PHTHALOCYANINE FOR CANCER RECURRENCE

REGULATORY STATUS

Summary

Hugo Manufacturing proposes the immunogenic sensitiser Phthalocyanine for consolidation therapy. To prevent recurrence, Phthalocyanine is to be used as a follow up to Chlorin-Chlorophyll debulking treatment. As soon as significant proof of efficacy has been obtained, a dossier will be submitted to EMA. Because proof is time dependent, submission of the dossier may take years.

dr. Wim Huppes MBA

Denison Chapman BSc

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Introduction

Cancer cells are immortal. The problem of consolidation is two-fold. Small clumps of cancer cells can seed throughout the body and they can be dormant. A dormant cancer cell has a low metabolism in which they scavenge nutrients from their surroundings without cellular duplication. Nevertheless, these dormant cancer cells can wake up to cause recurrence.

We believe Phthalocyanine could solve the problem of seedlings throughout the body and the problem of dormant cancer cells. Phthalocyanine can solve both problems because it attaches to the outer membrane of cancer cells, even when they are dormant. We believe that cancer cells lack the mechanisms to clear molecules such as Phthalocyanine from their outer membrane.

Approval of Phthalocyanine in Russia

In 2010 a phthalocyanine sensitiser under the name of Photosens was registered in Russia. [1] The registration was based on a Phase 2A Study in 42 humans with different types of untreatable cancers. Phthalocyanine was used in conjunction with standard chemotherapy and radiation. The rate of response was 92 percent. Complete remission was 50 percent, the remaining had partial responses. The primary data are in Russian, but the summary data have been published in French by Manneville and in English by Ben Hur. [2] A summary of the Russian experience was published by Filonenko E.V., Serova L.G.

In 2012, guidelines for most forms of cancer were approved by the Russian Minister of Health Mdm. V. I. Skvortsova. [3] We refer the reader to additional literature on the use of Phthalocyanine in conjunction with standard treatment. [4] [5] [6]

Pre-clinical development of Phthalocyanine started in the 1960's. Since then the concept has consistently shown promise for cancer. [7] The most promising form of the molecule for light therapy in animal studies is the highly immunogenic aluminium-phthalocyanine-disulfonate. [8] Extensive safety testing found it safe at high doses, up to 50 times the dose we use. [9]

Phthalocyanine as an Immunotherapy

Phthalocyanine was originally conceived as an immunogenic sensitiser. It was adopted into clinical practice in Russia as an add on to standard treatments without any measure of its immune effect. This precluded development into an immunogenic sensitiser for use in humans.

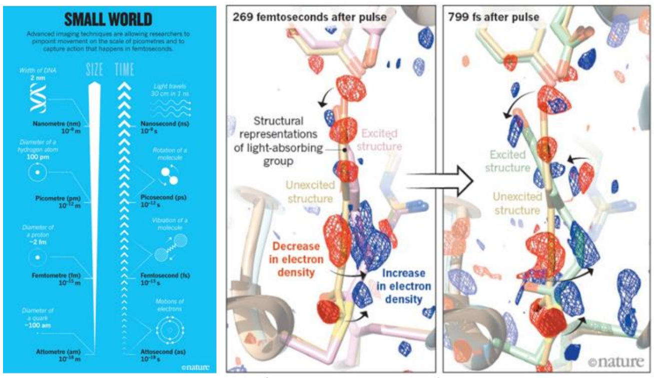

Figure 1 - Electromagnetic Cascade
Source Nature 2017

We take the original hypothesis of Phthalocyanine as an immunogenic sensitiser as the basis for our consolidation therapy.

The Phthalocyanine molecule contains two aluminum atoms. We believe the presence of aluminum is in the phthalocyanine molecule presents the cancer to the patients' immune system. This generates a true immune response against the combination of the phthalocyanine and the cancers membrane. A true immunological response makes the body's immune system respond everywhere.

We believe Phthalocyanine interacts with the immune system through physics.[10] [11] [12] Only through physics can we explain the cascade of interactions between photons of light, the phthalocyanine sensitiser and the immune system. Using light to generate a pulse of luminescence in the sensitiser changes the electrical charge on the immune cells causing them to activate against cancer. See *Figure 1 – Electromagnetic Cascade*

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