Canada's Drug Agency
L'Agence des médicaments du Canada
Drugs. Health Technologies and Systems. Médicaments, technologies de la santé et systèmes.

Proposed Project Scope

Regorafenib for Metastatic Osteosarcoma

Date: October 2024
For Stakeholder Input

Background and Rationale

CDA-AMC received a request from public drug programs for a Non-Sponsored Reimbursement Review of regorafenib for osteosarcoma patients

Table I: Policy Questions

Item	Policy Question
1	Should regorafenib be publicly reimbursed for patients with metastatic osteosarcoma who have received at least 1 prior line of therapy?

Table II: Products Available in Canada

Product	Manufacturer
Regorafenib (Stivarga)	Bayer Canada Inc.

Project Description

Table III: Project Scope

Criteria	Description
Population	Patients with advanced or metastatic bone or extraskeletal osteosarcoma
Intervention(s)	Regorafenib 160mg orally in the morning with a low-fat meal on days 1 to 21 of each 28-day cycle
Comparators	Placebo Other chemotherapeutic agents: high dose methotrexate, doxorubicin, cisplatin (MAP regimen); ifosfamide +/- etoposide; sorafenib; cabozantinib; cyclophosphamide and topotecan; gemcitabine +/- docetaxel; sorafenib and everolimus
Outcomes	**Efficacy** • Overall Survival • Progression Free Survival **Safety** • Adverse events • Serious adverse events • Withdrawal due to adverse events • Mortality • Notable harms

Table IV: Research Questions

Item	Policy Question
1	What is the effectiveness of regorafenib for metastatic osteosarcoma?
2	What are the harms associated with regorafenib for metastatic osteosarcoma?
3	What is the expected cost of regorafenib for metastatic osteosarcoma vs. other reimbursed regimes?

Key Project and Protocol Components

This project will follow the Procedures for Non-Sponsored Reimbursement Reviews.

Status of the Document

This proposed project scope is being posted for information.