CLAIMS

1. Use of poziotinib for the manufacture of a medicament for treating cancer in a subject, wherein an effective amount of the medicament is administered to the subject and wherein the subject has been determined to have one or more HER2 exon 19 mutations.

2. The use of claim 1, wherein the one or more HER2 exon 19 mutations comprise a point mutation, insertion, and/or deletion of 1-18 nucleotides between amino acids 668-769 of HER2.

3. The use of claim 1, wherein the one or more HER2 exon 19 mutations are further defined as HER2 point mutations.

4. The use of claim 1, wherein the subject has been determined to have 2, 3, or 4 HER2 exon 19 mutations.

5. The use of claim 2, wherein the one or more HER2 exon 19 mutations are at one or more residues selected from the group consisting of R668, R678, V754, L755, I767, and D769.

6. The use of any of claims 1-5, wherein the one or more HER2 exon 19 mutations are selected from the group consisting of R668Q, R678Q, V754M, L755P, L755S, L755W, D769H, D769N, I767M, and D769Y.

7. The use of claim 1, wherein the exon 19 mutation is L755P.

8. The use of any of claims 1-7, wherein the subject was determined to have an HER2 exon 19 mutation by analyzing a genomic sample from the patient.

9. The use of claim 9, wherein the genomic sample is isolated from saliva, blood, urine, normal tissue, or tumor tissue.

10. The use of any of claims 1-7, wherein the presence of an HER2 exon 19 mutation is determined by nucleic acid sequencing or PCR analyses.

11. The use of claim 1, further comprising administering an additional anti-cancer therapy.

12. The use of claim 11, wherein the additional anti-cancer therapy is chemotherapy, radiotherapy, gene therapy, surgery, hormonal therapy, anti-angiogenic therapy or immunotherapy.

13. The use of claim 11, wherein the poziotinib and/or anti-cancer therapy are administered intravenously, subcutaneously, intraosseously, orally, transdermally, in sustained release, in controlled release, in delayed release, as a suppository, or sublingually.

14. The use of claim 11, wherein administering the poziotinib and/or anti-cancer therapy comprises local, regional or systemic administration.

15. The use of claim 11, wherein the poziotinib and/or anti-cancer therapy are administered two or more times.

16. The use of clam 1, wherein the poziotinib is administered orally.

17. The use of claim 1, wherein the poziotinib is administered at a dose of 5-25 mg.

18. The use of claim 1, wherein the poziotinib is administered at a dose of 8 mg, 12 mg, or 16 mg.

19. The use of claim 1, wherein the poziotinib is administered daily.

20. The use of claim 19, wherein the poziotinib is administered on a continuous basis.

21. The use of claim 19, wherein the poziotinib is administered on 28 day cycles.

22. The use of any of claims 1-15, wherein the cancer is oral cancer, oropharyngeal cancer, nasopharyngeal cancer, respiratory cancer, urogenital cancer, gastrointestinal cancer, central or peripheral nervous system tissue cancer, an endocrine or neuroendocrine cancer or hematopoietic cancer, glioma, sarcoma, carcinoma,

lymphoma, melanoma, fibroma, meningioma, brain cancer, oropharyngeal cancer, nasopharyngeal cancer, renal cancer, biliary cancer, pheochromocytoma, pancreatic islet cell cancer, Li-Fraumeni tumors, thyroid cancer, parathyroid cancer, pituitary tumors, adrenal gland tumors, osteogenic sarcoma tumors, multiple neuroendocrine type I and type II tumors, breast cancer, lung cancer, head and neck cancer, prostate cancer, esophageal cancer, tracheal cancer, liver cancer, bladder cancer, stomach cancer, pancreatic cancer, ovarian cancer, uterine cancer, cervical cancer, testicular cancer, colon cancer, rectal cancer or skin cancer.

23. The method of any of claims 1-15, wherein the cancer is non-small cell lung cancer (NSCLC).

24. The use of any of claims 1-15, wherein the cancer is colorectal cancer.

25. The use of any of claims 1-15, wherein the subject is human.

26. Use of a pharmaceutical composition comprising poziotinib for the manufacture of a medicament for treating a subject determined to have one or more HER2 exon 19 mutations.

