratio of RO5217790: placebo. They will be stratified on the basis of their HPV genotyping with stratum 1 consisting of those women with HPV 16 single infection and stratum 2 consisting of those with single or multiple infections with other high risk genotypes. Three injections of RO5217790 (5 x 107pfu) will be administered subcutaneously, each one week apart. Interim colposcopy, cytology and HPV assessments will be performed at Month 3. All patients will undergo conization at Month 6. The primary endpoint is histologic response at Month 6 in HPV 16 single infected patients, as assessed by central pathology review. The secondary endpoints include histologic response in all CIN2/3 patients enrolled regardless of genotype, viral clearance, safety, and immune response (cellular and humoral). After the Month 6 conization, the study will be unblinded and patients will undergo follow-up for an additional 2 years for efficacy and safety. This includes visits at Months 12, 18, 24 and 30 to assess histologic relapse/recurrence and viral re-infection as well as reporting of any serious adverse events. An interim analysis will be conducted when a minimum of 80 patients (at least 20 of whom have single infection with HPV 16 and 20 of whom have infection with HPV 16 plus HPV 16 related genotypes) have undergone conization.

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