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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Background and Purpose

Targeted Immunotherapy

Biomarkers Used in Study

Primary Outcome Measures

• Histologic resolution of CIN 2/3 lesion

Secondary Outcome Measures

• Viral clearance
  • Roche HPV genomic testing
• Immunological response to HPV antigens
• Safety and tolerability

Randomization to Intervention Arms:
received SC on days 1, 8 and 15
Experimental Drug: RO5217790 in 0.5 mL buffer solution
VS
Placebo Comparator Drug:
Placebo 0.5 mL buffer solution

Eligibility Criteria

Inclusion Criteria:
Females >/= 18 years of age
Diagnosis of CIN 2/3 w/in 2 mo prior to study entry confirmed by colposcopy-directed bx
Patients must have at least 1 quadrant of residual CIN 2/3 disease remaining after bx
Single or multiple HR-HPV types at screening by Roche HPV genomic testing

Exclusion Criteria:
Colposcopically visible CIN 2/3 disease extending over more than 2 quadrants
Previous excisional or ablative surgical treatment for CIN
Any anatomical variant interfering with future surveillance of CIN
Vulvar(VIN) or vaginal (VaIN) intraepithelial neoplasia
Atypical endometrial or glandular cells or evidence of carcinoma on bx
Proven or suspected immunosuppressive disorder or autoimmune disease