Research Title: Phase I/II Study of Lenalidomide in Patients with AIDS-Associated Kaposi's Sarcoma

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Objectives: To study the effects of Lenalidomide in treating patients with AIDS-Associated Kaposi's Sarcoma

Primary: To determine the maximum tolerated dose and assess for any correlation between immunologic and clinical responses.
Secondary: To evaluate changes in immune cells including B cells, CD 4 and CD 8 T cells, NK, granulocytes, monocytes, and more from patient's PBMC.
-To monitor changes in growth factors related to tumor development: IL-1β, IL-2, IL-4, IL-5, IL-6, IL-10, IL-15, IL-12, p70, TNFa, and IFNy.
-Study the changes in HHV- 8 copy number and viral gene/protein expression in tumor biopsies.

What is Kaposi's Sarcoma (KS)?
KS is a cancer of connective tissue (vascular endothelial cells beneath the skin) that gives rise to purple or brown-colored spots (called lesions) on the skin or inside the mouth, nose, or anus.

Why Lenalidomide?
Lenalidomide is classified as an "immunomodulatory agent" and an "antiangiogenic agent".
Approved to treat Multiple Myeloma and anemia caused by Myelodysplastic Syndrome (MDS)

Regimen:
Regimen: Patients are given predetermined dose of Lenalidomide for first 21 days of a 28 day cycle (total of 12 cycles if well tolerated). Lymphocytes are isolated from fresh PBMCs and stained with surface markers.

Method:
FACS representative plot
Gating strategy:
Live > lymph > T cells -> CD4 -> CD4 T reg

Results:
This is an ongoing research. So far our data suggest that Lenalidomide is increasing expression of regulatory T lymphocytes in patients with AIDS-associated Kaposi's Sarcoma.
Further investigation is needed to understand other effects on cytokines and HHV-8 viral counts.

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