Preliminary results of phase I/II study of SENL-B19 chimeric antigen receptor T cell therapy in pediatric and adult patients with relapsed/refractory acute lymphoblastic leukemia (r/r-ALL)

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Background: ALL is common in both childhood and adulthood. When patients (pts) relapse with chemotherapy, their clinical outcome is poor. Here, we reported results of SENL-B19 chimeric antigen receptor T cell therapy (CAR-T) in a Phase 1/2 study in r/r-ALL pediatric and adult pts.

Methods: A total of 27 pts (aged 3-63) with r/r-ALL were received dose of 0.1-2 X 10^6 CAR-T cells/kg after low dose conditioning chemotherapy of Fludarabine and Cyclophosphamide. Tocilizumab was used for pts with grade 3 or higher cytokine release syndrome (CRS). Primary endpoint is the incidence of adverse events (AE). Secondary endpoints are observation of treatment response, survival, cellular pharma-cokinetic (PK) measurements, clinical outcome of pediatric vs adult pts, and exploratory biomarker studies.

Results: As of March 23, 2018, 27 pts were enrolled and treated with SENL-B19, and were observed for 3 month or longer. CRS was observed in all pts but one with progressing disease, with grade 3 and 4 in 4 pts. 14 pts were observed with neurotoxicity, with 6 pts in grade 3 or 4. Response to treatment was also assessed and complete response (CR) were observed in 23 of 27 pts. 1 pts was with reduction of tumor cell growth, although death occurred at day 69 post treatment. 15 pts were still survived, with one survived for 603 days, and a total of 7 survived for 300-600 days post treatment. Quantitative PCR was used to generate cellular PK data such as Cmax, Tmax, and AUC. Response rate and AE was comparable between pediatric pts and adult pts and will be presented. Cytokine biomarkers and disease progression markers were assessed and data will be further discussed.
Conclusions: SENL-B19 was well tolerated and can be safely administrated into r/r-ALL pts to generate clinically meaningful response and was shown to dramatically extend life in some pts. Based on this result, we will continue to investigate its clinical application in advanced clinical testings.

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