

Sublocade® - Buprenorphine Modified Release Injection

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August 2019



What is Sublocade

- **Sublocade is a long acting buprenorphine injection to be administered by a healthcare professional only**
- **Buprenorphine only, no naloxone**
- **Approved 18 July 2019**
- **Contains buprenorphine 300 mg or 100 mg**
 - 300 mg/ 1.5 mL
 - 100 mg/ 0.5 mL
- **In the ATRIGEL® Delivery System**
 - Biodegradable polymer and solvent create a solid buprenorphine depot
 - Pre-filled syringe, administered subcutaneously, 19g needle



Sublocade Development Objectives

We know that buprenorphine:

- Has a high affinity for μ opioid receptors¹, percentage μ opioid receptors occupied related to buprenorphine dose given and time since last dose^{2,3}
- Higher doses are associated with improvements in treatment outcomes such as retention, reduction in on-top use^{4,5}
- Has a wide variability of oral absorption

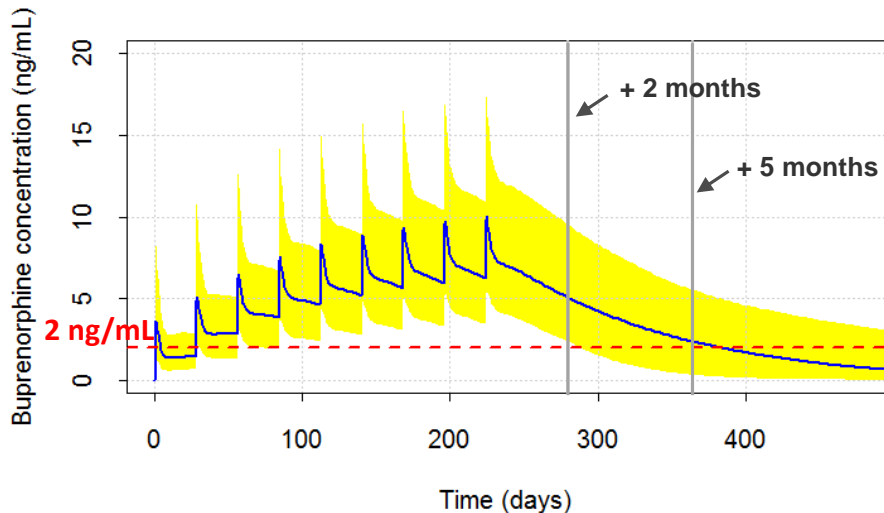
Development objectives:

- Achieve clinically significant control of craving and withdrawal symptoms and opioid blockade from the first dose and across the entire monthly dosing interval
- At buprenorphine plasma concentrations that are well-tolerated
- Limit possibility of abuse/misuse, diversion, and accidental overdose

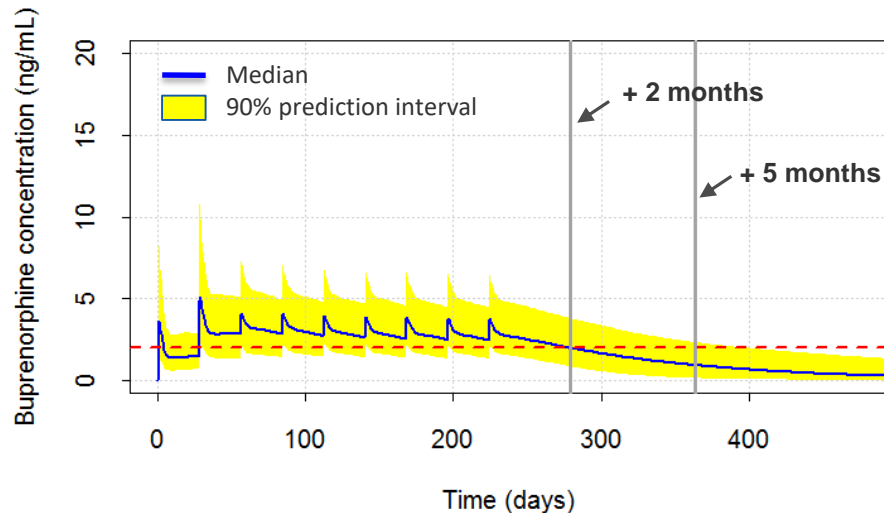


Predicted Buprenorphine Concentrations Over 9 Months and Upon Discontinuation of Treatment

