[^{89}Zr]-PANITUMUMAB; [^{89}Zr]-PAN

FREQUENTLY ASKED QUESTIONS

What is the status of [89Zr]-panitumumab at the Cancer Imaging Program?

We have an established IND (10/2012) for [89Zr]-panitumumab that we actively encourage investigators to cross-file on

- We freely provide manufacturing and quality control documentation to assist this effort http://imaging.cancer.gov/programsandresources/Cancer-Tracer-Synthesis-Resources,
- We encourage academic and pharmaceutical investigators to evaluate [89Zr]-panitumumab for therapeutic drug evaluation/development
- We anticipate that the data resulting from wider availability of this agent will support an eventual New Drug Application (NDA) by a commercial entity

What is the Regulatory Status of [89Zr]-panitumumab?

[89Zr]-panitumumab is an investigational PET agent. Individuals and organizations may apply for and hold an Investigational New Drug (IND) Exemption from the FDA under which they are permitted to make and use [89Zr]-panitumumab. IND information can be found here: **http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm**

How can I use [89Zr]-panitumumab in my clinical trial?

In order to use [89Zr]-panitumumab, you must hold an IND or have your basic science trial approved by your Institution's RDRC (Radioactive Drug Research Committee). In either case, you must have your trial approved by an Institutional Review Board (IRB).

Can I make my own [89Zr]-panitumumab?

If you have appropriate facilities (cyclotron, radiochemistry lab and personnel, capacity to manufacture PET agents for human use), you can make [89Zr]-panitumumab. Your chemistry procedures must be acceptable to FDA for your IND or to the RDRC, and to the IRB.

Can I buy [89Zr]-panitumumab from someone to use in my trial?

Some commercial firms may provide [89Zr]-panitumumab for research use. That material can be used in your clinical trial only if you are allowed to submit the full chemistry information to FDA in your IND or provided with a letter of authorization to a Drug Master File (DMF). At this time, to the best of our knowledge, no company has a DMF on file with the FDA for this agent, which would permit use of this material in your IND-approved trial if the company provides you with an appropriate authorization letter.

How can NCI help?

NCI can assist in two ways. NCI holds an IND for [89Zr]-panitumumab that is based on a specific synthesis from clinical panitumumab [**Bhattacharyya S**, Kurdziel K, Wei L, Riffle L, Kaur G, Hill GC, Jacobs PM, Tatum JL, Doroshow JH, Kalen JD., Zirconium-89 labeled panitumumab: a potential immuno-PET probe for HER1-expressing carcinomas. Nucl Med Biol. 2013. 40:451–457; http://dx.doi.org/10.1016/j.nucmedbio.2013.01.007]. Documents necessary to prepare and test [89Zr]-panitumumab for use in clinical trials are available on the Cancer Imaging Program (CIP) website.

http://imaging.cancer.gov/programsandresources/Cancer-Tracer-Synthesis-Resources

The documents include a full set of manufacturing and QC documents ("SOPs") which have been accepted by the FDA as part of the NCI IND. Investigators at each site can implement this synthesis and testing in their radiochemistry laboratory. There is a CMC template that may need to be modified to match the local procedures (e.g. specific brands of equipment). Investigators can then write and file their own IND with the FDA by modifying the CMC section to fit local conditions and adding the Investigator's proposed Clinical protocol.

Additionally, CIP will provide a Letter of Authorization (cross-file letter) to the FDA in conjunction with your IND that can simplify your IND application. This letter may substitute for the Pharmacology, Toxicology, Radiation Dosimetry and Previous Human Experience sections of the IND.

If you do purchase [89Zr]-panitumumab from a company that holds a DMF, their Letter of Authorization will substitute for the Chemistry, Manufacturing, and Control section of your IND.

For additional information

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