

# ★health care

## NuSirt hopes for diabetes breakthrough

Company believes work could cause major changes

Nashville company NuSirt is about to start clinical trials for its treatment, marking one of the most important events in the company's history.

In 2013 NuSirt researchers discovered a treatment that pairs metformin, a generic diabetes drug that tends to cause gastric discomfort in patients, with a common amino acid called leucine. In early studies, the company has seen that leucine helps the body process the drug more effectively, so that lower doses can be therapeutic.

NuSirt's board chairman, Joe Cook, talks with Tennessee

reporter Shelley DuBois about the importance of the upcoming clinical trial and how this type of treatment could change the pharmaceuticals industry.

**When do you expect this treatment to be available to patients?**

This will be the trial that measures the effect in humans. If this data is as we believe it to be, based on the trials that we did in animals, we will move to more advanced trials that will test the medicine over six months. We're probably talking about it hopefully being available some time toward the end of 2017.

**This question may be out there, but how do you measure reduced gastric discomfort in lab rats?**

You know, there's this whole family of patient-reported outcomes, where you're dependent

entirely on the patient's ability to accurately describe how they feel compared to how they felt before.

In this case, we ask a series of specific questions before patients go into the trial, during the trial and then after the trial. We hope that through these questions, we will be able to detect whether the adverse-effect profile changes.



Cook

Obviously, for the studies we have done with animal models, the animals cannot tell us whether their GI distress is better or not.

**This seems like a new kind of drug development model — adding a common substance that sort of piggybacks onto another pharmaceutical that's already out**

**there.**

What was so interesting to me, having started my career in developing medicines at Eli Lilly in 1965, is that I have not often seen a new concept like this developed. And what's really interesting is that metformin is such a well-recognized treatment all over the world. If our data are positive and it works like we think it will, it would potentially encourage people to take their medicine every day just like they're supposed to. We could actually make a difference in the treatment of diabetes.

**Say the model works and lower doses of metformin can be equally effective. Would that cause tension in the drug industry?**

Well, not yet. But I expect that some of my former colleagues might even say, "Wait a minute, what are you doing?"

I'll say, "Well, we're developing a better solution that happens to be lower priced. What are you doing?"

Actually, since metformin is generic, no one will really come to the defense of pricing. But for lots of new drugs that have recently launched or are currently in development, our treatment is going to really change the economics of some of these new drugs.

**I guess that's business.**

It's the good part of business. It's what the free market process should do — deliver better solutions that are more effective. Hopefully we get greater participation, and hopefully we get greater market share. That'd be sort of good all the way around.

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