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IN THIS ISSUE

COVID-19 Update: Remdesivir (*Veklury*) FDA-Approved for Children <12 Years Old

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COVID-19 UPDATE

Remdesivir (Veklury) FDA-Approved for Children <12 Years Old

The IV antiviral drug remdesivir (Veklury) has now been FDA-approved for treatment of COVID-19 in patients ≥ 28 days old who weigh ≥ 3 kg and are either hospitalized or at high risk for progression to severe disease.¹ Remdesivir was already FDA-approved for these indications in patients ≥ 12 years old who weigh ≥ 40 kg; it was available under an Emergency Use Authorization (EUA) for younger or lighter patients. Remdesivir is the first drug to be FDA-approved for treatment of COVID-19 in children <12 years old.¹

Data on the efficacy of remdesivir in children aged <12 years or weighing <40 kg are limited. Approval of the drug for use in such patients was based on clinical and pharmacokinetic data from studies in adults and on the results of an unpublished single-arm study (summarized in the package insert) in 53 pediatric patients (41 aged <12 years) who were hospitalized with COVID-19. Patients received IV

remdesivir once daily while hospitalized for up to 10 days. The safety and pharmacokinetics of remdesivir in this population were similar to those in adults.

Treatment with remdesivir should be started as soon as possible after symptom onset. The drug should be given by IV infusion once daily over 30-120 minutes. The recommended pediatric dose is 5 mg/kg (max 200 mg) on day 1 and 2.5 mg/kg (max 100 mg) on subsequent days. Treatment should be given for 3 days in high-risk outpatients and for 10 days in hospitalized patients requiring invasive mechanical ventilation and/or extracorporeal membrane oxygenation (ECMO). Hospitalized patients not requiring invasive mechanical ventilation or ECMO should be treated for 5 days, but if clinical improvement does not occur, remdesivir can be continued for up to 5 additional days. ■

1. FDA News Release. Coronavirus (COVID-19) update: FDA approves first COVID-19 treatment for young children. April 25, 2022. Available at: <https://bit.ly/3wjqtz1>. Accessed May 23, 2022.

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