What is claimed is:

1. A pharmaceutical combination comprising regorafenib or its hydrate, solvate, or pharmaceutically acceptable salt, and nivolumab.

2. The combination of claim 1 which is a combination pack containing the components separate from one another.

3. The combination of claim 1 or 2 wherein the components are in separate dosage forms to be administered simultaneously or sequentially for use in the treatment of the same disease.

4. The combination of claim 3, wherein regorafenib is to be administered first followed by nivolumab.

5. Use of regorafenib or its hydrate, solvate, or pharmaceutically acceptable salt, in the manufacture of a medicament for use in combination therapy for treating hyper-proliferative disorders, wherein the regorafenib is to be administered in combination with nivolumab, wherein the hyper-proliferative disorders are cancers.

6. The use of claim 5 wherein the cancers are selected from the group consisting of cancers of the breast, respiratory tract, brain, reproductive organs, digestive tract, urinary tract, eye, liver, skin, head and neck, thyroid, parathyroid and their distant metastases.

7. The use of any of claims 5 wherein the cancers are selected from the group consisting of hepatic cell cancer, colorectal cancer and gastrointestinal stromal tumors (GIST).

8. The use of claim 5, wherein the regorafenib is to be administered simultaneously or sequentially with nivolumab.

9. The use of claim 5, wherein the regorafenib is to be administered first followed by nivolumab.