Doctor's Note — Clinical Trial Summary

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TRIAL

A Dose Escalation and Dose Expansion Study of Intratumoral ONM-501 Alone and in Combination With Cemiplimab in Patients With Advanced Solid Tumors and Lymphomas.

NCT ID: NCT06022029 Phase: PHASE1 Sponsor: OncoNano Medicine, Inc. Status: Recruiting

SUMMARY

A phase 1, multicenter, open label, non-randomized dose escalation and dose expansion study to examine the maximum tolerated dose, (MTD), minimum effective dose (MED) and/or recommended dose for expansion (RDE) of intratumoral ONM-501 as monotherapy and in combination with a PD-1 checkpoint inhibitor in patients with advanced solid tumors and lymphomas.

KEY ELIGIBILITY CRITERIA

- 1. Ability to understand and willingness to sign written informed consent before performance of any study procedures
- 2. Age e 18 years
- 3. Participants with solid tumors or lymphomas, confirmed by available histopathology records or current biopsy, that are advanced, nonresectable, or recurrent and progressing since last antitumor therapy, and for which no alternative standard therapy exists.
- 4. Participants must have a minimum of one injectable and measurable lesion.
- 5. Participants with prior Hepatitis B or C are eligible if they have adequate liver function
- 6. Participants with human immunodeficiency virus (HIV) are eligible if on established HAART for a minimum of 4 weeks prior to enrollment, have an HIV viral load \<400 copies/mL, and have CD4+ T-cell (CD4+) counts e 350 cells/uL
- 7. Adequate bone marrow function:
- 8. Adequate liver function
- 1. Other malignancy active within the previous 2 years except for basal or squamous cell skin cancer, superficial bladder cancer, or carcinoma in situ of the cervix or breast that has completed curative therapy.
- 2. Major surgery within 4 weeks before the first dose of study drug.

ENROLLMENT CONTACT

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Total sites: 16 | 5 currently recruiting

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