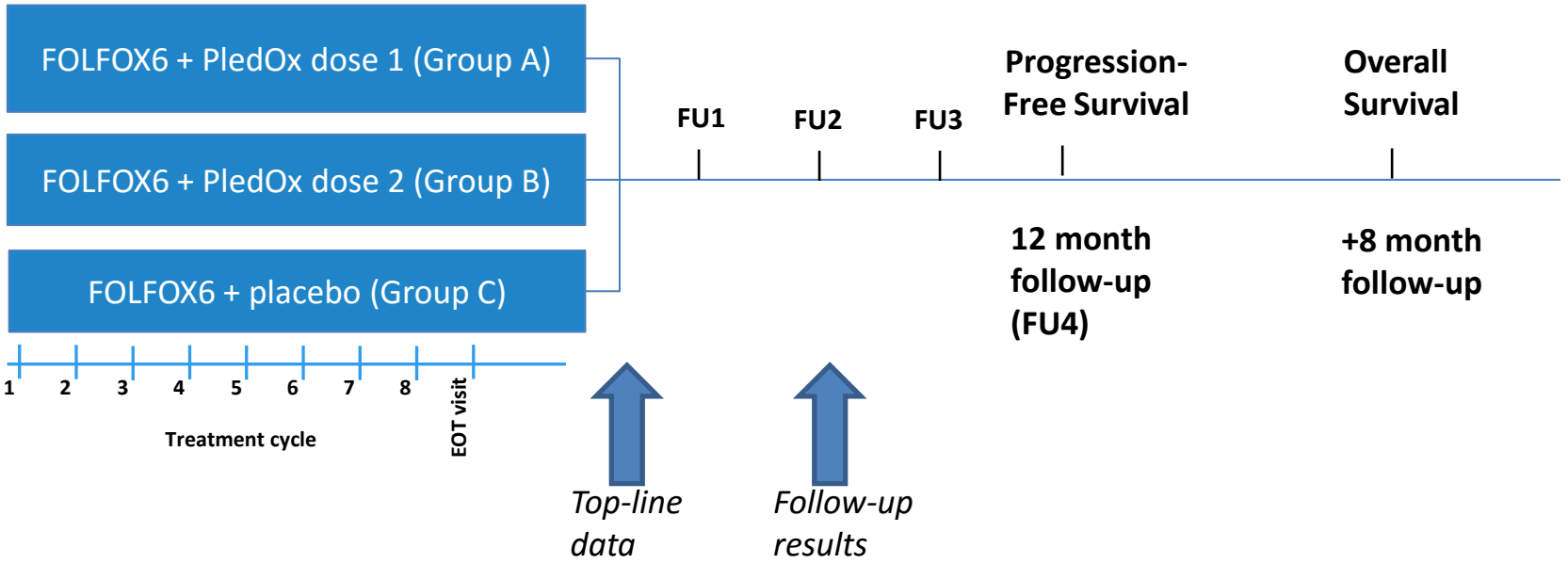
2015

PledPharma

Follow-up data from
phase IIb study
December 1, 2015

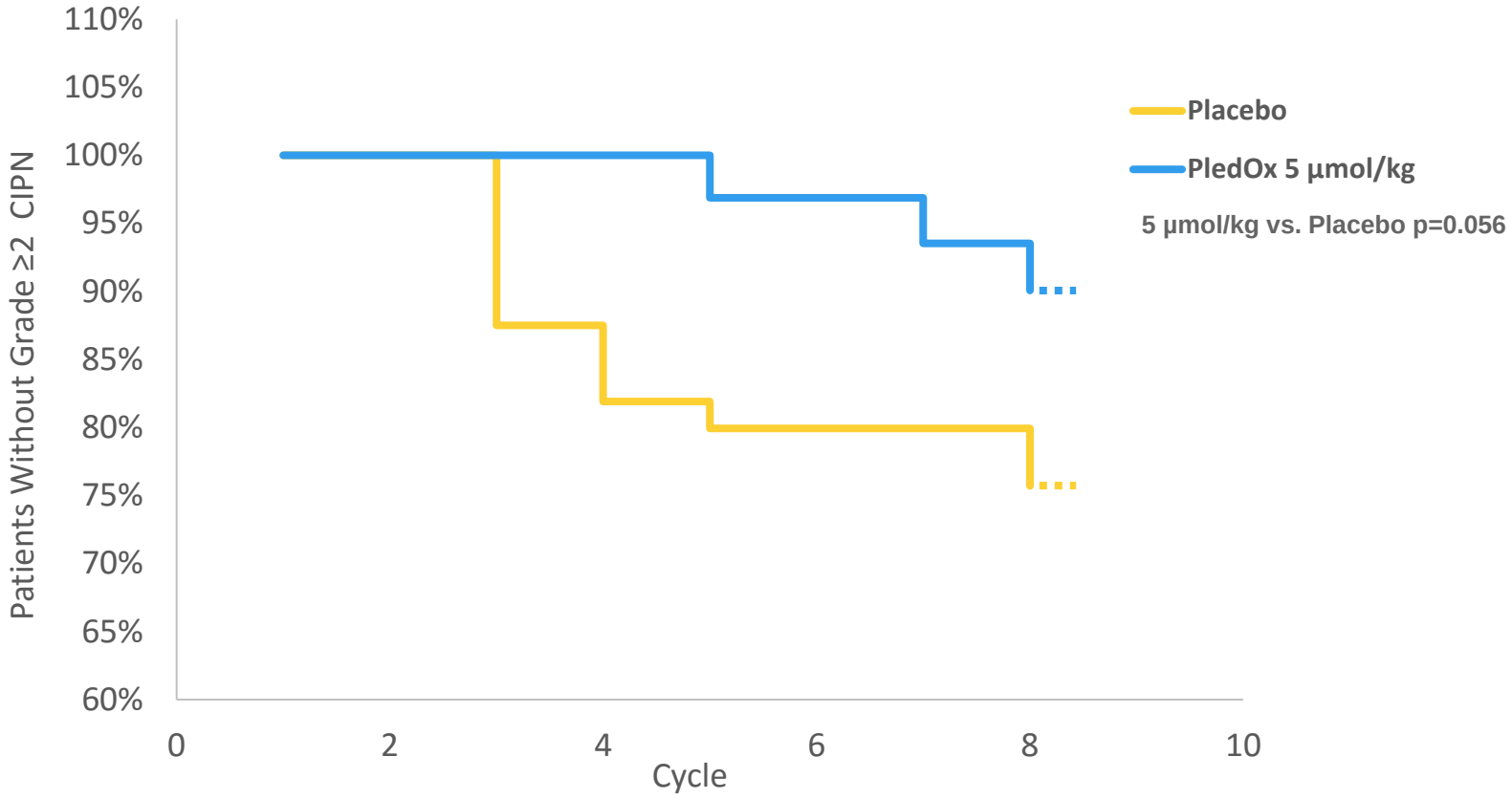
PLIANT Phase IIb study outline



- International, randomized, double blind, placebo controlled phase IIb study
- The study compared pretreatment with PledOx® (two doses) against standard chemotherapy (FOLFOX)
- 173 patients with metastatic colorectal cancer

