

Exelixis Inc. (NMS:EXEL) Plunges as FDA Refuses to Sign Off on Drug Study

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Tallahassee, FL 11/1/11 ([StreetBeat](#)) --Exelixis Inc. ([NMS: EXEL](#)), a biotechnology company with no approved products, fell 31 percent in early trading after failing to agree with U.S. regulators on special rules for a study of its experimental prostate cancer drug.

Exelixis had been hoping to reach agreement with the U.S. Food and Drug Administration that a relatively small and quick phase III study of cabozantinib demonstrating pain reduction in very late-stage prostate cancer patients would be sufficient to get the drug approved. But FDA chose not to endorse this strategy and refused to grant Exelixis a so-called Special Protocol Assessment for the cabozantinib pain study, Exelixis disclosed Monday night. An SPA is a declaration from the FDA that a firm's clinical-trial design will be capable of supporting a drug-efficacy claim before the trial begins. "This was surprising and unexpected," said Exelixis CEO Michael Morrissey, referring to the FDA's decision, on a conference call.

The setback introduces new risk into the development of the promising prostate cancer drug, which caused investors to flee Exelixis. The company has decided to push ahead and conduct the cabozantinib study with a pain reduction endpoint without an FDA endorsement. It hopes that overwhelmingly positive data will convince FDA to approve cabozantinib early.

Exelixis suggested Monday night that cabozantinib could still be approved in 2014 even if two studies are required. Analysts like Canaccord Genuity's George Farmer are skeptical about that timeline, predicting cabozantinib's approval could be pushed back to 2015 or 2016.

The company's shares have declined 5.9 percent this year. Currently, the stock is trading down 38% at \$4.78/share.

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