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FDA grants 7-year orphan drug exclusivity to Eagle

July 9, 2018 | News

As a result, and consistent with the order issued by the U.S. District Court for the District of Columbia (the Court) on June 8, 2018, the FDA will not approve any drug applications referencing BENDEKA until the ODE expires in December 2022.



Singapore – Eagle Pharmaceuticals announced that the U.S. Food and Drug Administration (FDA) has granted seven years of orphan drug exclusivity (ODE) in the U.S., for BENDEKA (bendamustine hydrochloride injection, or bendamustine HCI), a liquid, low-volume (50 mL) and short-time 10-minute infusion formulation of bendamustine hydrochloride.

As a result, and consistent with the order issued by the U.S. District Court for the District of Columbia (the Court) on June 8, 2018, the FDA will not approve any drug applications referencing BENDEKA until the ODE expires in December 2022. Additionally, on July 7, 2018, the FDA filed a motion with the Court asking it to clarify that the order was not intended to affect applications referencing TREANDA. Eagle continues to believe that an appropriate application of ODE would first allow generic TREANDA entrants in December 2022, rather than November 2019, and expects to vigorously defend the scope of its exclusivity grant.