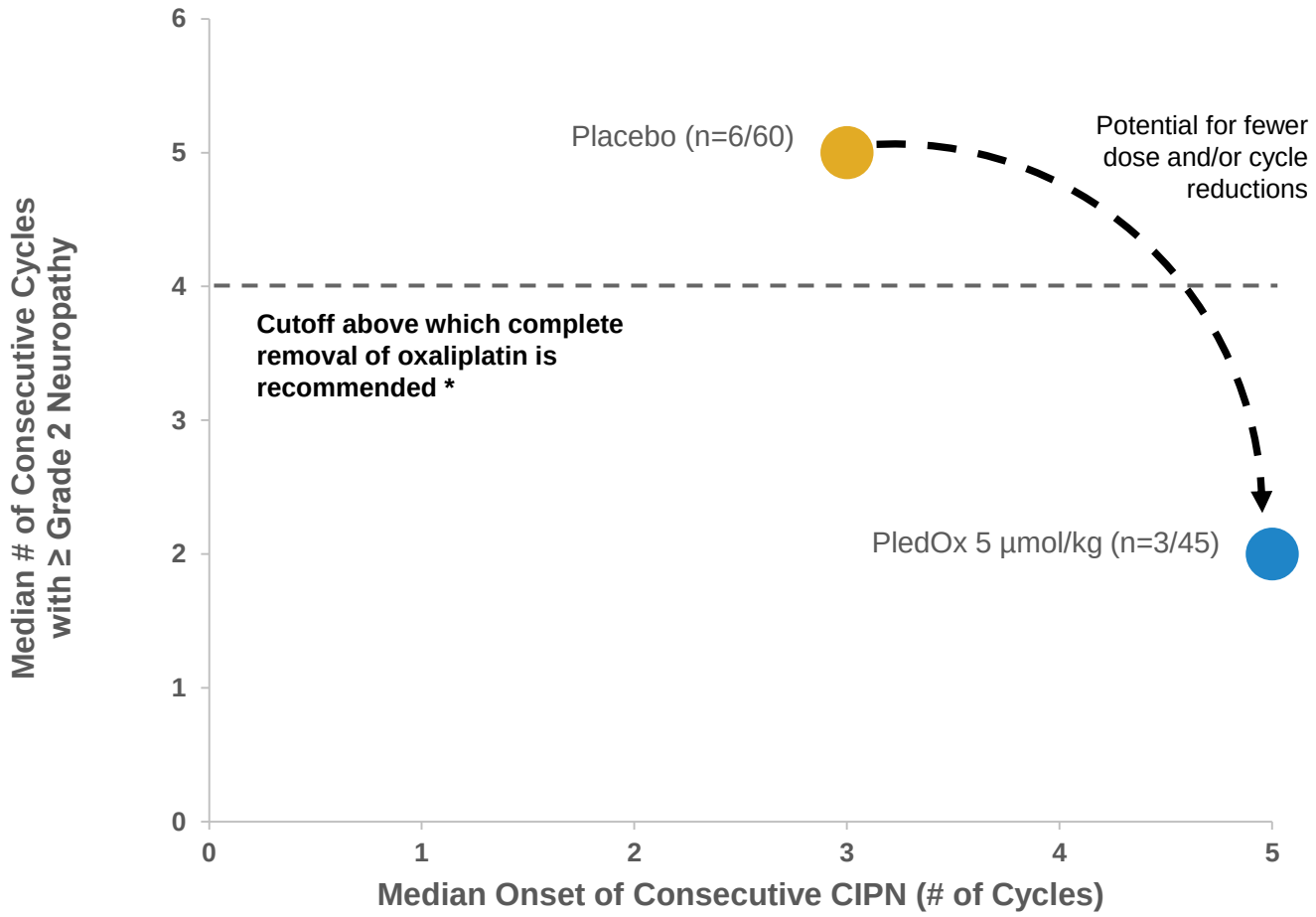
Top-line data from PLIANT-study with PledOx® - physician reported Oxaliplatin Sanofi Specific Scale

Kaplan-Meier plot (excl. first two cycles)
PledOx® reduces the indicence of grade 2 or higher CIPN – detailed data behind 43% reduction in OR



