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Kyowa Kirin addresses sepsis-associated acute kidney injury in Japanese population

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AM-Pharma and Kyowa Kirin sign exclusive license agreement for commercialization of Ilofotase Alfa



The Netherlands based AM-Pharma B.V. and Japanese firm Kyowa Kirin have entered into an exclusive license agreement under which Kyowa Kirin gains the rights to develop and commercialize ilofotase alfa, AM-Pharma's proprietary recombinant human alkaline phosphatase.

Ilofotase alfa is currently being evaluated in the global pivotal REVIVAL Phase III clinical study as the potential first disease-altering treatment for sepsis-associated acute kidney injury (SA-AKI). In July of this year, AM-Pharma announced the enrollment of the first patient in Japan as part of the ongoing REVIVAL trial.

Under the terms of the agreement, AM-Pharma will receive EUR 20 million upfront payment, and EUR 30 million related to milestones prior to regulatory submission, and up to EUR 195 million upon submission, NHI price listing and sales milestone payments bringing the overall deal value to EUR 245 million.

Kyowa Kirin will gain the exclusive right to develop and commercialize ilofotase alfa in Japan. AM-Pharma is responsible for the completion of the REVIVAL pivotal Phase III study, as well as a Phase I pharmacokinetics, safety and tolerability study in Japan and drug supply, whereas Kyowa Kirin will be responsible for the regulatory approval process and commercialization of ilofotase alfa in Japan.