

As the healthcare community continues to be on the front lines of the evolving novel coronavirus (COVID-19), I want to offer our support and thanks for all you are doing in continuing to care for patients who are particularly susceptible to this infection during this time.

Also, I would like to share some important news. I'm excited to announce that the US Food and Drug Administration (FDA) has approved KOSELUGO™ (selumetinib) capsules for the treatment of children two years of age and older with neurofibromatosis type 1 (NF1) who have plexiform neurofibromas (PN) that cannot be completely removed by surgery. It is not known if KOSELUGO is safe and effective in children under two years of age.¹ **(See Important Safety Information below.)**

The approval by the FDA was based on positive results from the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP)-sponsored Phase II SPRINT Stratum 1 trial coordinated by the NCI's Center for Cancer Research, Pediatric Oncology Branch. Results showed an overall response rate (ORR) of 66% (n=33/50 patients; confirmed partial response) in pediatric patients with NF1 who have symptomatic, inoperable PN when treated with KOSELUGO as a twice-daily oral monotherapy.¹ ORR is defined as the percentage of patients with a confirmed complete response or confirmed partial response of at least 20% reduction in PN volume.¹ The most common adverse reactions (reported in ≥40% of patients) are vomiting, rash (all), abdominal pain, diarrhea, nausea, dry skin, fatigue, musculoskeletal pain, pyrexia, acneiform rash, stomatitis, headache, paronychia, and pruritus.¹

Having this new treatment option for pediatric patients with NF1 PNs is pivotal for addressing an unmet medical need for this patient population.

For more information regarding the approval, please see AstraZeneca's release announcing the news [here](#).

For more information about KOSELUGO including Important Safety Information, please see below.

IMPORTANT SAFETY INFORMATION

Before taking KOSELUGO, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems
- have eye problems
- are pregnant or plan to become pregnant. KOSELUGO can harm your unborn baby.
 - Females who could become pregnant and males with female partners who could become pregnant should use effective birth control (contraception) during treatment with KOSELUGO and for 1 week after your last dose
 - Tell your healthcare provider right away if you become pregnant during treatment with KOSELUGO
- are breastfeeding or plan to breastfeed. It is not known if KOSELUGO passes into your breast milk.

- Do not breastfeed during treatment with KOSELUGO and for 1 week after your last dose
- Talk to your healthcare provider about the best way to feed your baby during this time

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, or herbal supplements. Especially tell your healthcare provider if you are taking aspirin, blood thinners, or other medicines to treat blood clots. KOSELUGO contains vitamin E which may increase your risk of bleeding

KOSELUGO may cause serious side effects, including:

- **Heart Problems.** KOSELUGO can lower the amount of blood pumped by your heart which is common and can also be severe. Your healthcare provider will do tests before and during treatment with KOSELUGO to check how well your heart is working. Tell your healthcare provider right away if you get any of the following signs or symptoms:
 - persistent coughing or wheezing
 - shortness of breath
 - swelling of your ankles and feet
 - tiredness
 - increased heart rate
- **Eye Problems.** KOSELUGO can cause eye problems that can lead to blindness. Your healthcare provider will check your vision before and during treatment with KOSELUGO. Tell your healthcare provider right away if you get any of the following signs or symptoms:
 - blurred vision
 - loss of vision
 - dark spots in your vision (floaters)
 - other changes to your vision
- **Severe diarrhea.** Diarrhea is common with KOSELUGO and can also be severe. Tell your healthcare provider right away the first time that you get diarrhea during treatment with KOSELUGO. Your healthcare provider may give you medicine to help control your diarrhea and may tell you to drink more fluids
- **Skin Rash.** Skin rashes are common with KOSELUGO and can also be severe. Tell your healthcare provider if you get any of the following signs or symptoms:
 - rash that covers a large area of your body
 - blisters
 - peeling skin
- **Muscle problems (rhabdomyolysis).** Muscle problems are common with KOSELUGO and can also be severe. Treatment with KOSELUGO may increase the level of a muscle enzyme in your blood which may be a sign of muscle damage. Your healthcare provider should do a blood test to check your muscle enzyme levels before you start taking KOSELUGO and during treatment. Tell your healthcare provider right away if you get any of the following signs or symptoms:

- muscle aches or pain
- muscle spasms and weakness
- dark, reddish urine

Your healthcare provider may change your dose, temporarily stop, or permanently ask you to stop taking KOSELUGO if you have any of these side effects.

The most common side effects of KOSELUGO are:

- vomiting
- stomach pain
- nausea
- dry skin
- feeling of tiredness, weakness or lacking energy
- muscle and bone pain
- fever
- inflammation of the mouth
- headache
- redness around the fingernails
- itching

These are not all the possible side effects of KOSELUGO.

What is KOSELUGO?

KOSELUGO is a prescription medicine that is used to treat children 2 years of age and older with neurofibromatosis type 1 (NF1) who have plexiform neurofibromas that cannot be completely removed by surgery.

It is not known if KOSELUGO is safe and effective in children under 2 years of age.

Please click [here](#) for the full Prescribing Information, including Patient Information (Medication Guide).

Best Regards,

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“Your smile is your logo, your personality is your business card, and the way you make others feel is your trademark”

REFERENCE

1. KOSELUGO™ (selumetinib) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2020.