Top-line data from PLIANT-study of PledOx®

PledOx® reduces the incidence and delays onset of persistent CIPN

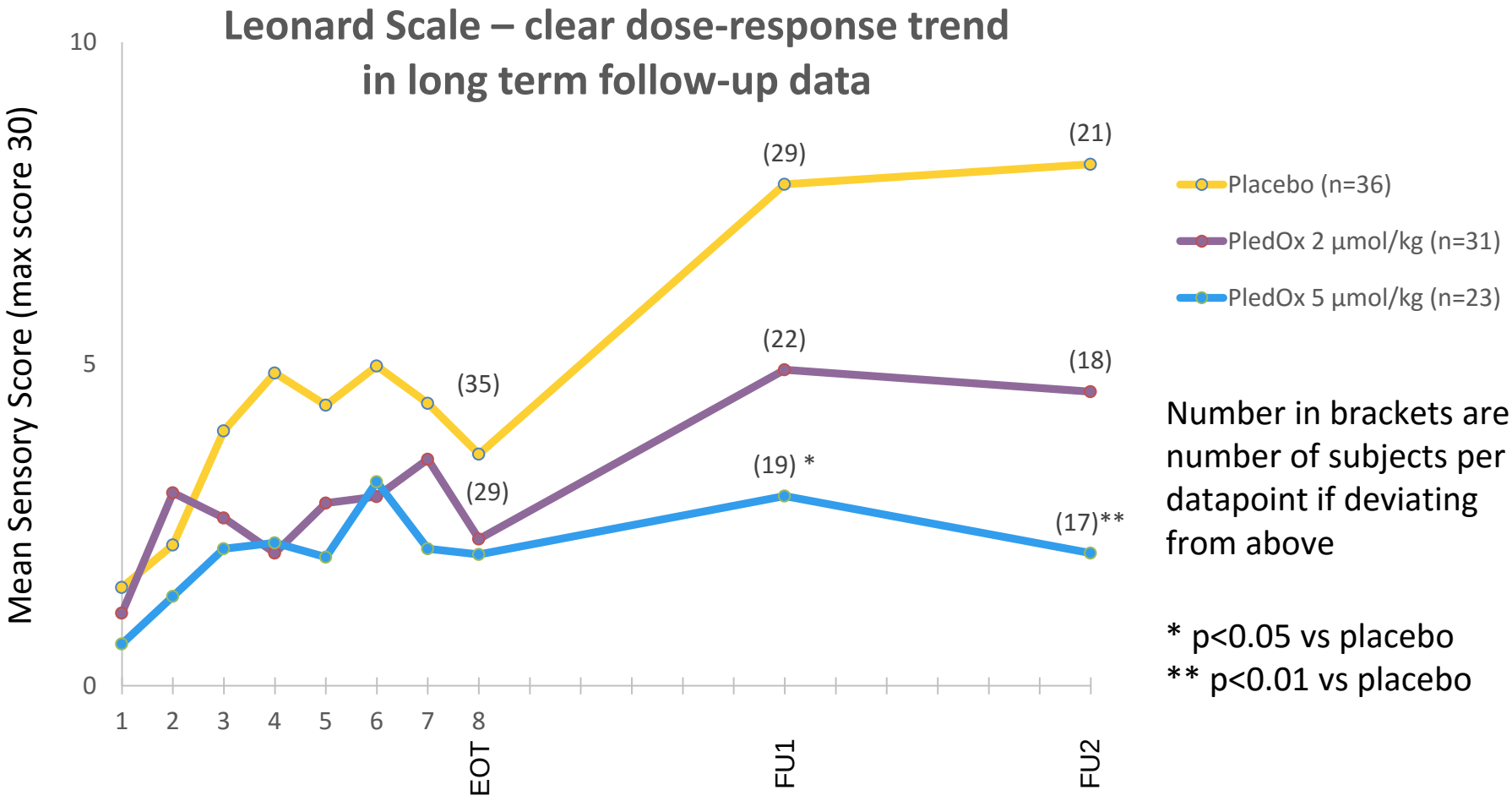


* Treatment guidelines recommend decreasing or complete removal of the dose of oxaliplatin after the fourth occurrence of persistent grade 2 CIPN. Decreasing occurrence and persistence may increase the ability to administer higher doses for more cycles.

Top-line results: PledOx® demonstrates clinical benefits

- PledOx® reduces incidence and delays onset of neuropathy.
- It can potentially enable the completion of more cycles of chemotherapy.
- First controlled trial that shows a meaningful reduction of symptoms from nerve damage without a negative anti-cancer effect.
- IP right granted to December 2032.
- Substantial commercial opportunity with a more than $1B worldwide market within colorectal cancer, and more than $5B worldwide when including other potentially applicable cancers.

Follow-up data – patient-reported symptoms from nerve damage



Number in brackets are number of subjects per datapoint if deviating from above

* p<0.05 vs placebo
** p<0.01 vs placebo

EOT *– end of treatment* ***FU1*** *– first follow-up, 12 weeks after EOT*
FU2 *– second follow-up, 24 weeks after EOT*
Mean Sensory Score *– average sum of Leonard scores for the sensory symptoms tingling (pins and needles), numbness and burning pain to cold, in hands and feet respectively. Max score for sum is 30.*

