SKIN CANCER (OTHER THAN MELANOMA)

PHASE I/IIA STUDY TO ASSESS THE EFFICACY AND SAFETY OF ASN-002 IN ADULT SPORADIC AND BASAL CELL NEVUS SUBJECTS WITH NODULAR BASAL CELL CARCINOMA

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Introduction: Basal cell carcinoma (BCC) is the most common human skin malignancy and nodular BCC the most common subtype. First line treatment for nodular BCC (nBCC) is surgical excision which is not always optimal, particularly when multiple lesions are present. Direct intra-tumoral injections of interferons is an effective treatment for nBCC. ASN-002, a recombinant adenovirus that can safely produce sustained, local concentration of IFNγ in the tumor microenvironment.

Objectives: The primary objective was to confirm the safety and efficacy of ASN-002 in individuals with Sporadic nBCC and Basal Cell Nevus Syndrome (BCNS).

Material and Method: A Phase 1/2a study of ASN-002 comprising fifteen eligible low-risk nBCC subjects were recruited into three dose escalation cohorts. Each subject received one intra-tumoral ASN-002 per week for three weeks and lesions were excised at Week 16-17.

Results and Conclusions: Histological complete response, (CR) was observed in 1 of 3 subjects in the first cohort (33%), 5 of 6 subjects in the second cohort and 5 of 6 subjects in the third cohort (83%). All subjects that did not have histological CR had a partial response (PR) on clinical assessment. Pathology review of PR excisions also showed evidence of on-going active regression at week 16/17. Subjects treated with ASN-002 also demonstrated regression in non-injected lesions with 70% (14/20) of such lesions showing clinically measurable regressions.
Toxicity was limited to injection site reactions and flu-like symptoms. Grade 1-2 local reactions (erythema, induration, ulceration and pain) at the ASN-002 injection site in all subjects. Grade 1 flu-like symptoms (headache, malaise, and fever) were observed in 7 of 12 subjects in the higher two dose cohorts and Grade 2 flu-like symptoms were observed in 2 of 6 eligible subjects in the highest dose cohort. No dose limiting toxicities were observed in any of the cohorts.