300 mg/300 mg RBP-6000



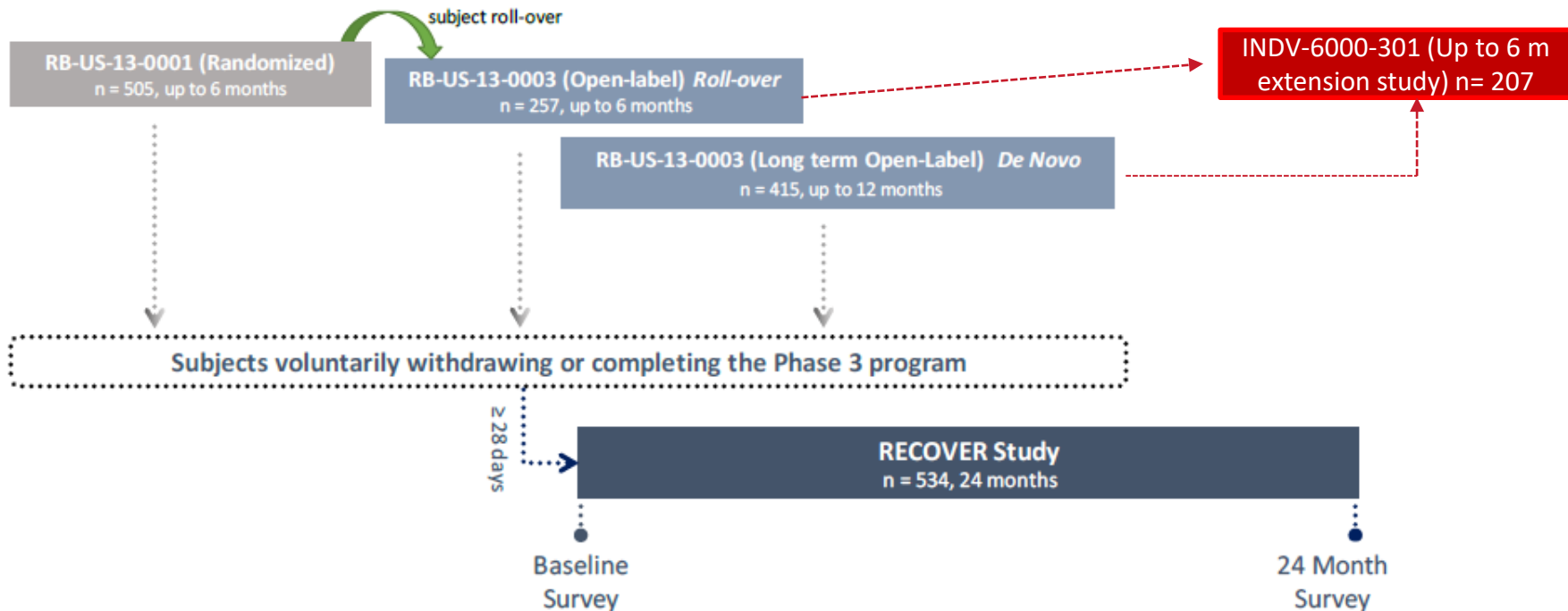
300 mg/100 mg RBP-6000



- Slow decrease in concentrations after last injection
- Concentrations ≥ 2 ng/mL for ~ 5 months (300 mg) or 2 months (100 mg) on average



Sublocade Studies



- COLAB Study Australia, 100 patients in NSW, Vic and SA
- EXPO Study UK study, comparison with SL buprenorphine or methadone



Potential Benefits Identified by Patients and Health Care Professionals

- Increased Treatment Choices
- Convenience, reduction in time
- Reduced pharmacy and transport costs
- Anonymity
- Flexibility
- Dose stability, feeling stable/normal, getting on with everyday life¹
- Avoid ritual of daily supervised dosing¹
- Protection from contingencies such as missed doses, reduction of harms¹
- Reduced diversion
- Reduced time discussing takeaways and dosing



Long acting injectable buprenorphine -An update

Emma Grace

Clinical Nurse, Alcohol and Drug Service

Metro North Mental Health

15th August 2019

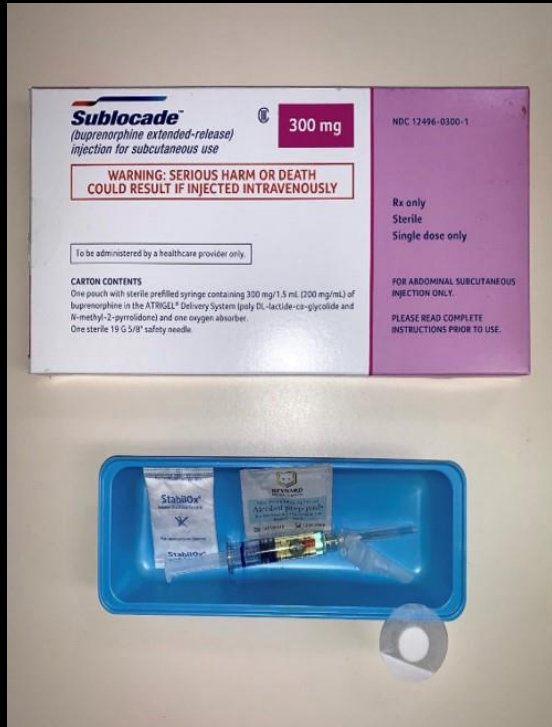
Roma Street Clinic

Located in Brisbane city and managed approx. 550 clients.
First public clinic in the world to offer the long acting injection-
Sublocade.

