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Advisory Commission on Childhood Vaccines (ACCV)

Food and Drug Administration Update

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1

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New Vaccine Approval – Dengue Tetravalent Vaccine, Live (Dengvaxia)

- Dengue disease is a major global public health concern and is endemic in the U.S. territories of American Samoa, Guam, Puerto Rico and the U.S. Virgin Islands.
- On May 1, 2019, the FDA approved **Dengvaxia** for the prevention of dengue disease caused by all dengue virus serotypes (1, 2, 3 and 4) in people ages 9 through 16 who have laboratory-confirmed previous dengue infection and who live in endemic areas.
  - Dengvaxia is not approved for use in individuals not previously infected by any dengue virus serotype or for whom this information is unknown.
  - Health care professionals should evaluate individuals for prior dengue infection to avoid vaccinating individuals who have not been previously infected by dengue virus.
- The safety and effectiveness of the vaccine was determined in three randomized, placebo-controlled studies involving approximately 35,000 individuals in dengue-endemic areas, including Puerto Rico, Latin America and the Asia Pacific region.

2

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