What is claimed is:

1. A method of analyzing a biological sample of a subject with cancer, comprising determining a level of expression of the biomarkers GLI-1, OTX-2, SHROOM2, PDLIM3, and SPHK1 in the biological sample taken from the subject, wherein the level of expression of the biomarkers in comparison to a control provide a diagnostic indicator of whether the subject has an increased likelihood of response to a methyl-4'-trifluoromethoxy-biphenyl-3-carboxylic acid [6-(cis-2,6-dimethyl-morpholin-4-yl)-pyridin-3-yl]-amide or 2-[(R)-4-(6-benzyl-4,5-dimethyl-pyridazin-3-yl)-2-methyl-3,4,5,6-tetrahydro-2H-[1,2']bipyrazinyl-5'-yl]-propan-2-ol.

2. A method of selecting a subject having cancer for treatment with a Hedgehog signaling inhibitor, the method comprising determining the level of expression of at least three biomarkers selected from the group consisting of GLI-1, OTX-2, SHROOM2, PDLIM3, SPHK1, SFRP1, APBA2 and SPATA20, in a biological sample derived from the subject, thereby to predict an increased likelihood of response to a Hedgehog signaling inhibitor.

3. The method according to claim 2 comprising determining the level of at least four biomarkers.

4. The method according to claim 2 comprising determining the level of at least five biomarkers.

5. A method of selecting a subject having cancer for treatment with methyl-4'-trifluoromethoxy-biphenyl-3-carboxylic acid [6-(cis-2,6-dimethyl-morpholin-4-yl)-pyridin-3-yl]-amide or 2-[(R)-4-(6-benzyl-4,5-dimethyl-pyridazin-3-yl)-2-methyl-3,4,5,6-tetrahydro-2H-[1,2']bipyrazinyl-5'-yl]-propan-2-ol, the method comprising determining the level of SHROOM2 in a biological sample derived from the subject, thereby to predict an increased likelihood of response to methyl-4'-trifluoromethoxy-biphenyl-3-carboxylic acid [6-(cis-2,6-dimethyl-morpholin-4-yl)-pyridin-3-yl]-amide or 2-[(R)-4-(6-benzyl-4,5-dimethyl-pyridazin-3-yl)-2-methyl-3,4,5,6-tetrahydro-2H-[1,2']bipyrazinyl-5'-yl]-propan-2-ol.

6. A method of selecting a subject having cancer for treatment with methyl-4'-trifluoromethoxy-biphenyl-3-carboxylic acid [6-(cis-2,6-dimethyl-morpholin-4-yl)-pyridin-3-yl]-amide or 2-[(R)-4-(6-benzyl-4,5-dimethyl-pyridazin-3-yl)-2-methyl-3,4,5,6-tetrahydro-2H-[1,2']bipyrazinyl-5'-yl]-propan-2-ol, the method comprising determining the level of SPHK1 in a biological sample derived from the subject, thereby to predict an increased likelihood of response to methyl-4'-

trifluoromethoxy-biphenyl-3-carboxylic acid [6-(cis-2,6-dimethyl-morpholin-4-yl)-pyridin-3-yl]-amide or 2-[(R)-4-(6-benzyl-4,5-dimethyl-pyridazin-3-yl)-2-methyl-3,4,5,6-tetrahydro-2H-[1,2']bipyrazinyl-5'-yl]-propan-2-ol.

7. The method according to any of claims 2, wherein the hedgehog signaling inhibitor is methyl-4'-trifluoromethoxy-biphenyl-3-carboxylic acid [6-(cis-2,6-dimethyl-morpholin-4-yl)-pyridin-3-yl]-amide or 2-[(R)-4-(6-benzyl-4,5-dimethyl-pyridazin-3-yl)-2-methyl-3,4,5,6-tetrahydro-2H-[1,2']bipyrazinyl-5'-yl]-propan-2-ol.

8. The method according to any of claims 1-7, wherein the determining is the level of expression of mRNA.

9. A kit comprising a plurality of agents for determining the level of expression of the biomarkers listed in claims 1 or 2 in a sample and instructions for use.

10. A method of treating cancer in a patient in need thereof, comprising selectively administering a Hedgehog signaling inhibitor to the patient on the basis of the patient has an elevated level of expression of the biomarkers GLI-1, SHROOM2, PDLIM3, and SPHK1 and a decreased level of expression of the biomarker OTX-2.

11. The method of claim 10, wherein a sample from the patient is assayed for the expression of the biomarkers and the sample is a Formalin-Fixed, Paraffin-Embedded tissue (FFPE).

12. The method of claims 1-8 and 10-11, wherein the cancer is BCC, medulloblastoma, rhabdomyosarcoma, CML, bone sarcoma, soft tissue sarcoma, pancreatic cancer, small cell lung cancer, prostate cancer Gorlin syndrome, or breast cancer.

