injection of the imaging agent. On the other hand, ^{99m}Tc labeled Affibody molecules have predominant hepatobiliary clearance, which causes a high radioactivity accumulation in the intestine, which restricts its use for detecting HER2 tumors and metastates in the abdominal area.

[0009] Therefore, there is a need for chemistries and methods for synthesizing radiolabeled polypeptides in which the radioactive moiety, such as ^{18}F can be introduced at the final stage, which in turn will provide high radiochemical yields. In addition, there is a need for a new HER2 based imaging agent for PET or SPECT imaging with improved properties particularly related to renal clearance and toxicity effects.

SUMMARY

[0009a] In a first aspect, there is provided an imaging agent composition comprising:

an isolated polypeptide comprising SEQ. ID No 1 or SEQ. ID No 2, conjugated with a ^{99m}Tc via a diaminedioxime chelator; wherein the isolated polypeptide binds specifically to HER2, or a variant thereof.

[0009b] In a second aspect, there is provided a method for preparing a chelator conjugated polypeptide composition comprising:

(i) providing an isolated polypeptide comprising SEQ. ID No 1 or SEQ. ID No 2;

(ii) reacting a diaminedioxime chelator with the polypeptide to form the chelator conjugated polypeptide.

BRIEF DESCRIPTION

[0010] The compositions of the invention are a new class of imaging agents that are capable of binding specifically to HER2 or variants thereof.

[0011] In one or more embodiments, the imaging agent composition comprises an isolated polypeptide comprising SEQ. ID No. 1, SEQ. ID. No 2 or a conservative variant thereof, conjugated with a ^{99m}Tc via a diaminedioxime chelator. The diaminedioxime chelator may comprise Pn216, cPn216, Pn44, or derivatives thereof. The isolated polypeptide binds specifically to HER2 or variants thereof.

[0012] In one or more embodiments, the imaging agent composition comprises an isolated polypeptide comprising SEQ. ID No. 1, SEQ. ID. No 2 or a conservative variant thereof, conjugated with ^{67}Ga or ^{68}Ga via a NOTA chelator. The isolated polypeptide binds specifically to HER2 or variants thereof.

[0013] In one or more embodiments, the imaging agent composition comprises an isolated polypeptide comprising SEQ. ID No. 1, SEQ. ID. No 2 or a conservative variant thereof, conjugated with ^{18}F via a linker. The linker comprises a group derived from an aminoxy group, an azido group, or an alkyne group. The isolated polypeptide binds specifically to HER2 or variants thereof.

[0014] An example of the methods of the invention, for preparing an imaging agent composition, comprises (i) providing an isolated polypeptide comprising SEQ. ID No. 1, SEQ. ID No. 2 or a conservative variant thereof; and (ii) reacting a diaminedioxime chelator with the polypeptide to form a chelator conjugated

5. The composition of claim 4, wherein the composition is to be used for diagnosing the subject with a HER2-associated disease condition.

6. The composition of claim 5, wherein the HER2-associated disease condition is breast cancer.

7. The composition~~method~~ of claim 4, wherein the diagnostic device employs an imaging method selected from the group consisting of MRI, PET, SPECT, radioimaging, and combinations thereof.

8. A method for preparing a chelator conjugated polypeptide composition comprising:

(i) providing an isolated polypeptide comprising SEQ. ID No 1 or SEQ. ID No 2;

(ii) reacting a diaminedioxime chelator with the polypeptide to form the chelator conjugated polypeptide.