

16/5/16

To whom it may concern
Re: Marmolad Lital

Lital is currently eight and a half years old, previously healthy, lovely and lively girl.

She presented in June 2015, with abdominal pain and distention. Imaging studies revealed multiple abdominal masses: pelvic, sub diaphragmatic, surrounding the spleen, adjacent to lower ribs and chest wall, as well as a moderate amount of ascites.

An open biopsy was performed, and the tumor was diagnosed as malignant mesothelioma.

Mesothelioma is extremely rare in children, and carries (in children as well as in adults) a grave prognosis. Treated with conventional chemotherapy and surgery, with only about 40% of the patients alive 12 months post diagnosis, and 10% of the patients alive 60 months post diagnosis.

Lital responded poorly to conventional chemotherapy, and after five cycles, with minimal response, was referred for a "state of the art" HIPEC surgery: extensive surgery combined with intra-abdominal heated chemotherapy.

On imaging after surgery, there was no visible disease, but, since it was resected without "oncologic" margins, microscopic disease obviously persists, and is likely to relapse.

According to a recently published study, keytruda showed "unprecedented results" in mesothelioma patients, exceeding by far response rates to conventional chemotherapy (Alley et al, Cancer Res August 1, 2015).

In a first phase II study, published in April 2015, another immune checkpoint inhibitor has shown prolonged disease control in advanced melanoma.

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Lital began treatment with Keytruda six months ago, she has so far received eight cycles of treatment. PET-CT performed in February 2016 showed no evidence of disease, and another one is to be performed shortly.

On Keytruda treatment Lital leads a normal and active life, attending school and dancing classes,

After seven months of remission of an advanced, chemoresistant disease (last local treatment was administered in October 2015) we believe keytruda might be a life saving, or at least a life prolonging treatment for Lital.

We would like to be able to continue the same treatment for another six months, assuming Lital remains in remission, with PET-CT follow up every two to three months.

The dose required is 50mg every 21 days.

Unfortunately, since keytruda is not yet approved by Israeli health ministry for that indication, it will not be supplied by the health insurance provider.

Sincerely

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