15-2375

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

Daniel Canter, Elkins Park, PA, Stephen Boorjian, Rochester, MN, Kenneth Ogan, Atlanta, GA, Neal Shore, Myrtle Beach, SC, Trinity Bivalacqua, Baltimore, MD, Bernard Bochner, New York City, NY, Tracy Downs, Madison, WI, Leonard Gomella, Philadelphia, PA, Robert Grubb III, St. Louis, MO, Brant Inman, Durham, NC, Ashish Kamat, Houston, TX, Larry Karsh, Denver, CO, Tracey Krupski, Charlottesville, VA, Seth Lerner, Houston, TX, Yair Lotan, Dallas, TX, Matthew Milowsky, Chapel Hill, NC, Mark Schoenberg, Bronx, NY, Robert Svatek, San Antonio, TX, Michael Woods, Chapel Hill, NC, Colin Dinney, Houston, TX*

INTRODUCTION AND OBJECTIVES: A Phase I study of intravesical rAd-IFNα/Syn3 in patients with HG NMIBC who failed prior BCG therapy indicated that rAd-IFNα/Syn3 was well-tolerated, induced prolonged expression of IFNα in the urine, and produced a number of durable complete clinical responses (CR). A randomized Phase II trial, sponsored by FKD Therapies was designed in conjunction with the Society of Urologic Oncology's Clinical Trial Consortium's Bladder Cancer Committee. The primary objective is to establish the efficacy of rAd-IFNα/Syn3 defined as freedom from HG recurrence at 1 year (CR) in patients with HG NMIBC recurring after adequate BCG (ClinicalTrials.gov Identifier NCT01687244).

METHODS: Forty patients with refractory or relapsing HG NMIBC after at least two courses of BCG have been randomized into one of 2 treatment cohorts. Treatment with rAd-IFNα/Syn3 (1x1011 or 3x1011 particles/mL) was administered and repeated at 3, 6, and 9 months if the patient remained free from a histologically confirmed HG recurrence. Repeat biopsy was performed as clinically indicated and mandated at the 1 year study endpoint.

RESULTS: Preliminary data from the 34 patients evaluable at the time of this abstract, showed intravesical administration of Ad-IFNα/Syn3 was well tolerated, with only minor urgency post-instillation controlled with anticholinergics. To date, 10 patients have achieved a CR at the 12-month endpoint.

CONCLUSIONS: While the trial remains ongoing and is expected to complete early in 2015, the results so far are consistent with the previous Phase 1 trial. The product appears safe and a CR in excess of a 20% at 12months would be of clinical significance in this high risk BCG failure population. Work will continue to finalize the endpoint and path to complete the development of rAd-IFNα/Syn3 as a therapeutic option to cystectomy.

Source of Funding: FKD Therapies Oy

The National Cancer Institute supported much of the preliminary work prior to this clinical trial.