WHAT IS CLAIMED

1. Use of one or more inhibitors of apoptosis protein ("IAP") antagonists in the manufacture of a medicament for treating a human patient having locally advanced squamous cell carcinoma, wherein the one or more IAP antagonists is to be administered to the human patient in need thereof, wherein the method comprises:
   (a) a first regimen comprising concomitant administration of the one or more IAP antagonists, a platinum-based chemotherapeutic drug, and radiation; and
   (b) a second regimen comprising administration of the one or more IAP antagonists.

2. The use of claim 1, wherein the first regimen comprises at least one 21-day cycle in which the one or more IAP antagonists is to be administered for 14 consecutive days followed by seven days in which no IAP antagonist is to be administered.

3. The use of claim 2, wherein the first regimen comprises three consecutive 21-day cycles.

4. The use of claim 3, wherein the platinum-based chemotherapeutic drug of the first regimen is to be administered on the first day of each 21-day cycle, or on the second day of each 21-day cycle.

5. The use of any one of claims 3-4, wherein radiation is to be administered on the first five consecutive days of each 21-day cycle.

6. The use of any one of claims 1-5, wherein the second regimen comprises at least one 21-day cycle in which at least one IAP antagonist is to be administered for 14 consecutive days followed by seven days in which no IAP antagonist is to be administered.

7. The use of claim 6, wherein the second regimen comprises two or three consecutive 21-day cycles.

8. The use of any one of claims 1-7, wherein no platinum-based chemotherapeutic drug or radiation is to be administered in the second regimen.

9. The use of any one of claims 1-8, wherein the one or more IAP antagonists is selected from the group consisting of Compound A, or pharmaceutically acceptable salt thereof, LCL-161, or pharmaceutically acceptable salt thereof, CUDC 427/GDC 0917, or pharmaceutically acceptable salt thereof, birinapant, or pharmaceutically acceptable salt thereof, AZD5582, or pharmaceutically acceptable salt thereof, APG-1387, or pharmaceutically acceptable salt thereof, ASTX660, or pharmaceutically acceptable salt thereof, SBP-0636457, JP1201, or pharmaceutically acceptable salt thereof, or combinations thereof.

10. The use of claim 1-9, wherein a first IAP antagonist that is Compound A, or pharmaceutically acceptable salt thereof, and a second IAP antagonist selected from the group consisting of birinapant, or pharmaceutically acceptable salt thereof, AZD5582, or pharmaceutically acceptable salt thereof, and APG-1387, or pharmaceutically acceptable salt thereof, and combinations thereof, is to be administered to the human patient, wherein a third IAP antagonist selected from the group consisting of ASTX660, or pharmaceutically acceptable salt thereof, SBP-0636457, JP1201, or pharmaceutically acceptable salt thereof, and combinations thereof, is to be optionally administered to the human patient.

11. The use of any one of claims 1-10, wherein at least one IAP antagonist that is Compound A, or pharmaceutically acceptable salt thereof, preferably in an amount corresponding to about 100 mg to about 500 mg of Compound A as its free base, in particular about 100 mg, about 150 mg, or preferably about 200 mg of Compound A, or pharmaceutically acceptable salt, based on its free base, in both the first and second regimens, is to be administered to the human patient daily.

12. The use of any one of claims 1-11, wherein the human patient has a positive smoking history, is a heavy consumer of alcohol, and/or has HPV-negative OPC.

13. The use of any one of claims 1-12, wherein at least one IAP antagonist is Compound A in free base form.

14. The use of any one of claims 1-12, wherein at least one IAP antagonist is Compound A as a pharmaceutically acceptable salt, preferably selected from the group consisting of acetate, hydrochloride, citrate, lactate, fumarate, succinate, phosphate, maleate, sulfate, tartrate, benzoate, mesylate, malate, hydrobromide, tosylate, nitrate, N-acetylglycine, ascorbate, butanate, ethane-1,2-disulfonate, gentisate, glucoronate, glutarate, glycolate, isethionate, ketoglutarate, malonate, napadisylate, napsylate, nicotinate, pyroglutamate, pyruvate, sebacate, and succinate, more preferably selected from the group consisting of sulfate, tosylate, gentisate, hydrochloride, napadisylate, napsylate, laurylsulfate, xinafoate, and pamoate.

15. The use of any one of claims 1-14, wherein at least one IAP antagonist is Compound A, or pharmaceutically acceptable salt thereof, that is to be administered orally.

16. The use of any one of claims 1-15, wherein at least one IAP antagonist is Compound A, or pharmaceutically acceptable salt thereof, that is to be administered as a solid dosage form, preferably a capsule or tablet.

17. The use of any one of claims 1-15, wherein at least one IAP antagonist is Compound A, or pharmaceutically acceptable salt thereof, that is to be administered as a solution, preferably an aqueous solution.

18. The use of claim 17, wherein the solution of Compound A, or pharmaceutically acceptable salt thereof, is to be administered orally via a nasogastric tube, percutaneous endoscopic gastrostomy tube, or percutaneous endoscopic jejunostomy tube, and/or wherein the solution comprises Compound A, or pharmaceutically acceptable salt thereof, at a concentration of between about 10 mg/mL to about 50 mg/mL, preferably about 20 mg/mL, based on Compound A as its free base.

19. The use of any one of claims 1-18, wherein at least one IAP antagonist is Compound A, or pharmaceutically acceptable salt thereof, that is to be administered as one dose one time per day, or is divided into multiple doses that are to be administered two, three, or four times per day.

20. The use of any one of claims 1-19, wherein the platinum-based chemotherapeutic drug of the first regimen is to be intravenously administered.