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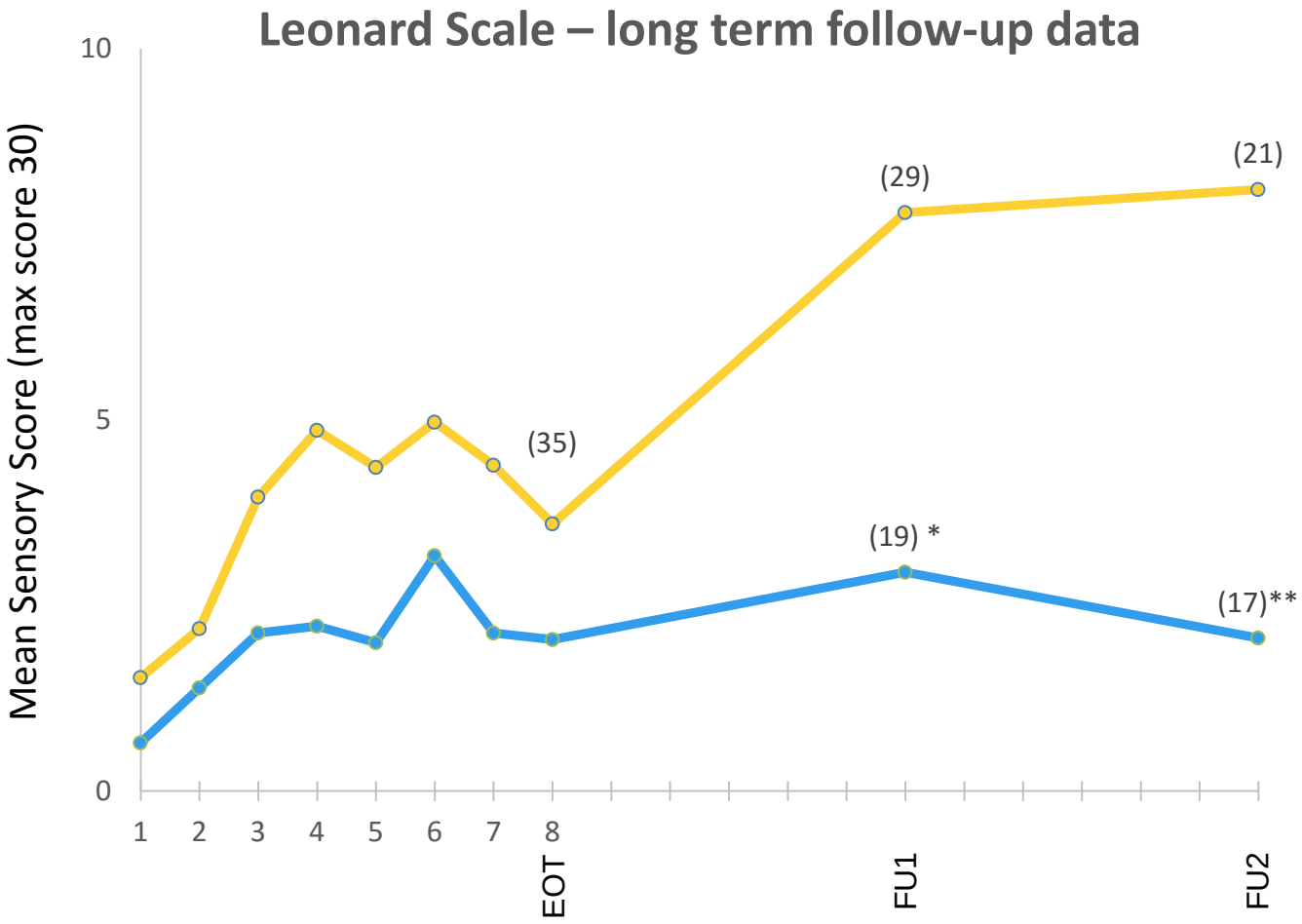

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Follow-up results: Clinical benefits of PledOx®

- A patient reported outcome (PRO) is the end-point of choice for a pivotal phase III study since the correlation between a physicians reported outcome and a PRO is mediocre at best.
- After end of treatment, the prevalence and magnitude of symptoms increased significantly in the placebo group up to and including week 12, and then levelled out at a high level.
- For the group with a dosage of 5 µmol/kg, the presence of symptoms was low and fairly stable over time.
- At 12-week follow-up after end of treatment, patients in the 5 µmol/kg group estimate their symptoms 62 percent lower than patients in the placebo group ($p<0,05$).
- At a corresponding follow-up after 24 weeks, the positive effect of PledOx® was even more pronounced – the difference compared to placebo increased to 75 percent ($p<0,01$).

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