

ELESCLOMOL FACT SHEET

What is elesclomol?

- Elesclomol is an investigational first-in-class compound currently in Phase III development for patients with metastatic melanoma.¹
- Elesclomol is not yet approved by any regulatory body.¹

How does elesclomol work?

- Administered by intravenous infusion, elesclomol affects cancer cells by increasing the levels of reactive oxygen species (ROS) within the cells to push them over a breaking point, causing programmed cell death (apoptosis).²
- Cancer cells in general and specific types of cancer, such as melanoma, have higher levels of ROS and when exposed to an oxidative stress inducer like elesclomol are stressed beyond recovery to apoptosis or cell death.²
- This unique mechanism of action has shown little detectable effect on normal, or non-cancerous cells, as they have lower levels of ROS than cancer cells.²

What data support the use of elesclomol for metastatic melanoma?

- A Phase IIb trial in 81 patients with metastatic melanoma across 21 centers showed that elesclomol, in combination with paclitaxel, doubled the median time patients survived without their disease progressing (from 1.8 months to 3.7 months), compared to paclitaxel alone (p=0.035).¹
- Regardless of prior chemotherapy, the most serious adverse events (Grade 3 or higher) in a clinical setting for patients receiving elesclomol and paclitaxel included fatigue, alopecia, constipation, nausea, hypoaesthesia, arthralgia, insomnia, diarrhoea, and anaemia.³
- The most serious adverse events (Grade 3 or higher) for the combination arm were similar to those seen in patients receiving paclitaxel alone, and included neutropenia, back pain, fatigue and neuropathy.³
- Elesclomol is currently being studied in a large Phase III trial called SYMMETRYSM. The SYMMETRY study is being conducted at approximately 150 centers worldwide to determine the efficacy of elesclomol in combination with paclitaxel for the treatment of patients with metastatic (Stage IV) melanoma.¹
- Additional studies to evaluate elesclomol as a therapy for other cancers are currently being planned.¹

What are the current approved treatments for metastatic melanoma?

- In the past 35 years, the FDA has only approved two types of therapies for metastatic melanoma – IL-2 and (D)TIC.⁴
- Currently, there are no approved therapies that improve survival for patients with metastatic melanoma.⁴

What is the regulatory status of elesclomol?

- Elesclomol has received fast-track and orphan drug status from the FDA for the treatment of metastatic melanoma. The Phase III trial is being conducted under a Special Protocol Assessment.¹

For more information on the SYMMETRY trial, please visit:
<http://www.syntapharma.com/ClinicalTrialHome.aspx>.

REFERENCES

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4. Tarhini A, Agarwala S. Cutaneous Melanoma: Available therapy for metastatic disease. Dermatologic Therapy. 2006; 19:19-25.