Update on Phase 1 trial of Tegavivint (BC2059)

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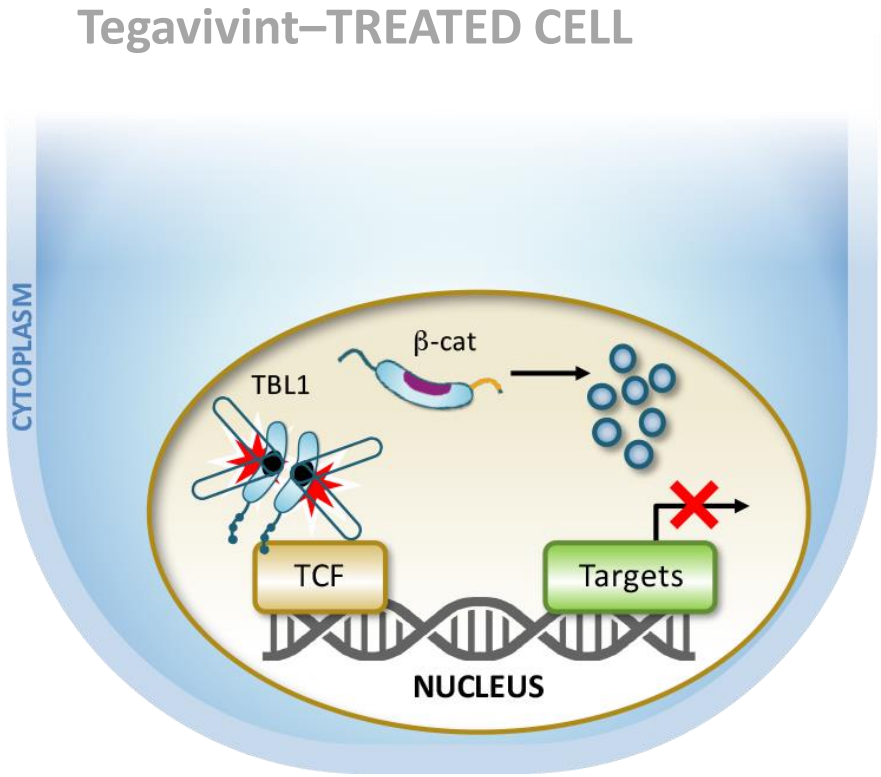
Tegavivint inhibits beta catenin

There have been many past attempts to develop a drug that inhibits beta catenin but the protein is difficult for drugs to bind.

Tegavivint does not bind directly to beta catenin. Instead, it binds to another protein, TBL1, that does bind to beta catenin.

Increased beta catenin signaling is a hallmark of desmoid tumor formation.



It makes sense to see if Tegavivint can inhibit the growth of desmoid cells.
So, Iterion has started a phase 1 trial.

What is a phase 1 trial?

- Phase 1 trials are often the first time the drug has been tested in people.
- The primary purpose is to define safety and determine the proper dose.
- Tegavivint has been extensively tested in a variety of animals, but is just now being tested in people.
- Because of that, patients on this trial will be monitored closely and frequently
  - Only a few patients at a time are treated initially
  - Doses start low and then are increased with each succeeding group of patients

- It's important to understand that, while there is a lot of biologic rationale for the drug, we don't know if it will work.
- We want to work closely with the DTRF in this process so that we can learn as much about Tegavivint in desmoid as possible.

FAQs about the trial

- Who is eligible?
  - Patients with desmoid tumors “in need of treatment”
    - Tumor is progressing OR
    - Causing quality of life issues

    Note: FAP patients will not be eligible initially.
- What will we measure?
  - Safety, safety, safety….then,
  - Size of the tumor
  - Quality of life as measured by a questionnaire
- How will the drug be given?
  - Tegavivint is a drug given intravenously for a 4 hour infusion once a week for three out of four weeks
- What about patients in the first groups that got a low dose of the drug?
  - If they are doing well, they can have their dose increased later

Current status of the trial - sites

- The trial is now open at:
  - U Washington/Fred Hutchinson (Dr. Lee Cranmer)
  - Princess Margaret/ U Toronto (Dr. Albiruni Razak)
  - Partners (MGH/DFCI) (Dr. Edwin Choy)
  - MD Anderson (Dr. Vinod Ravi)
  - Memorial Sloan Kettering (Dr. Mrinal Gounder)
- Later this year it will be open at:
  - UCLA Cancer Center (Dr. Noah Federman)
  - James Cancer Center/OSU (Dr. David Liebner)
- We will work with the DTRF to communicate with the desmoid tumor the exact dates and locations where the trial will be available.

Current status of the trial - clinical

- Nine (9) subjects have been enrolled to date.
- Six (6) have received at least one cycle (3 doses) of Tegavint
- No significant toxicity (side effects) has been seen.
- Current dose level is 3 mg/kg BW which is high enough that we can start to look for signs of efficacy.
- One way to do that is to look at changes in the tumor before and after dosing. So, the trial calls for pre-and post-first treatment biopsies.
- During this dose-finding portion of the trial, enrollment is strictly controlled to only a few patients at a time.

What comes next?

- We will continue to carefully monitor patients and look for signs that the dose of the drug can be safely increased – or not.
- Once we have determined that we are at the proper dose by
  - Changes in the tumor biology.
  - No further increases in drug levels.
  - Side effects that tell us we shouldn't go any higher.

……then we will open enrollment to a larger group of patients at more sites.

We'll keep you updated.

Thank you!