Genentech US Medical Affairs BioOncology Scientific Collaborations Precision Medicine

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Ms. Brockman discussed the participation of Genentech in precision medicine trials.

It takes the presence of cutting edge medicines + diagnostics and genomic sequencing + new technologies to bring new medicines to market for patients. In the 1990s, we had blockbuster drugs that were used to treat broad patient populations, such as those with colon cancer or breast cancer. The next development was targeted medications for specific groups based on the heterogeneous features of the cancer and patient characteristics. In the future, treatments will be more individualized with patient based molecular information, so that a drug is individualized just for you.

Genentech-Roche has supported or sponsored a number of precision medicine trials. These include MATCH, NCI Lung Map, ASCO TAPUR, Exceptional Responder (cases put forward when there is a durable response to therapy), and a specialized program at Genentech called MY Pathway. Genentech likes to partner in these studies and see them extended. Genentech supports MATCH 2.0, for example.

Genentech is taking the information about MATCH and putting it on internal slides so that it can be used to get more support from groups within the company for participation in further trials. One of the most impressive features that helps sell the idea is how rapidly the MATCH trial recruited. Although it may be slower to begin, it's worth it because recruitment is so robust.

The MATCH Trial has been a positive experience for Genentech. Genentech has had medications in four arms of the trial, some of which are continuing and others of which are completed: trastuzumab + pertuzumab target HER2 amplification in Arm J, vismodegib targets SMO/PTCH1 in Arm T, ado-trastuzumab emtansine targets HER2 amplification in Arm Q, and taselib targeted PIK3CA in Arm I. Genentech is currently in negotiations to open another arm for ipatesertib, which targets AKT mutations.

<u>Audience Questions and Answers</u>

- *How do you think we can make industry and NCI collaborations work even better for future trials?* Some companies may be under the misconception that, once they include their drugs in these trials, they no longer have any say in the study. They believe that NCI may not be open to dialog or collaboration. That is not the experience of Genentech at all, and it may be a matter of helping companies to understand that.

- *If Genentech has a drug that they want tested, how do they decide whether to test it themselves or put it into a program like MATCH?* Depending on the drug, there is more or less sensitivity on the part of the company to putting it in outside programs. In general, more mature molecules are more accessible for outside programs.
- *In MATCH, did companies keep providing drug to patients who were responding even if they decided that the drug was ultimately not going to be successful in the marketplace?* Genentech does have a policy under which we try to make the drug available for patients who are responding in cases like the one you cite. It's possible there might be a conflict if the drug is discontinued from manufacturing. Answer from Dr. Conley: Within MATCH, we asked for a commitment to a certain number of cycles. The drug at NCI has an expiration date and can't be given beyond that. If the company shuts down manufacturing, it is a problem, but we haven't had many of those issues.
- *What can advocates do to help other companies understand the positive nature of collaboration with NCI?* Genentech and some other companies have strong connections with the NCI. NCI could reach out to companies that have big portfolios and attempt to persuade them.
- *Can we contact NCI and encourage them to reach out to other companies and can we ask you (from Genentech) to talk about your positive experience?* Yes, that would be a good idea to put the various parties in the room to discuss.
- *I'm on the Roche-Genentech Ethics Advisory Board and there is tremendous support for providing medication to patients in clinical trials who are responding to the drug, in cases where the drug will not be going forward into other trials.*

How are drugs named? Initially a drug's name is based on its chemical structure. After that, its target and function drive its name, but the commercial team strives to develop a brand identity. This is proprietary, and is tested in market research.