TREATMENT WITH NALOXEGOL VERSUS PLACEBO: PAIN ASSESSMENT IN PATIENTS WITH NONCANCER PAIN AND OPIOID-INDUCED CONSTIPATION

Lynn Webster, MD
PRA Health Sciences

INTRODUCTION / AIM
To present results of pain assessments from phase 3 studies of naloxegol, an FDA-approved medication, in patients with OIC and noncancer pain.

METHODS
Two phase 3 randomized, double-blind, 12-week studies investigated the effects of daily oral naloxegol (12.5 or 25 mg vs placebo) on pain and opioid use in outpatients with OIC and noncancer pain. Pain level was assessed using an 11-point numeric rating scale (0=no pain; 10=worst imaginable pain). Mean weekly pain scores and opioid dose over 12 weeks were analyzed using mixed model repeated measures.

RESULTS
In KODIAC-04 (N=652; NCT01309841), mean scores for average pain at baseline ranged from 4.5–4.8 in each group; mean±SD changes from baseline for placebo, naloxegol 12.5 mg, and naloxegol 25 mg were –0.2±1.07, –0.3±1.05 (P=0.773 vs placebo), and –0.2 ±0.95 (P=0.837 vs placebo), respectively. Mean baseline daily opioid doses ranged from 135.6–143.2 morphine-equivalent units (MEUs/day); mean±SD changes from baseline dose were –1.8±30.19, –2.3±20.52 (P=0.724 vs placebo), and 0.4±13.01 (P=0.188 vs placebo), respectively. In KODIAC-05 (N=700; NCT01323790), mean pain scores at baseline were 4.6 for each group; mean±SD changes from baseline for placebo, naloxegol 12.5 mg, and naloxegol 25 mg were –0.1±0.87 (P=0.744), and 0.0±1.18 (P=0.572), respectively. Mean baseline opioid doses ranged from 119.9–151.7 MEUs/day; mean±SD changes from baseline dose were –0.3±17.14, –1.3±17.11 (P=0.669 vs placebo), and 0.1±8.54 (P=0.863 vs placebo), respectively.

DISCUSSION / CONCLUSIONS
Naloxegol does not have a clinically relevant effect on patient-reported pain levels or daily opioid dose versus placebo.

OTHER AUTHORS
Jaakko Lappalainen
Ulysses Diva
Raj Tummala
Mark Sostek