

What is claimed is:

1. A method of treating chemotherapy-induced diarrhea (CID) in a human subject undergoing chemotherapy comprising administering to a subject in need thereof a composition comprising an effective amount of crofelemer to treat CID.
2. The method of claim 1, wherein the crofelemer may be administered in combination with other chemotherapy agents.
3. The method of claim 1, wherein the crofelemer is administered at the same time as chemotherapy to reduce or delay the onset of CID.
4. The method of claim 1, wherein the crofelemer is administered before chemotherapy to prevent, reduce or delay the onset of CID.
5. The method of claim 1, wherein the crofelemer is administered after chemotherapy to reduce the onset of or treat CID.
6. The method of any previous claim, wherein the chemotherapy is selected from alkylating agents, anthracyclines, cytoskeletal disruptors (taxanes), epothilones, histone deacetylase inhibitors, inhibitors of topoisomerase I, inhibitors of topoisomerase II, kinase inhibitors, nucleotide analogs and precursor analogs, peptide antibiotics, platinum-based agents and retinoids.
7. The method of claim 6, wherein the chemotherapy comprises one or more tyrosine kinase inhibitors.
8. The method of claim 7, wherein the tyrosine kinase inhibitor is selected from lapatinib, sunitinib, sorafenib, erlotinib, gefitinib, axitinib, imatinib, nilotinib, dasatinib, cabozantinib, ruxolitinib, neratinib, bosutinib, pazopanib, afatinib, lenvatinib, tucatinib, vandetanib, ceritinib, crizotinib, dacomitinib, and valatinib.
9. The method of claim 7, wherein the tyrosine kinase inhibitor (TKI) is selected from anaplastic lymphoma kinase (ALK) TKI (e.g., crizotinib, ceritinib and alectinib),
10. The method of claim 6, wherein the chemotherapy is a phosphoinositide 3-kinase inhibitor.

11. The method of claim 10, wherein the phosphoinositide 3-kinase inhibitor is alpelisib.
12. The method of claim 6, wherein the chemotherapy is a CDK (cyclin-dependent kinase) 4/6/ inhibitor, optionally, abemaciclib.
13. The method of any one of claims 1 to 6, wherein the chemotherapy comprises one or more HER (Human epidermal growth factor receptor) inhibitors.
14. The method of claim 9, wherein the HER (Human epidermal growth factor receptor) inhibitor is selected from RG7116, RG1273 (pertuzumab, Perjeta®), RG3502 (trastuzumab emantansine, T-DMI), RG597 (trastuzumab, HERCEPTIN), RGA201 (RG7160), erlotinib (Tarceva®), dacomitinib (PF-00299804), PF-05280014 (Pfizer's biosimilar mAB to RG597).
15. The method of claim 1, wherein the crofelemer is administered after a subject begins to exhibit symptoms of CID.
16. The method of claim 1, wherein the crofelemer is administered for the duration of treatment with the chemotherapy.
17. The method of claim 1, wherein the crofelemer is administered until symptoms of CID are ameliorated and then crofelemer is discontinued.
18. The method of claim 1, wherein the administering comprises administering about 250 mg to about 1000 mg per day; administering about 250 mg per day; administering about 500 mg per day; administering about 1000 mg per day; administering about 125 mg two times per day; administering about 250 mg two times per day; or administering about 500 mg two times per day of crofelemer to a subject in need thereof.
19. The method of claim 1, wherein the crofelemer is administered as an enteric coated oral dosage form.
20. The method of claim 1, wherein the crofelemer is administered as an oral dosage form that is not enteric coated.
21. The method of claim 1, wherein the subject can tolerate a chemotherapeutic agent that the subject could not tolerate without the administration of crofelemer or can tolerate a higher dosage of chemotherapeutic than the subject could tolerate without administration of crofelemer.

22. The method of claim 1, wherein a subject is considered treated if the subject demonstrates one or more of a decrease in the number of bowel movements per day, a decrease in the number of watery bowel movements per day, an improvement in the daily abdominal score for pain or discomfort, an improvement in the score for daily stool consistency, a decrease in stool consistency, a decrease in the number of days per week that subjects experienced urgency, a decrease in the number of days per week that subjects experienced fecal incontinence, or a decrease in the unscheduled visit for a significant worsening of diarrhea.

23. The method of claim 1, wherein the administration results in a decrease in 1, 2 or 3 Grades of the Grade of diarrhea according to the Common Toxicity Criteria.

24. The method of claim 1, wherein the subject is undergoing chemotherapy to treat a cancer selected from breast cancer, ovarian cancer, prostate cancer, bladder cancer, cervical cancer, uterine cancer, testicular cancer, kidney cancer, thyroid cancer, oral or oropharyngeal cancer, astrocytoma, sarcoma, mesothelioma, meningioma, lymphoma, myeloma, head and neck cancer, lung cancer, carcinoma (e.g., squamous cell carcinoma), malignant melanoma, peritoneal cancer, gastric cancer, hepatic cancer, colorectal cancer, gallbladder cancer, bone cancer, pancreatic cancer, tongue cancer, esophageal cancer, brain tumor, brain stem glioma, a metastases thereof, and leukemia.

25. A method of treating CID in a human subject undergoing chemotherapy for HER positive breast cancer, said method comprising administering to said human subject a composition comprising an crofelemer at a dose of 125 mg twice per day, wherein the chemotherapy is trastuzumab, pertuzumab, docetaxel, paclitaxel, or neratinib, or a combination thereof, with or without carboplatin.