FORM 2

THE PATENTS ACT, 1970
(39 of 1970)
&
THE PATENTS RULES, 2003

COMPLETE SPECIFICATION
(See section 10, rule 13)

***1. Title of the invention*:** ANTI-HUMAN PD-1 ANTIBODY CRYSTALS AND METHODS OF USE THEREOF

2. Applicant(s)

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3. Preamble to the description

COMPLETE SPECIFICATION

The following specification particularly describes the invention and the manner in which it is to be performed.

40. The composition of claim 38, wherein the concentration of the anti-PD-1 mAb is ≥75 mg/mL.

41. The composition of any of claims 35-40, further comprising about 5 mM to about 20 mM buffer.

42. The composition of any of claims 33-39, further comprising about 0.01 % to about 0.10 % w/v non-ionic surfactant.

43. The composition of any of claims 33-40, further comprising a second active pharmaceutical ingredient (API).

44. The composition of claim 43, wherein the second API is a small molecule or a biologic.

45. A method of treating cancer in a human patient comprising administering the crystal of any of claims 31-34, the crystalline pembrolizumab of any of claims 35 – 37, or the composition of any of claims 38-44 to a human patient in need thereof.

46. The method of claim 45, wherein the crystal or the composition is administered to the patient intravenously or subcutaneously.

47. The method of claim 45 or 46, wherein the cancer is selected from the group consisting of: melanoma, non-small cell lung cancer, small cell lung cancer, Hodgkin lymphoma, head and neck cancer, primary mediastinal large B-cell lymphoma, urothelial carcinoma, gastric cancer, esophageal cancer, renal cancer, endometrial cancer, hepatocellular carcinoma, merkel cell carcinoma, and cervical cancer.

48. The method of claim 45 or 46, wherein the cancer is a microsatellite instability-high or mismatch repair deficient solid tumor or colorectal cancer.

49. The method of claim 45 or 46, wherein the patient's tumor has a high mutational burden.

50. The method of any of claims 45 to 48, wherein the dosage of anti-PD-1 mAb is 200 mg, which is administered to the patient about every 3 weeks.

51. The method of any of claims 45 to 48, wherein the dosage of crystalline mAb is 400 mg, which is administered to the patient about every 6 weeks.

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To,
The Controller of Patents
The Patent Office at Chennai