21. The use of any one of claims 1-20, wherein the platinum-based chemotherapeutic drug of the first regimen is one or more selected from the group consisting of cisplatin, carboplatin, oxaliplatin, and nedaplatin.

22. The use of claim 21, wherein the platinum-based chemotherapeutic drug of the first regimen is cisplatin, wherein the cisplatin is to be preferably administered at a dose between about 10 mg/m^2 weekly and 150 mg/m^2 weekly, more preferably at a dose between about 40 mg/m^2 weekly and about 100 mg/m^2 weekly, in particular at a dose of about 100 mg/m^2 weekly.

23. The use of claim 22, wherein the cisplatin is to be administered at a dose of about 50 mg/m^2 or more to about 100 mg/m^2 or less on Day 2 of a 21-day cycle.

24. The use of claim 21, wherein the platinum-based chemotherapeutic drug of the first regimen is carboplatin, wherein the carboplatin is to be preferably administered at a dose sufficient for the human patient to exhibit an area under the curve of about 1.0 to about 5.5 mg*min/mL, more preferably about 1.5 to about 2.0 mg*min/mL weekly, or about 4.5 to about 5.0 every three weeks.

25. The use of any one of claims 1-24, wherein the human patient is provided a suitable amount of radiation up to a maximum of 70 grays in the first regimen, preferably up to a maximum of 56 grays in the first regimen.

26. The use of any one of claims 1-25, wherein the radiation is intensity-modulated radiation therapy.

27. The use of any one of claims 1-26, wherein at least one IAP antagonist is to be administered to the human patient in the first regimen after the human patient has fasted for at least two hours, and/or wherein the human patient fasts for at least one hour after at least one IAP antagonist is to be administered to the human patient in the first regimen.

28. The use of any one of claims 1-27, wherein at least one IAP antagonist is to be administered to the human patient in the second regimen after the human patient has fasted for at least two hours, and/or wherein the human patient fasts for at least one hour after at least one IAP antagonist is to be administered to the human patient in the second regimen.

29. The use of any one of claims 1-28, wherein the locally advanced squamous cell carcinoma is of the head and neck region.

30. The use of claim 29, wherein the locally advanced squamous cell carcinoma of the head and neck region is squamous cell carcinoma of the head and neck region of oropharynx, larynx, hypopharynx, or oral cavity and more specifically selected from the group consisting of oropharynx, larynx, and hypopharynx.

31. The use of claim 30, wherein the locally advanced squamous cell carcinoma of the head and neck region is oropharyngeal cancer, wherein the oropharyngeal cancer is unrelated to human papillomavirus (HPV) infection, or wherein the oropharyngeal cancer is related to HPV infection.

32. The use of any one of claims 1-31, wherein the locally advanced squamous cell carcinoma is Stage III, Stage IVA, or Stage IVB according to the American Joint Committee on Cancer 1998 staging system or wherein the locally advanced squamous cell carcinoma is Stage III, Stage IVA, or Stage IVB according to the American Joint Committee on Cancer 2010 or 2018 staging system.

33. Use of Compound A or pharmaceutically acceptable salt thereof in the manufacture of a medicament for treating a human patient having locally advanced squamous cell carcinoma, wherein the Compound A, or pharmaceutically acceptable salt thereof, is to be administered to the human patient in need thereof, wherein the method comprises:

    1. a first regimen comprising three 21-day cycles that comprise administering Compound A, or pharmaceutically acceptable salt thereof, on Days 1-14 of each cycle, cisplatin on Day 2 of each cycle, and radiation on Days 1-5, 8-12, and 15-19 of each cycle, wherein cisplatin may be replaced by carboplatin after the first cycle; and
    2. a second regimen comprising three 21-day cycles that comprise administering Compound A, or pharmaceutically acceptable salt thereof, on Days 1-14 of each cycle.

34. The use of claim 33, wherein Compound A, or pharmaceutically acceptable salt thereof, in an amount corresponding to about 100 mg to about 500 mg of Compound A as its free base, in particular about 200 mg of Compound A, or pharmaceutically acceptable salt, based on its free base, in both the first and second regimens, is to be administered to the human patient daily.

35. The use of claim 33 or 34, wherein the cisplatin is to be administered at a dose of about 50 mg/m^2 or more to about 100 mg/m^2 or less on Day 2 of a 21-day cycle.

36. The use of any one of claims 33-35, wherein the locally advanced squamous cell carcinoma is of the head and neck region.

37. The use of claim 36, wherein the locally advanced squamous cell carcinoma of the head and neck region is squamous cell carcinoma of the head and neck region of oropharynx, larynx, hypopharynx, or oral cavity and more specifically selected from the group consisting of oropharynx, larynx, and hypopharynx.

38. The use of claim 37, wherein the locally advanced squamous cell carcinoma of the head and neck region is oropharyngeal cancer, wherein the oropharyngeal cancer is unrelated

to human papillomavirus (HPV) infection, or wherein the oropharyngeal cancer is related to HPV infection.

39. The use of any one of claims 33-38, wherein the locally advanced squamous cell carcinoma is Stage III, Stage IVA, or Stage IVB according to the American Joint Committee on Cancer 1998 staging system or wherein the locally advanced squamous cell carcinoma is Stage III, Stage IVA, or Stage IVB according to the American Joint Committee on Cancer 2010 or 2018 staging system.

40. The use of any one of claims 33-39, wherein no platinum-based chemotherapeutic drug or radiation is to be administered in the second regimen.

41. A kit comprising:(a) a first pharmaceutical composition comprising an inhibitor of apoptosis protein ("IAP") antagonist (e.g. Compound A or a pharmaceutically acceptable salt thereof); and (b) an insert instructing use of the first pharmaceutical composition for treating locally advanced squamous cell carcinoma via any of the methods as defined in any one of claims 1 to 40.