13. The method of claim 12, wherein the cancer is medulloblastoma.

14. The method according to any of claims 1-8 or 10-13, wherein the inhibitor is methyl-4'-trifluoromethoxy-biphenyl-3-carboxylic acid [6-(cis-2,6-dimethyl-morpholin-4-yl)-pyridin-3-yl]-amide.

15. The method according to any of claims 1-8 or 10-13, wherein the inhibitor is 2-[(R)-4-(6-benzyl-4,5-dimethyl-pyridazin-3-yl)-2-methyl-3,4,5,6-tetrahydro-2H-[1,2']bipyrazinyl-5'-yl]-propan-2-ol.

What is claimed is:

1. A method of analyzing a biological sample of a subject with cancer, comprising determining a level of expression of the biomarkers GLI-1, OTX-2, SHROOM2, PDLIM3, and SPHK1 in the biological sample taken from the subject, wherein the level of expression of the biomarkers in comparison to a control provide a diagnostic indicator of whether the subject has an increased likelihood of response to a methyl-4'-trifluoromethoxy-biphenyl-3-carboxylic acid [6-(cis-2,6-dimethyl-morpholin-4-yl)-pyridin-3-yl]-amide or 2-[(R)-4-(6-benzyl-4,5-dimethyl-pyridazin-3-yl)-2-methyl-3,4,5,6-tetrahydro-2H-[1,2']bipyrazinyl-5'-yl]-propan-2-ol.

2. A method of selecting a subject having cancer for treatment with a Hedgehog signaling inhibitor, the method comprising determining the level of expression of at least three biomarkers selected from the group consisting of GLI-1, OTX-2, SHROOM2, PDLIM3, SPHK1, SFRP1, APBA2 and SPATA20, in a biological sample derived from the subject, thereby to predict an increased likelihood of response to a Hedgehog signaling inhibitor.

3. The method according to claim 2 comprising determining the level of at least four biomarkers.

4. The method according to claim 2 comprising determining the level of at least five biomarkers.

5. A method of selecting a subject having cancer for treatment with methyl-4'-trifluoromethoxy-biphenyl-3-carboxylic acid [6-(cis-2,6-dimethyl-morpholin-4-yl)-pyridin-3-yl]-amide or 2-[(R)-4-(6-benzyl-4,5-dimethyl-pyridazin-3-yl)-2-methyl-3,4,5,6-tetrahydro-2H-[1,2']bipyrazinyl-5'-yl]-propan-2-ol, the method comprising determining the level of SHROOM2 in a biological sample derived from the subject, thereby to predict an increased likelihood of response to methyl-4'-trifluoromethoxy-biphenyl-3-carboxylic acid [6-(cis-2,6-dimethyl-morpholin-4-yl)-pyridin-3-yl]-amide or 2-[(R)-4-(6-benzyl-4,5-dimethyl-pyridazin-3-yl)-2-methyl-3,4,5,6-tetrahydro-2H-[1,2']bipyrazinyl-5'-yl]-propan-2-ol.

6. A method of selecting a subject having cancer for treatment with methyl-4'-trifluoromethoxy-biphenyl-3-carboxylic acid [6-(cis-2,6-dimethyl-morpholin-4-yl)-pyridin-3-yl]-amide or 2-[(R)-4-(6-benzyl-4,5-dimethyl-pyridazin-3-yl)-2-methyl-3,4,5,6-tetrahydro-2H-[1,2']bipyrazinyl-5'-yl]-propan-2-ol, the method comprising determining the level of SPHK1 in a biological sample derived from the subject, thereby to predict an increased likelihood of response to methyl-4'-trifluoromethoxy-biphenyl-3-carboxylic acid [6-(cis-2,6-dimethyl-morpholin-4-yl)-pyridin-3-yl]-amide or 2-[(R)-4-(6-benzyl-4,5-dimethyl-pyridazin-3-yl)-2-methyl-3,4,5,6-tetrahydro-2H-[1,2']bipyrazinyl-5'-yl]-propan-2-ol.

7. The method according to any of claims 2, wherein the hedgehog signaling inhibitor is methyl-4'-trifluoromethoxy-biphenyl-3-carboxylic acid [6-(cis-2,6-dimethyl-morpholin-4-yl)-pyridin-3-yl]-amide or 2-[(R)-4-(6-benzyl-4,5-dimethyl-pyridazin-3-yl)-2-methyl-3,4,5,6-tetrahydro-2H-[1,2']bipyrazinyl-5'-yl]-propan-2-ol.

8. The method according to any of claims 1-7, wherein the determining is the level of expression of mRNA.

9. A kit comprising a plurality of agents for determining the level of expression of the biomarkers listed in claims 1 or 2 in a sample and instructions for use.