CLAIMS

1. A stable, lyophilized, copanlisib-containing solid, in particular powder or cake, suitable for dilution and for therapeutic applications, said solid, in particular powder or cake, comprising:

- copanlisib, particularly in an amount suitable as a therapeutic dose,
- one or more pH-adjusting agents, particularly a buffering agent which in particular comprises a weak acid, such as citric acid for example, and a strong base, such as sodium hydroxide, for example, and
- a bulking agent, which is mannitol,

said solid, in particular powder or cake, having a pH of between 4 and 5 (inclusive) when reconstituted with a suitable diluent, such as sterile water for injection or sterile aqueous sodium chloride solution, particularly 0.9% aqueous sodium chloride solution, for example.

2. The lyophilized, copanlisib-containing solid, in particular powder or cake, according to claim 1, wherein said therapeutic dose is 30, 45 or 60 mg of copanlisib.

3. The lyophilized, copanlisib-containing solid, in particular powder or cake, according to claim 1 or 2, wherein said pH-adjusting agent is a buffering agent.

4. The lyophilized, copanlisib-containing solid, in particular powder or cake, according to any one of claims 1 to 3, wherein said buffering agent is citric acid and sodium hydroxide.

5. The lyophilized, copanlisib-containing solid, in particular powder or cake, according to any one of claims 1 to 4, which contains citric acid in an amount of 0.7- 75 % w/w, particularly 1.5-30% w/w, in particular 2.98% w/w, of said lyophilized, copanlisib-containing solid.

6. The lyophilized, copanlisib-containing solid, in particular powder or cake, according to any one of claims 1 to 5, which contains sodium hydroxide in an amount of 0-6% w/w, particularly 3.3-4.0 % w/w, in particular 3.7% w/w, of said lyophilized, copanlisib-containing solid.

7. The lyophilized, copanlisib-containing solid, in particular powder or cake, according to any one of claims 1 to 6, which contains sodium hydroxide in an amount of 0.01-6% w/w, particularly 3.3-4.0 % w/w, in particular 3.7% w/w, of said lyophilized, copanlisib-containing solid.

8. The lyophilized, copanlisib-containing solid, in particular powder or cake, according to claim any one of claims 1 to 7, which contains mannitol in an amount of 15.4-82.1% w/w, particularly 30.8-82.1% w/w, in particular 61.6% w/w, of said lyophilized, copanlisib-containing solid.

9. The lyophilized, copanlisib-containing solid, in particular powder or cake, according to any one of claims 1 to 8, which contains said copanlisib free base in an amount of 7.7-92.4% w/w, particularly 7.7-61.6% w/w, in particular 30.8% w/w, of lyophilized, copanlisib-containing solid.

10. The lyophilized, copanlisib-containing solid, in particular powder or cake, according to any one of claims 1 to 9, wherein:

- said therapeutic dose of copanlisib is in an amount of 30.8% w/w of said lyophilized, copanlisib-containing solid,
- said citric acid is in an amount of 2.98% w/w of said lyophilized, copanlisib-containing solid,
- said sodium hydroxide is in an amount of 3.7% w/w of said lyophilized, copanlisib-containing solid, and
- said mannitol is in an amount of 61.6% w/w, of said lyophilized, copanlisib-containing solid,

said lyophilized, copanlisib-containing solid, in particular powder or cake, when reconstituted with a suitable diluent, such as sterile water for injection or sterile aqueous sodium chloride solution, particularly 0.9% aqueous sodium chloride solution, for example, having a pH of between 4 and 5 (inclusive).

11. The lyophilized, copanlisib-containing solid, in particular powder or cake, according to any one of claims 1 to 10, wherein:

- said therapeutic dose of copanlisib is in an amount of 30, 45 or 60 mg,
- said citric acid is in an amount of 5.8mg,
- said sodium hydroxide is in an amount of 6.3mg, and
- said mannitol is in an amount of 120mg,

said lyophilized, copanlisib-containing solid, in particular powder or cake, when reconstituted with a suitable diluent, such as sterile water for injection or sterile aqueous sodium chloride solution, particularly 0.9% aqueous sodium chloride solution, for example, having a pH of between 4 and 5 (inclusive).

12. The lyophilized, copanlisib-containing solid, in particular powder or cake, according to claim 1, wherein:

- said therapeutic dose of copanlisib is in an amount of 80 mg,
- said citric acid is in an amount of 7.7 mg,
- said sodium hydroxide is in an amount of 8.4 mg, and
- said mannitol is in an amount of 160 mg,

said lyophilized, copanlisib-containing solid, in particular powder or cake, when reconstituted with a suitable diluent, such as sterile water for injection or sterile aqueous sodium chloride solution, particularly 0.9% aqueous sodium chloride solution, for example, having a pH of between 4 and 5 (inclusive).

13. The lyophilized, copanlisib-containing solid, in particular powder or cake, according to any one of claims 1 to 12, which is contained in one container, particularly a sealed container, particularly an injection vial, more particularly a 6 ml injection vial.

14. The lyophilized, copanlisib-containing solid, in particular powder or cake, according to claim 1, containing copanlisib in an amount of 68.4 mg.

15. Use of a lyophilized, copanlisib-containing solid, in particular powder or cake, according to any one of claims 1 to 14 for the preparation of a medicament for the treatment of a cancer, particularly a non-Hodgkin’s lymphoma (NHL), such as 1st line, 2nd line, or up to 9 prior treatments, relapsed, refractory, indolent NHL, in particular follicular lymphoma (FL), marginal zone lymphoma (MZL), small lymphocytic lymphoma (SLL),

Lymphoplasmacytoid/Waldenström macroglobulinemia (LPL-WM), or aggressive NHL, in particular diffuse large B cell lymphoma (DLBCL), mantle cell lymphoma (MCL), peripheral T-cell lymphoma (PTCL), transformed lymphoma (TL), or chronic lymphocytic leukemia (CLL), as monotherapy or in combination with one or more immunotherapeutic, chemotherapeutic or immuno-chemotherapeutic anti-cancer agents.