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Ardelyx and Kyowa Kirin amend license agreement for Tenapanor

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Kyowa Kirin is finalizing its Phase 3 clinical program for tenapanor



US' Ardelyx, has reached an agreement with its Japanese collaboration partner, Kyowa Kirin Co. Ltd., to amend the license agreement, originally executed in 2017, that grants to Kyowa Kirin exclusive rights to develop and commercialize Ardelyx's tenapanor for the treatment of cardiorenal diseases, including hyperphosphatemia, in Japan.

Under the agreement, in consideration for a reduction in the royalty rate due Ardelyx upon net sales in Japan, Kyowa Kirin has agreed to pay Ardelyx consideration of up to additional $40 million payable in two tranches, with payment due following Kyowa Kirin's filing with the Japanese Ministry Health, Labour and Welfare (MHLW) of its application for marketing approval for tenapanor and the second payment due following Kyowa Kirin's approval to market tenapanor for hyperphosphatemia in Japan.

Kyowa Kirin is finalizing its Phase 3 clinical program for tenapanor for hyperphosphatemia and has disclosed its current expectation to file for approval with Kyowa Kirin in the second half of 2022 and its current expectation that it will receive a decision from Kyowa Kirin regarding its application in the second half of 2023. The royalty rate at which Kyowa Kirin will make payments on net sales to Ardelyx under the License Agreement will be reduced from the high teens to low double digits for a two-year period, and then to mid-single digits.