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Exploring Opioid Use Disorder Outcomes by Quantitative Urine Analysis: Post-hoc Analysis of a Phase 3 Randomised Clinical Trial Comparing a Subcutaneous Buprenorphine Depot (CAM2038) and Sublingual Buprenorphine

S. Peterson,[1] E. Nunes,[2] M. Lofwall,[3] S. Walsh,[3] F. Tiberg[1]

[1]Camurus AB, Lund, Sweden
[2]Columbia University Irving Medical Center, New York State Psychiatric Institute, New York, NY, USA
[3]University of Kentucky College of Medicine, Center on Drug and Alcohol Research, Lexington, KY, USA

Presenter: Elin Banke Nordbeck, Camurus AB, Lund, Sweden, +46 72 161 25 87, elin.bankenordbeck@camurus.com

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Objectives:
Urine drug tests can monitor response to opioid use disorder (OUD) treatment, but commonly used opioid immunoassays are limited to yes/no results and cannot detect concentrations of specific opioids for clinical assessment of medication adherence or indicate decreasing/increasing illicit opioid use. Here, we evaluate quantitative urine test results from a clinical trial for additional clinically meaningful information in OUD treatment studies, and how different cut-offs affect conclusions about apparent differences in outcomes.

Methods:
Treatment-seeking adults with moderate-to-severe OUD were randomised (N=428) to 24 weeks of treatment with weekly or monthly subcutaneous CAM2038, or daily sublingual buprenorphine/naloxone (SL-BPN). Urine samples were analysed for 11 opioids and metabolites by highly sensitive gas or liquid chromatography with mass spectrometry. The primary endpoint, based on detection of opioids above the lower limit of quantification (LLOQ), was explored using different cut-offs. Post-hoc analysis will also be presented.

Results and Conclusions:
CAM2038 treatment (n=213) resulted in significantly lower concentrations of morphine, hydromorphone, and codeine compared with SL-BPN (n=215). For primary endpoint using LLOQ, proportion of opioid-negative urine samples was 35.1% for CAM2038 and 28.4% for SL-BPN (difference: 6.7%; 95% confidence interval [CI]: −0.1%, 13.6%). Using standard cut-offs for opioid immunoassays (fentanyl/nor-fentanyl: 1 ng/mL; other opioids: 300 ng/mL) results were 39.6% for CAM2038 and 30.9% for SL-BPN (difference: 8.8%; 95% CI: 1.7%, 15.8%). Further increases in cut-offs led to greater differences, favouring CAM2038. There were significant treatment differences in mean concentrations over time and cumulative distribution functions of different illicit opioids. Quantitative urine analysis provides insights into patients' opioid use beyond basic assessment of abstinence; study outcomes are impacted by the sensitivity of analytical methods and cut-offs used. Our findings have important implications for the assessment of efficacy, including in regulatory contexts, hence careful consideration of analytical sensitivity and cut-offs is needed when designing, interpreting, and comparing results of clinical trials.

Disclosures:
SP: Dr. Peterson is an employee of Camurus AB.

EN: Dr. Nunes is an investigator on NIH-funded studies that have received in-kind donations of medications or digital therapeutics from Alkermes, Braeburn, Camurus, CHESS Health, Indivior, and Pear Therapeutics, and has served as a consultant without compensation for Alkermes, Camurus, Indivior, and Pear Therapeutics.
ML: Dr. Lofwall has received consultant fees from Journey Colab and Titan Pharmaceuticals in the last three years.
SW: Dr. Walsh has received consultant fees for advising on the development of products for the treatment of opioid use disorder from Arbor Pharmaceuticals, AstraZeneca, Brainsway, and Cerevel in the past three years.
FT: Current employee and shareholder of Camurus AB.

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