FOOD AND DRUG ADMINISTRATION (FDA)
Office of the Commissioner (OC)

Meeting of the Pediatric Advisory Committee (PAC)
September 15, 2020

FINAL QUESTIONS

I. Center for Drug Evaluation and Research (CDER):

1. **VYVANSE VOTE:** FDA identified acute dystonia as a potential signal in the pediatric focused safety review. A subsequent signal review for acute dystonia and ADHD medications did not identify sufficient evidence to support a signal for acute dystonia and ADHD medications at this time. FDA recommends to continue ongoing, postmarket safety monitoring. Does the Pediatric Advisory Committee concur?

2. **MYDAYIS VOTE:** FDA will incorporate DDI of acute hyperkinetic movement disorder into all risperidone and methylphenidate product labelings in Drug Interaction section. FDA recommends continuing routine, ongoing postmarket safety monitoring of Mydayis. Does the Pediatric Advisory Committee concur?

3. **ADZENYS ER VOTE:** FDA will incorporate DDI of acute hyperkinetic movement disorder into all risperidone and methylphenidate product labelings in Drug Interaction section. FDA recommends continuing routine, ongoing postmarket safety monitoring of Adzenys ER. Does the Pediatric Advisory Committee concur?

4. **ORENCIA VOTE:** Angioedema was identified as a potential signal, assessed in a concurrent signal review, and added to labeling in June 2020. Low use of abatacept in pediatric population. Pediatric reported adverse events are consistent with known adverse events described in labeling. FDA recommends to continue ongoing, postmarketing safety monitoring. Does the Pediatric Advisory Committee concur?

II. Center for Blood Evaluation and Research:

1. **GAMUNEX-C VOTE:** FDA recommendations for Gamunex-C include routine safety monitoring, close monitoring of all reports of hypersensitivity, including lot-specific analyses, and continue discussion with manufacturer to further investigate root cause. Does the Committee agree with FDA's conclusions and recommendations?

III. Center for Devices and Radiological Health:

1. **FLUORISH Pediatric Esophageal Atresia Device** (humanitarian device exemption)
   DISCUSSION: The FDA will report on the following to the PAC in 2021:
   - Annual distribution number
   - PAS follow-up results
     - Revised PAS study (FDA working in collaboration with Cook)
   - Literature review
   - MDR review

   Does the Committee agree with the FDA's plan for continued surveillance of the Flourish device?