[Non Patent Literature 6] "Clinical Cancer Research", (USA), 2002; 8 (12): 3702-3709

[Non Patent Literature 7] "Cancer Research", (USA), 2013; 73 (1): 62-73

[Non Patent Literature 8] "Cancer Research", (USA), 2016; 76 (13): 3756-3766

[Summary of Invention]

In one aspect, the disclosure provides a use of a human-derived cell in the manufacture of a pharmaceutical composition for treating or preventing a cancer, wherein the cell expresses exogenous CD1d and has α-GalCer loaded on the cell surface, and wherein the composition is to be administered to a human such that a single dose of α-GalCer loaded on the cell surface is 1.7 ng to 275 ng per kg body weight of the human.

In one aspect, the disclosure provides a method for producing a human-derived cell that expresses exogenous CD1d and has α-GalCer loaded on the cell surface, wherein the cell is to be administered to a human such that a single dose of α-GalCer loaded on the cell surface ranges from 1.7 ng to 275 ng per kg body weight of the human, and wherein the method comprises the step of culturing human-derived cells expressing exogenous CD1d in a culture medium containing 56 ng/mL to 3000 ng/mL α-GalCer, and the step of measuring the amount of α-GalCer

loaded on the cells obtained by the culture step, and selecting a cell wherein the amount of α-GalCer loaded on the cell surface is in the range of 3.9 to 275 ng per 1 × 10^6 cells.

[Technical Problem]

[0009]

An object of the present invention is to provide an effective and safe method for treating or preventing a cancer using aAVC.

[Solution to Problem]

[0010]

The present inventors have conducted diligent studies on the clinical application of aAVC. The present inventors have found that the amount of α-GalCer loaded on aAVC in the course of aAVC manufacturing processes varies depending on the type of cells and conditions for pulsing cells with α-GalCer, etc. The need of standardizing the amount of α-GalCer loaded on aAVC has thereby been found in order to produce aAVC as medicaments. Accordingly, the present inventors have established a method for measuring the amount of α-GalCer loaded on cell surface in order to quantify the amount of

~~[Document Name] Claims~~

~~[Claim 1]~~

~~A method for treating or preventing a cancer, comprising the step of administering a human-derived cell to a human,~~

~~wherein the cell expresses exogenous CD1d, has α-galactosylceramide (α-GalCer) loaded on the cell surface, and wherein the cell is administered to the human such that a single dose of α-GalCer loaded on the cell surface ranges from 1.7 ng to 275 ng per kg body weight of the human.~~

~~[Claim 2]~~

~~The method according to claim 1, wherein the human-derived cell expresses an exogenous cancer antigen.~~

~~[Claim 3]~~

~~The method according to claim 1 or 2, wherein the CD1d is human CD1d.~~

~~[Claim 4]~~

~~The method according to any of claims 1 to 3, wherein the human-derived cell is a human embryonic kidney cell 293 (HEK293)-derived cell.~~

~~[Claim 5]~~

~~The method according to any of claims 1 to 4, wherein the amount of α-GalCer loaded on the cell surface is in the range of 3.9 to 275 ng per 1×10^6 cells.~~

[Claim ~~6~~1]

~~A pharmaceutical composition for treating or preventing a cancer, comprising~~ Use of a human-derived cell in the manufacture of a pharmaceutical composition for treating or preventing a cancer,
wherein the cell expresses exogenous CD1d and has α-GalCer loaded on the cell surface,
and wherein the composition is to be administered to a human such that a single dose of α-GalCer loaded on the cell surface is 1.7 ng to 275 ng per kg body weight of the human.

[Claim ~~7~~2]

The ~~pharmaceutical composition~~ use according to claim ~~6~~1, wherein the human-derived cell expresses an exogenous cancer antigen.

[Claim ~~8~~3]

The ~~pharmaceutical composition~~ use according to claim ~~6~~ 1 or ~~7~~2, wherein the CD1d is human CD1d.

[Claim ~~9~~4]

The ~~pharmaceutical composition~~ use according to any of claims ~~6~~ 1 to ~~8~~3, wherein the human-derived cell is a human embryonic kidney cell 293 (HEK293)-derived cell.

[Claim ~~10~~5]

The ~~pharmaceutical composition~~ use according to any of claims ~~6~~ 1 to ~~9~~4, wherein the amount of α-GalCer loaded on the cell surface is in the range of 3.9 to 275 ng per 1×10^6 cells.

~~[Claim 11]~~

~~Use of a human-derived cell for producing a pharmaceutical composition for treating or preventing a cancer,~~

~~wherein the cell expresses exogenous CD1d and has α-GalCer loaded on the cell surface,~~

~~and wherein the composition is administered to a human such that a single dose of α-GalCer loaded on the cell surface ranges from 1.7 ng to 275 ng per kg body weight of the human.~~

~~[Claim 12]~~

~~The use according to claim 11, wherein the human-derived cell expresses an exogenous cancer antigen.~~

~~[Claim 13]~~

~~The use according to claim 11 or 12, wherein the CD1d is human CD1d.~~

~~[Claim 14]~~

~~The use according to any of claims 11 to 13, wherein the human-derived cell is a human embryonic kidney cell 293 (HEK293)-derived cell.~~

~~[Claim 15]~~

~~The use according to any of claims 11 to 14, wherein the amount of α-GalCer loaded on the cell surface is in the range of 3.9 to 275 ng per 1×10^6 cells.~~

~~[Claim 16]~~

~~A human-derived cell for use in treating or preventing a cancer,~~

~~wherein the cell expresses exogenous CD1d and has α-GalCer loaded on the cell surface,~~

~~and wherein the cell is administered to a human such that a single dose of α-GalCer loaded on the cell surface ranges from 1.7 ng to 275 ng per kg body weight of the human.~~

~~[Claim 17]~~

~~The human-derived cell according to claim 16, wherein the human-derived cell expresses an exogenous cancer antigen.~~

~~[Claim 18]~~

~~The human-derived cell according to claim 16 or 17, wherein the CD1d is human CD1d.~~

~~[Claim 19]~~

~~The human-derived cell according to any of claims 16 to 18, wherein the human-derived cell is a human embryonic kidney cell 293 (HEK293)-derived cell.~~

~~[Claim 20]~~

~~The human-derived cell according to any of claims 16 to 19, wherein the amount of α-GalCer loaded on the cell surface is in the range of 3.9 to 275 ng per 1×10^6 cells.~~

[Claim ~~21~~6]

A method for producing a human-derived cell that expresses exogenous CD1d and has α-GalCer loaded on the cell surface, wherein the cell is to be administered to a human such that a single dose of α-GalCer loaded on the

cell surface ranges from 1.7 ng to 275 ng per kg body weight of the human, and wherein the method comprises the step of culturing human-derived cells expressing exogenous CD1d in a culture medium containing 56 ng/mL to 3000 ng/mL α-GalCer, and the step of.

~~[Claim 22]~~

~~The method according to claim 21, further comprising the step of~~ measuring the amount of α-GalCer loaded on the cells obtained by the culture step, and selecting a cell wherein the amount of α-GalCer loaded on the cell surface is in the range of 3.9 to 275 ng per 1×10^6 cells.