

AMERICAN ASSOCIATION OF GENITOURINARY SURGEONS (AAGUS) 2015

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Phase II trial of intravesical adenoviral mediated interferon- α gene therapy with the excipient Syn3 (rAd-IFN α /Syn3) in patients with BCG refractory or relapsing high grade (HG) non muscle invasive bladder cancer (NMIBC).

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A Phase I study of intravesical rAd-IFN α /Syn3 in patients with HG NMIBC recurring after BCG indicated it was well-tolerated, induced prolonged expression of urine IFN α and a number of durable complete responses (CR). A Phase II trial in 40 BCG refractory or relapsing patients was conducted by the Society of Urologic Oncology's Clinical Trial Consortium. Preliminary data from 34 patients indicated that Ad-IFN α /Syn3 was well tolerated with only minor urgency post-instillation controlled with anticholinergics. Ten patients achieved a CR at the 12-month endpoint. rAd-IFN α /Syn3 appears safe and the CR in excess of 20% at 12 months is of clinical significance.