Media Release: Updated Information About Safety Events after Gonadotropin Releasing Hormone Agonist Therapy.

3/21/17

Dear Colleagues,

On 2/2/17, Kaiser Health News published an article raising concerns about potential long-term side effects of leuprolide acetate for depot suspension in women previously treated with this medication. In the article, it was reported that the FDA issued the following statement: "We are currently conducting a specific review of nervous system and psychiatric events in association with the use of GnRH agonists, [a class of drugs] including Lupron, in pediatric patients."

On 2/9/17, we issued the following statement: "At this time, we are not aware of any new documented safety concerns with this class of drugs that should change prescribing practices or warrant discontinuation of these medications."

Since that time, members of our committee, with the assistance of other PES members, have investigated these safety issues further. We have conducted a literature search and contacted the manufacturers of GnRH agonists in the U.S. and pediatric endocrinology colleagues in the US, UK, EU and South America to inquire about any new safety issues. These queries have identified no safety concerns that are not currently reflected in the product labels.

We have also spoken with our colleagues at the Food and Drug Administration who acknowledge that a Tracked Safety Issue (TSI, **https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm471071.htm**) has been initiated for review of potential safety concerns in this class of medications. The FDA collects information about adverse events via the FDA Adverse Event Reporting System (FAERS, **https://www.fda.gov/Safety/MedWatch/HowToReport/default.htm**). TSIs are generated when a safety review is undertaken for potential safety concerns that are not considered urgent. The TSI review process is expected to take 6-12 months.

After further review of available information, we do not feel that there is any new safety concern with GnRH agonists that should change our prescribing practices at this time.

As always, for any of the medications prescribed by pediatric endocrinologists, we encourage our colleagues to report to the FDA any unexpected adverse events that may be related to use of these medications. In aggregate, these reports serve as a key source of information for FDA inquiries and are critical to identify post-marketing safety issues. Reports can be completed online at the following link: https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home.

We will update you as further information becomes available.

Sincerely,

Bradley S. Miller, MD, PhD and Takara Stanley, MD

On Behalf of the Drug & Therapeutics Committee

Pediatric Endocrine Society