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GlaxoSmithKline drug fails in late-stage study (Update)

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A potential GlaxoSmithKline heart disease treatment acquired in a key company takeover fell short in a big, late-stage study.

The British drugmaker said Tuesday that the treatment, darapladib, failed to produce a statistically significant reduction in major cardiovascular events like heart attacks, strokes or death when added to a patient's standard of care that could include a cholesterol treatment, aspirin and blood pressure medications.

Adult patients with chronic, coronary heart disease were given either darapladib or a fake drug in the trial. More than 15,000 patients enrolled in the international study.

GlaxoSmithKline PLC, or GSK, said it will wait for results from a separate late-stage study before deciding what to do next with the drug. It acquired the experimental treatment when it bought longtime drug development partner Human Genome Sciences for more than $3 billion in 2012.

The deal gave GSK full ownership of darapladib, an experimental diabetes drug and Human Genome's only marketed medicine, the lupus treatment Benlysta. Diabetes and heart disease are both core areas for the British drugmaker that have been hurt by a revenue drop due in part to generic competition.

WBB Securities President Steve Brozak said the drug developer and

others saw huge sales potential in darapladib.

"This clearly did not meet their expectations, and this clearly is not just a blow to Glaxo but a blow to the entire system that fishes for these kinds of blockbuster drugs," the analyst said. "This approach cannot predictably provide the results that management, shareholders and, most importantly, patients need."

Bernstein Research analyst Dr. Tim Anderson said in a note that the darapladib news did not come as a surprise, but it contributes to a bigger question about GSK's decision making when it comes to moving treatments into late-stage research. That is normally the most expensive phase of a drug's clinical development.

Even so, the analyst added that the company's long-term growth outlook "continues to screen as reasonably solid."

GSK also said in September that an experimental melanoma treatment did not meet its first goal in a mid-stage clinical trial, as patients who received the therapy did not have greater disease-free survival than patients who were given a placebo. The company also said a potential treatment for Duchenne muscular dystrophy it is developing with Dutch biotech Prosensa Holding N.V. failed in another late-stage study.

GSK said the results released Tuesday are preliminary, and it will release full results next year at a scientific meeting.

U.S.-traded shares of GlaxoSmithKline slipped 1.6 percent, or 86 cents, to $52.17 in morning trading. The stock is up 22 percent so far this year.