LONG-TERM RESULTS FROM AN EXPANDED DATA SET, JULY 2020 CUTOFF[1]

VITRAKVI® FOR ADULT AND PEDIATRIC PATIENTS WITH SOLID TUMORS WHERE AN *NTRK* GENE FUSION HAS BEEN IDENTIFIED[1]

A FIRST-IN-CLASS SELECTIVE TRK INHIBITOR FOR TRK FUSION CANCER ACROSS SOLID TUMORS[1-3]

Positive results:

- 72% ORR (95% CI: 65%, 79%; n=139/192); 23% CR, 7% pCR, and 43% PR[1]
- Median DOR: 34.5 months[1]

Long, durable responses: Median DOR of 34.5 months[1]

Study design: Pooled efficacy analysis based on 3 multicemter, open-label, single-arm clinical studies in adult and pediatric patients with TRK fusion cancer who had measurable non-CNS disease.[1]

CNS, central nervous system; CR, complete response; DOR, duration of response; *NTRK*, neurotrophic tyrosine kinase; ORR, overall response rate; PR, partial response; pCR, pathological complete response; TRK, tropomyosin receptor kinase.

VITRAKVI® (larotrectinib) 25-mg/100-mg CAPSULES 20-mg/mL ORAL SOLUTION

TEST. TREAT. TRANSFORM.

REFERENCES: **1.** VITRAKVI [Summary of product characteristics]. Leverkusen, Germany: Bayer AG; 2021. **2.** Amatu A, Sartore-Bianchi A, Siena S. *NTRK* gene fusions as novel targets of cancer therapy across multiple tumour types. *ESMO* Open. 2016;1(2):e000023. **3.** Laetsch TW, DuBois SG, Mascarenhas L, et al. Larotrectinib for paediatric solid tumours harbouring NTRK gene fusions: phase 1 results from a multicentre, open-label, phase 1/2 study. Lancet Oncol. 2018;19(5):705-714.

ABBREVIATED PRESCRIBING INFORMATION

VITRAKVI® (larotrectinib) 25 mg, 100 mg capsules and 20 mg/ml oral solution. Indication Vitrakvi is indicated for the treatment of adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have no satisfactory alternative treatments or that have progressed following treatment. **Dosage and administration** Confirm the presence of an NTRK gene fusion in a tumor specimen prior to initiation of treatment with Vitrakvi. Vitrakvi is available as a capsule or oral solution formulation with equivalent oral bioavailability, and may be used interchangeably. The recommended dose of Vitrakvi in adults is 100 mg taken orally, twice daily until the patient is no longer clinically benefiting from therapy or until unacceptable toxicity occurs. In pediatric patients (1 month to 18 years) recommended dose is 100 mg/m^2 taken orally, twice daily with a maximum of 100 mg per dose until the patient is no longer clinically benefiting from therapy or until unacceptable toxicity occurs. **Contraindications** There is no contraindication to the use of Vitrakvi. **Special warnings and precautions for use** *Neurologic reactions:* neurologic reactions including dizziness, gait disturbance and paresthesia were reported in patients receiving larotrectinib. For the majority of neurologic reactions, onset occurred within the first three months of treatment. Caution patients about driving and using machines, until they are reasonably certain Vitrakvi therapy does not affect them adversely. Withholding, reducing or discontinuing Vitrakvi dosing should be considered, depending on the severity and persistence of these symptoms. *Transaminase elevations:* ALT and AST increase were reported in patients receiving larotrectinib. The majority of ALT and AST increases occurred in the first 3 months of treatment. Monitor liver function before the first dose and monthly for the first 3 months of treatment, then periodically during treatment, with more frequent testing in patients who develop transaminase elevations. Withholding, reducing or discontinuing Vitrakvi dosing should be considered, depending on the severity and persistence of the transaminase elevation. **Interaction with other medicinal products** Avoid co-administration of strong CYP3A4 inhibitors with Vitrakvi (e.g. clarithromycin, grapefruit, grapefruit juice, itraconazole, ketoconazole, voriconazole). If co-administration of a strong CYP3A4 inhibitor cannot be avoided, reduce Vitrakvi dose by 50%. Avoid co-administration of strong CYP3A4 inducers with Vitrakvi (e.g. rifampicin, phenytoin, carbamazepine, phenobarbital and St John's Wort). If co-administration of a strong CYP3A4 inducer cannot be avoided, double the Vitrakvi dose. *See PI for full details.* **Undesirable effects** The most common adverse drug reactions (≥20%) of Vitrakvi in order of decreasing frequency were fatigue (32%), increased ALT (31%), dizziness (30%), increased AST (29%), constipation (29%), nausea (26%), anaemia (24%) and vomiting (20%). The majority of adverse reactions were Grade 1 or 2. For a full listing of undesirable effects, please refer to the full product insert. **For full prescribing information, please contact:** Bayer (South East Asia) Pte. Ltd. 2, Tanjong Katong Road #07-01, Paya Lebar Quarter 3, Singapore 437161. **Date of revision text:** 5 November 2020.

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For Healthcare Professionals Only

Full prescribing information is available on request