REGORAFENIB FOR THE TREATMENT OF SARCOMA

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SARCOMA connect
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REGORAFENIB AS A POTENTIAL THERAPY IN SARCOMA: REVIEW OF CLINICAL TRIALS

BACKGROUND

Sarcomas are a rare group of tumours with many subtypes, conventionally classified into soft-tissue sarcomas (STSs) and bone sarcomas.

Unmet needs include:

- **Few effective standardised chemotherapy regimens for relapsed osteosarcoma or Ewing sarcoma**
- **Lack of effective regimens for chondrosarcoma and chordoma**
- **Overcoming inherent or acquired resistance to chemotherapy**

Tyrosine kinase inhibitors (TKIs) such as regorafenib, may be an option for some sarcoma subtypes. This paper reviews regorafenib data from five phase 2 clinical trials and one phase 1b trial in over 10 sarcoma subtypes (both soft-tissue and bone) in adult and paediatric patients.

RESULTS

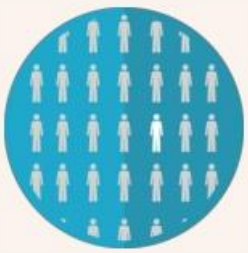
Clinical trials reviewed

PHASE 2

Controlled studies
REGOSARC (NCT01900743)
SARC024 (NCT02048371)
REGOBONE (NCT02389244)

Single-arm studies
RESOUND (NCT02307500)
Angiosarcoma (NCT02048722)

PHASE 1/1b
Paediatric dose-finding study (NCT02085148)



Clinical activity of regorafenib in sarcoma subtypes:

Observed or clinically meaningful activity

Osteosarcoma
Significantly longer median PFS

Ewing sarcoma
Positive PFS outcomes

STSs
Significantly longer median PFS (including patients with prior pazopanib treatment)

Angiosarcoma
Clinical activity observed

Too early to determine the degree of activity
Rhabdomyosarcoma

No clinical activity
Liposarcoma, chondrosarcoma

The safety profile of regorafenib was consistent across the clinical studies and with the reported safety profile in patients with other tumour types (colorectal cancer, gastrointestinal stromal tumour, and hepatocellular carcinoma).

STSs, soft-tissue sarcomas (including leiomyosarcoma, synovial sarcoma, and other STSs)

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