

# TRIALIST WORKSHOP – TENTATIVE PROGRAMME

## 6<sup>th</sup> - 7<sup>th</sup> December 2010

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Cancer Cachexia Trialist Workshop

8.45-10.45

Welcome & introductions, 10'

### The patients of interest

- a) Muscle wasting in cancer: the clinical & survival impact, 15'
- b) Symptom generation and causes of death in cancer cachexia, 10'
- c) Defining patients with cancer cachexia using weight loss & BMI, 10'
- d) Trial challenges: dealing with poor compliance, drop-outs & mortality, 10'
- e) Recruitment strategies for cancer cachexia trials, 10'
- f) Recruitment in academic centers in Europe, 10'
- g) General moderated discussion, 45'

10.45-11.05 Break

11.05-12.20

### The approval process for cachexia medicines: focus on endpoints

- a) FDA statement, 10'
- b) EMEA statement, 10'
- c) NIH statement, 10'
- d) Patient reported outcomes [PROs] (short review), 10'
- e) General moderated discussion, 45'

12.20-13.00 Lunch break

13.00-14.20

### Focus on endpoints

- a) Assessment of body composition: challenges and solutions, 10'
- b) Muscle function & exercise capacity tools (short review), 10'
- d) QoL assessment in cancer cachexia (short review), 10'
- f) Mortality & Morbidity – from power calculation to reality, 10'
- g) Cachexia therapy as palliative care: learning from past approvals, 10'
- h) General moderated discussion, 30'

14.20-14.40 Break

14.40-16.40

### Endpoint and results of ongoing and past trials - learning from experience

- a) Anabolic interventions (focus on SARMs, IGF-1), 15'
- b) Targeting muscle wasting (Anti-Myostatin approaches, Activin), 15'
- c) Other approaches (Cytokinetics approach, ACE inhibitors, ACTAs), 15'
- d) Anti-inflammatory therapies, 10'
- e) Appetite stimulants, 10'
- f) Nutrition approaches, 10'
- g) General moderated discussion, 30'

16.40-17.00 Break

17.00-18.00

### Other important consideration developing anti-cachexia medicines

- a) The value of anti-cachexia drugs in oncology, 10'
- b) Co-medication problems, 10'
- c) Safety considerations, 10'
- d) General moderated discussion, 30'

8.45-10.50

Definition (I)

- a) Setting the stage on sarcopenia: definition, epidemiology, 15'
- b) Sarcopenia vs. osteopenia, 10'
- c) Sarcopenia vs. dynopenia vs. function, 10'
- d) Effects of inactivity on muscle mass, 10'
- d) Defining sarcopenia: US perspective, 10'
- e) Defining sarcopenia: EU perspective, 10'
- f) General moderated discussion on the sarcopenia definition, 60'

10.50-11.10 Break

11.10-13.00

Definition (II)

- a) Past and current trials and their inclusion & exclusion criteria, 15'
- b) Sarcopenia research: the NIH perspective, 15'
- c) Assessing muscle mass in sarcopenia trials, 10'
- d) Functional testing in sarcopenia trials, 10'
- e) FDA statement, 15'
- f) EMEA statement, 15'
- g) General moderated discussion, 30'