

## Oral ON-042

### Set-up of the first pilot study on intraoperative 5-ALA PDT: INDYGO trial



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Nowadays, Glioblastoma Multiform (GBM) remains an incurable brain tumour despite of recent advances in the standard of care. Patients harboring newly diagnosed GBM, de novo GBM, undergo to surgery for maximal tumour resection followed by radiation therapy and concomitant and adjuvant chemotherapy (Temozolomide). This protocol has raised the overall survival to 14.5 months. Promising results have been documented concerning 5-ALA interstitial photodynamic therapies. However, interstitial PDT has always been delivered to treat recurrent or non-operable tumours. Because of heterogeneous population of patients with different care protocols in the context of their relapsing disease or the absence of controlled clinical trial, efficacy of 5-ALA PDT is not still evidenced and thus not included in the standard protocol.

In order to prove the 5-PDT efficacy on patients harboring de novo GBM, our group has developed a specific medical device to deliver PDT intraoperatively in the surgical cavity.

The main idea is to benefit from the course of 5-ALA Fluorescence Guided Resection (FGR) to achieve an illumination with the suitable wavelength (635 nm). Treatment of the infiltrating cells by a PDT effect is expected in the first millimeters of the surgical cavity. In such manner, intraoperative PDT is a simple add-on to the standard protocol that is more ethically acceptable and more efficient to assess PDT efficacy.

Ten patients will be enrolled. Each patient will undergo standard treatment protocol including PDT early after surgery.  $25 \text{ J/cm}^2$  will be delivered at 5 mm of the surgical cavity borders. A fractionation scheme will be applied: 5 fractions of  $5 \text{ J/cm}^2$  each with off-period of 2 min between each fraction. A first early post-operative MRI will be acquired on the intraoperative MRI of our department. Then, MRI will be acquired quarterly to monitor the treatment response.

The primary endpoint is the feasibility of intraoperative PDT, estimated by the proportion of patients who undergone intraoperative PDT without unacceptable toxicity. The expected objective is 70%, 7 of 10 patients that we plan to include. Secondary endpoints are progression-free survival (PFS), overall survival, and evaluation at 3 months, 6 months and 12 months of radiation treatment response and patients' quality of life. Finally, after the feasibility and the absence of adverse effects, our protocol will be experienced through a controlled multicenter clinical trial (Phase II) which will focus on dose escalation (light and 5-ALA) and new biomarkers findings. This multicenter clinical trial will be set-up and performed with the support of the European network Synaps (<http://www.synaps-project.eu>).

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