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Amicus Therapeutics, Inc. Q2 2008 Earnings Call Transcript

Question-and-Answer Session

Operator

Thank you, sir. (Operator instructions) And we'll go first today to Geoffrey Meacham of J.P. Morgan.

Terry Coyne – J.P. Morgan

Hi, guys, can you hear me?

John Crowley

I sure can.

Terry Coyne – J.P. Morgan

This is Terry Coyne for Geoff today. Thanks for taking the question.

John Crowley

Sure, Terry.

Terry Coyne – J.P. Morgan

I was just hoping maybe you could expand a little more on why you will no longer conduct a long-term Phase 2 switching study, and maybe give us some explanation on the insights that Shire was able to provide?

John Crowley

Well, let me be specific, Terry. We had previously given guidance that we would do a longer term, meaning longer than the previous four-week study. And again, I'll just reiterate what Matt had previously said is that, as we looked at that data, as we're now into executing on the naïve patient study, as we've understood the experience of Shire in the Gaucher disease area, we think there may be a more efficient path to getting to Phase 3 and toward approval, which would obviate the need for doing that interim Phase 2 study and put us on a better path toward Phase 3. So that's what something we spent a lot of time thinking through and we think is smart drug development.

Terry Coyne – J.P. Morgan

Okay. So just to follow up on that, does that have any implications for potential switching study for the Fabry Phase 3 program?

John Crowley

I'm sorry, I –

Terry Coyne – J.P. Morgan

As you've changed your thoughts about switching studies in general?

John Crowley

No, no. I think we still believe that there is a lot of value to switching studies and see that obviously as the primary vision for how our drugs will be used commercially in the future. So, no, it doesn't mean to suggest that at all. It simply means that specific to the Plicera program and the data we feel we need to collect in Phase 2 to get to Phase 3 that this is a smart decision, that the dataset we're going to have with the studies we've described, we believe it will be adequate to get us into Phase 3. And we base that based on the combination of our data as well as speaking with our outside experts and our folks at Shire. Yes. Just to be clear, we view that as a very positive development as we continue to develop our plans to move into and through the pivotal studies for Gaucher.

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