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CytRx gets FDA nod Aldoxorubicin cancer trial

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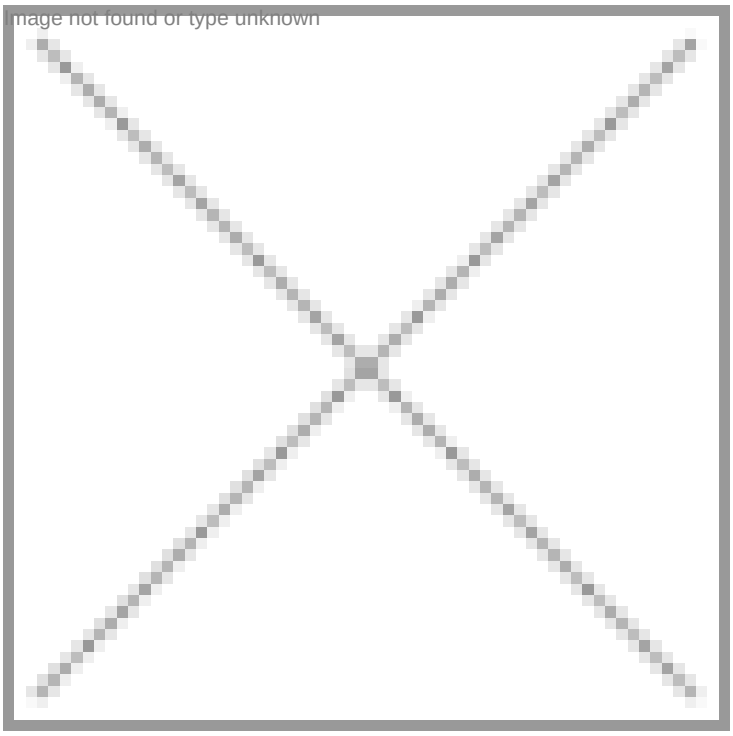

Singapore: US-based CytRx, a biopharmaceutical R&D company specializing in oncology, reached an agreement with the US FDA under a special protocol assessment (SPA) for a global pivotal phase III trial with aldoxorubicin as a treatment for patients with soft tissue sarcomas, who have relapsed or were refractory following prior treatment with chemotherapy.

The SPA is a written agreement between the company, as the trial's sponsor, and the FDA regarding the design, endpoints and planned statistical analysis approach of the phase III clinical trial to be used in support of a potential New Drug Application (NDA) for aldoxorubicin. The company is actively making preparations for the pivotal phase III trial.

"By reaching an agreement on an SPA, the FDA deems that results from this single phase III clinical trial will be acceptable to support the regulatory approval of aldoxorubicin as a second-line treatment for patients with soft tissue sarcoma, with final marketing approval dependent on the results of the trial and other accomplishments," said Mr Steven A Kriegsman, CytRx president and CEO.

He added, "The ability to conduct the clinical trial under an SPA could save significant time compared with a standard regulatory pathway. Our optimism about aldoxorubicin's prospects in this difficult-to-treat indication is predicated on positive results from a phase Ib/II trial in which this novel agent was associated with objective responses and prolonged progression-free survival in several patients with advanced soft tissue sarcoma who had relapsed or not responded to prior treatments, as well as on additional clinical and preclinical data."

The international, open-label pivotal phase III clinical trial will enroll approximately 400 patients with metastatic, locally

advanced or unresectable soft tissue sarcomas who have either not responded to or have progressed following treatment with one or more systemic regimens of non-adjuvant chemotherapies.

Trial patients will be randomized 1:1 to be treated with aldoxorubicin or the investigator's choice of an approved chemotherapeutic regimen to include dacarbazine, pazopanib (Votrient), gemcitabine plus docetaxel, doxorubicin or ifosfamide, with up to three comparator regimens to be selected by the investigator at each clinical site. The clinical trial will be conducted at approximately 80 clinical sites in the US, Europe, China, Canada, Latin America and Australia. The primary endpoint of the study is progression-free survival, and secondary endpoints include overall survival and safety.