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Paradigm Halts Phase III PPS Trial For Knee Osteoarthritis

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has halted its phase III trial of injectable pentosan polysulfate sodium or Zilosul for knee osteoarthritis.

Paradigm said that the independent data safety monitoring board (DSMB) confirmed that the interim efficacy result “did not reach the pre-specified threshold required for the study to continue”.

In June, Paradigm said it had enrolled 538 of a hoped-for 466 patients in its phase III trial of injectable PPS for knee osteoarthritis pain (BD: Jun 15, 2026).

Today, Paradigm said the outcome followed the review of unblinded interim efficacy and safety data, while its staff remained “blinded to treatment allocation, the actual treatment effect size and the underlying treatment-group results”.

The company said that the planned interim analysis was conducted after about 50 percent of participants reached the day-112 primary efficacy endpoint.

Paradigm said that “the observed treatment effect fell below the minimum efficacy threshold for continuation under the study’s statistical design, indicating that the study is unlikely to meet its primary efficacy endpoint at the final analysis”.

The company said that “operational challenges during the trial resulted in a significant amount of missing data, which has impacted the interim efficacy results”.

Paradigm said it continued “to review the available data to obtain further information and better understand the nature and extent of that impact”.

The company said it would with the DSMB, its clinical partners and investigators to determine the appropriate remaining study activities and database processes; and following completion of the required database and unblinding processes, it would “undertake a detailed review of the available phase III data, including pain, function, safety and other pre-specified endpoints … [to assess] the outcome and the next steps”.

Paradigm executive chairman Paul Rennie said “the Board and the entire Paradigm team are deeply disappointed by this outcome”.

“We recognize the disappointment it brings to our shareholders and everyone who has supported the program,” Mr Rennie said.

“An initial review, by Paradigm's unblinded clinical staff, identified missing data,” Mr Rennie said. “Under the statistical analysis plan, missing data is imputed and this imputation impacted the efficacy outcome.”

“This is very disappointing given our broad and positive experience with iPPS in treating osteoarthritis,” Mr Rennie said.

“We remain optimistic in the therapeutic potential of PPS in treating osteoarthritis,” Mr Rennie said.

“Paradigm retains a substantial intellectual property portfolio,” Mr Rennie said.

“We are assessing the best path forward,” Mr Rennie said.

Paradigm said it would “reassess the timing, scope and objectives of future regulatory engagement following the data review”.

The company said that following the interim analysis outcome, it would assess the implications for its financial position and future operations, including potential trial wind-down costs, remaining contractual commitments, future funding requirements and the company’s rights and obligations under its existing funding arrangements.

Paradigm said it was working closely with secured convertible note facility provider Obsidian Global to assess the implications of the trial outcome under the facility.

Paradigm said it had requested a voluntary suspension while it assesses the financial implications of the trial outcome and progresses discussions with Obsidian.

The company said the suspension was expected to continue to September 28, 2026.

Paradigm last traded at 24.5 cents.