

WHAT IS CLAIMED IS:

1. A use of an effective amount of poziotinib in the manufacture of a medicament for treating cancer in a subject, wherein the subject has a tumor that has been determined to have one or more EGFR exon 20 insertion mutations, wherein the mutations comprise an insertion of 1–6 amino acids between amino acids 763-778.
2. The use of claim 1, wherein the subject has been determined to have 2, 3, or 4 EGFR exon 20 insertion mutations.
3. The use of claim 1, wherein the one or more EGFR exon 20 insertion mutations are at one or more residues selected from the group consisting of A763, A767, S768, V769, D770, N771, P772, and H773.
4. The use of claim 1, wherein the subject has been determined to not have a C797 or T790M EGFR mutation.
5. The use of claim 1, wherein the one or more exon 20 insertion mutations are selected from the group consisting of A763insFQEA, A767insASV, S768dupSVD, V769insASV, D770insSVD, D770insNPG, H773insNPH, N771del insGY, N771del insFH, and N771dupNPH.
6. The use of claim 1, wherein the exon 20 insertion mutation is D770insNPG.
7. The use of claim 1, further comprising administering an additional anti-cancer therapy.
8. The use of claim 7, wherein the additional anti-cancer therapy is chemotherapy, radiotherapy, gene therapy, surgery, hormonal therapy, anti-angiogenic therapy or immunotherapy.
9. The use of claim 7, 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.
10. The use of claim 7, wherein the poziotinib and/or anti-cancer therapy are administered daily.
11. The use of claim 1, wherein the cancer is non-small cell lung cancer, 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.

12. The use of claim 1, wherein the exon 20 insertion mutation is V769insASV.
13. The use of claim 1, wherein the exon 20 insertion mutation is A763insFQEA.
14. The use of claim 1, wherein the exon 20 insertion mutation is D770insSVD.
15. The use of claim 7, wherein the additional anti-cancer therapy is an mTOR inhibitor.
16. The use of claim 15, wherein the mTOR inhibitor is selected from the group consisting of rapamycin, temsirolimus, everolimus, ridaforolimus and MLN4924.
17. The use of claim 15, wherein the mTOR inhibitor is everolimus.
18. The use of claim 7, wherein the additional anti-cancer therapy is trastuzumab emtansine.