

## **BioGAL - Novel use of Erythropoietin (EPO) for the treatment of Multiple Myeloma (Mor)**

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### **Background**

MM is a severe and incurable plasma cell malignancy and the second most common blood cancer. The median survival of untreated patients is approximately 10 months. Aggressive chemotherapy may prolong life to an average of 15-40 months. No cure has been found for MM. There is an unmet need to develop novel therapy options to prolong survival and improve the quality of life of these patients.

### **Our Innovation**

BioGAL has discovered, investigated, clinically tested and patented a new use for the blockbuster drug Erythropoietin (EPO), for the treatment of multiple myeloma (MM) and other related hematological malignancies.

EPO is an approved drug for the treatment of patients with anemia associated with chronic renal failure and for the cancer-related anemia. We have observed that EPO significantly prolonged life of several MM patients with a very short expected survival (Mittelman et al, Eur J Haematol 2004:72:155). This was further supported by studies in our laboratories that showed, on murine myeloma models, that EPO possesses an anti-myeloma effect, probably mediated via the immune system (Mittelman et al. Proc Natl Acad Sci USA 2001:98:5181; Katz et al. Acta Haematol 2005:114:177). We have also demonstrated that EPO-treated MM patients with advance disease acquire improved immunological parameters and functions (Prutchi Sagiv et al, Br J Haematol 135:660-672).

We hypothesize that EPO boosts the immune system of MM patients, consequently achieving an anti-myeloma function; affecting disease progression and improving prognosis.

### **The Opportunity**

There are approximately 40,000-50,000 people in the US living with MM. About 14,000 new cases are diagnosed annually in the US and 16,000 in Western Europe. Over 11,000 deaths from MM occur annually.

BioGAL patents offer pharmaceutical giants, such as Amgen, Roche and J&J, a huge market opportunity for various reasons: a) EPO patents are expiring, and b) MediCare in the US has recently limited the use of EPO for chemotherapy-related anemia and big pharma companies have already lost huge market shares. These companies are thus looking for novel uses of this blockbuster drug.

### **Status**

Extensive in vitro, in vivo and clinical research has been performed at Prof Drorit Neuman's laboratory, Tel Aviv University, regarding the effects of EPO and its underlying mechanisms of action. Several articles have been published regarding its beneficial effects on the immune system of MM and related hematological malignancies.

An investment of \$0.6-1M is needed in order to perform a prospective clinical trial phase II in advanced stage MM patients. According to an already planned protocol, 24 patients will suffice in order to prove the efficacy of EPO on survival advantage and immune improvements.

### References

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### Patent Status

Granted in USA, pending in Europe

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