27. The use of claim 26, wherein the one or more HER2 exon 19 mutations comprise a point mutation, insertion, and/or deletion of 1-18 nucleotides between amino acids 668-769.

28. The use of claim 26, wherein the one or more HER2 exon 19 mutations are further defined as HER2 point mutations.

29. The use of claim 26, wherein the subject has been determined to have 2, 3, or 4 HER2 exon 19 mutations.

30. The use of claim 28, wherein the one or more HER2 exon 19 mutations are at one or more residues selected from the group consisting of R668, R678, V754, L755, I767, and D769.

31. The use of claim 26, wherein the one or more HER2 exon 19 mutations are selected from the group consisting of R668Q, R678Q, V754M, L755P, L755S, L755W, D769H, D769N, I767M, and D769Y.

32. The use of claim 26, wherein the subject is being treated with an anti-cancer therapy.

33. A method of predicting a response to poziotinib alone or in combination with a second anti-cancer therapy in a subject having a cancer comprising detecting an HER2 exon 19 mutation in a genomic sample obtained from said patient, wherein if the sample is positive for the presence of the HER2 exon 19 mutation, then the patient is predicted to have a favorable response to the poziotinib alone or in combination with an anti-cancer therapy.

34. The method of claim 33, wherein the HER2 exon 19 mutation is further defined as a HER2 exon 19 point mutation.

35. The method of claim 33, wherein the genomic sample is isolated from saliva, blood, urine, normal tissue, or tumor tissue.

36. The method of claim 33, wherein the presence of a HER2 exon 19 mutation is determined by nucleic acid sequencing or PCR analyses.

37. The method of claim 36, wherein the HER2 exon 19 mutation comprises a point mutation, insertion, and/or deletion of 1-18 nucleotides between amino acids 668-769.

38. The method of claim 37, wherein the one or more HER2 exon 19 mutations are at one or more residues selected from the group consisting of R668, R678, V754, L755, I767, and D769.

39. The method of any of claims 33-38, wherein the one or more HER2 exon 19 mutations are selected from the group consisting of R668Q, R678Q, V754M, L755P, L755S, L755W, D769H, D769N, I767M, and D769Y.

40. The method of claim 33, wherein a favorable response to poziotinib alone or in combination with an anti-cancer therapy comprises reduction in tumor size or burden, blocking of tumor growth, reduction in tumor-associated pain, reduction in cancer

associated pathology, reduction in cancer associated symptoms, cancer non-progression, increased disease free interval, increased time to progression, induction of remission, reduction of metastasis, or increased patient survival.

41. Use of poziotinib alone or in combination with a second anti-cancer therapy in the manufacture of a medicament wherein the medicament is administered to said patient predicted to have a favorable response.

42. A composition comprising:

(a) nucleic acids isolated from human cancer cells; and

(b) a primer pair that can amplify at least a first portion of mutated exon 19 of a human HER2 coding sequence.

43. The composition of claim 42, further comprising a labeled probe molecule that can specifically hybridize to the first portion of exon 19 of the human HER coding sequence when there is a mutation in the sequence.

44. The composition of claim 42, further comprising a thermostable DNA polymerase.

45. The composition of claim 42, further comprising dNTPS.

46. The composition of any of claims 43-45, wherein the labeled probe hybridizes to the first portion of exon 19 of the human HER2 coding sequence when there is a mutation selected from the group consisting of R668Q, R678Q, V754M, L755P, L755S, L755W, D769H, D769N, I767M, and D769Y.

47. An isolated nucleic acid encoding a mutant HER2 protein, wherein said mutant protein differs from wild-type human HER2 by one or more HER2 exon 19 mutations comprising one or more point mutations, insertions, and/or deletions of 1-18 nucleotides between amino acids 668-769.

48. The isolated nucleic acid of claim 47, wherein the one or more HER2 exon 19 mutations are at residue R668, R678, V754, L755, I767, and/or D769.

49. The isolated nucleic acid of claim 47 or 48, wherein the one or more HER2 exon 19 mutations are selected from the group consisting of R668Q, R678Q, V754M, L755P, L755S, L755W, D769H, D769N, I767M, and D769Y.