

Current Commercial and Regulatory Status of Photodynamic Therapy and Diagnosis

S. Kuusiluoma, S. Orsila, P. Uusimaa, Modulight, Inc., Tampere, Finland
(sampsa.kuusiluoma@modulight.com)

Photodynamic therapy has substantial history and even few success stories (such as Visudyne ®, Metvix ® and Gliolan ®), however, the wider adoption as a treatment modality has been limited due to various reasons, such as complexity of the treatment and related regulatory hurdle, specificity of the applied indications, treatment parameters and reimbursements, lack of well-planned and conducted trials, just to name a few [1, 2]. While it has been recognized that the application itself has its strengths and limitations in the clinical setting, the regulatory and commercial aspects of photodynamic therapy are repeatedly brought up as significant obstacle. The purpose of this presentation is to outline those obstacles, their status and ways they are addressed now and in the future.

Current commercial success within the field of photodynamic therapy and diagnosis is limited to a handful of drug-device combinations. Regulatory challenge posed by the combination treatment is different from geographical region to another, nevertheless, the requirement of presence of both – the drug and the light-dose – poses both commercial and regulatory challenges to the combination products. Whereas USFDA has adopted the requirement of combinatory approval and use of the PMA, in Europe and most everywhere else the regulatory pathway to clinics is more straight-forward, but requires of course similarly the sufficient clinical evidence for each indication and drug.

Commercial pathway includes not only the permission to enter the market, but sufficient strategy for reimbursement, sales and marketing, and logistics. Different approaches and status of available commercial treatments globally will be discussed in the presentation.

[1] Ron R Allison (2014) *Future Oncol.* (2014) 10(1), 123–142. [2] P. Agostinis et al (2011) *CA CANCER J CLIN*, Volume 61, Issue 4, 250–281.