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FDA approvals in 2020 represent many firsts for children

by from the Food and Drug Administration's Office of Pediatric Therapeutics and Center for Drug Evaluation and Research, Division of Pediatric and Maternal Health

Recent Food and Drug Administration (FDA) approvals for drugs, biological products and devices represent innovative pediatric development in a variety of therapeutic areas and include several firsts for pediatric conditions.

In October, the FDA approved Inmazeb (atoltivimab, maftivimab and odesivimab-ebgn), the first Ebola virus treatment for adults and pediatric patients, including neonates. Inmazeb is a combination of three monoclonal antibodies that bind Ebola virus glycoprotein and prevent virus entry into host cells. Approval was based on clinical studies conducted during the 2018-'19 Ebola virus outbreak that demonstrated reduced mortality with Inmazeb.

In September, the FDA approved two advanced therapeutics for pediatric rheumatologic conditions:

- Xeljanz (tofacitinib) for patients 2 years and older with active polyarticular juvenile idiopathic arthritis (pJIA), marking the first Janus kinase inhibitor approved for use in children. Unlike other advanced therapies for pJIA that require injections or infusions, Xeljanz provides an oral treatment option.
- Simponi Aria (golimumab) for patients 2 years and older with active psoriatic arthritis and pJIA. Simponi Aria is the first tumor necrosis factor inhibitor approved for pediatric psoriatic arthritis.

In August, the FDA approved:

- MiniMed 770G System, the first device approved to automatically adjust background insulin delivery based on continuous glucose monitoring for patients ages 2 to 6 years with type 1 diabetes. The device can connect with a smartphone to allow users and caregivers to view glucose level and insulin delivery trends.
- Evrysdi (risdiplam), the first orally administered drug to treat patients 2 months and older with spinal muscular atrophy. Efficacy was established based on clinical studies showing improved gross motor function and survival without permanent ventilation in infants, and improved motor function in older children and adults.

In June, the FDA granted marketing authorization for EndeavorRx to improve attention in patients ages 8 to 12 years with attention-deficit/hyperactivity disorder (ADHD). It is the first game-based digital therapeutic device to receive marketing authorization for any condition. The device uses sensory stimuli and corresponding motor challenges to target brain pathways involved in attention and is intended to be part of a comprehensive ADHD therapeutic program.

In May, the FDA approved VESIcare LS (solifenacin succinate) for patients 2 years of age and older with bladder dysfunction due to neurogenic detrusor overactivity, becoming the first approved treatment for this

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condition.

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