- ▶ Sublocade is administered into the abdomen of adults to treat moderate to severe opioid dependence.
- ▶ Dosages of 300mg/1.5ml or 100mg/0.5ml
- ▶ Generally, the first two doses are 300mg
- ▶ Administered with a 19G needle due to viscosity
- ▶ Stabilised on 7 days minimum of buprenorphine prior to long acting injection (LAI)



System factors



- ▶ TGA approval process
- ▶ Cold chain medication-No cold S8 storage at Roma Street Clinic
- ▶ Coordinating delivery of product within 7 day window due to cold chain or discarded
- ▶ Large package size with minimal storage space
- ▶ Ensuring debts are paid at pharmacy prior to switching to LAI
- ▶ Doctor only LAI administration
- ▶ Difficulty following clients up after injection as they don't answer their phones and we can no longer communicate through the pharmacy

Case study 1

- ▶ 34yr old female, in and out of homelessness and DV relationships
- ▶ Son removed by DOCS
- ▶ Long term heroin and amphetamine use
- ▶ Erratic client requiring frequent restarts/re-stabilisation after days of missed doses.
- ▶ Wanted to go on LAI to get into Rehab, approved but left after a couple of days
- ▶ Unable to contact, presumed she had returned to her cycle
- ▶ Phoned months later after de-registered stating she had a unit, had completed an outpatient drug and alcohol program and was in the process of having son transitioned back into home
- ▶ Restabilised with oral Suboxone and restarted on LAI

Case study 2

- ▶ 50yr old male, opiate stable for years on the program.
- ▶ Using ice 1-2X per week prior to LAI.
- ▶ Working long hours as a sound technician therefore often missed doses and required restarts.
- ▶ Had 2 LAIs before he became unreachable and was eventually deregistered.
- ▶ Despite never presenting intoxicated he showed up over a month later asking when his LAI is due fully inebriated and aggressive
- ▶ Client turned away and asked to return the next day -did not present.
- ▶ Phone calls back and forth, appts made-never attended.
- ▶ Client has been lost to follow up.

Case study 3

- ▶ 32 yr old homeless male, hx of prescription opiates and heroin, now predominantly ice
- ▶ Client too disorganised and dependent on the service to collect doses from pharmacy
- ▶ Given ultimatum to collect dose for 7 days straight or he can't get LAI and will be deregistered from program
- ▶ Since LAI, client has maintained housing, appts and has engaged in counselling.
- ▶ Noticeably more functional, coherent and organised.
- ▶ Contemplating detox and rehab.
- ▶ Some adverse effects from LAI.



Increased non-opioid drug use? Subjective withdrawals?

- ▶ Case study 3: increased from 3pts to 9pts of amphetamines per day after he commenced the LAI
- ▶ States he can't get "the rush" anymore
- ▶ Some clients report the loss of routine from going to pharmacy has "messed" with their heads
- ▶ Increased cravings as they have less to do each day
- ▶ "Doesn't feel like it's holding"
- ▶ Most clients that have stated this have been abusing other medications/illicits which has complicated Sublocade treatment



Case study 3 injection sites

Third injection: normal polymer



Fourth injection: Erythema, swelling, bruising and tracking of polymer.



Client factors

- ▶ Moderate pain on administration
- ▶ Persistence of lump at injection site, still present after four months
- ▶ Clients responsibility to return for next injection within timeframe
- ▶ De-registered if don't return within 2wks of LAI being due, same as SL Suboxone
- ▶ Poor compliance/engagement due to lack of withdrawals
- ▶ Loss of routine, “messaging with my head”
- ▶ Some clients not being held on the LAI, requiring oral top up
- ▶ Noted increase in amphetamines and other illicit/prescriptions in some clients



The Praise



- ▶ “Life changing.”
- ▶ “I no longer have to go to pharmacy and be reminded of my old life and run into old friends, I can leave the past behind me and move forward.”
- ▶ “Best I’ve ever felt.”
- ▶ “The first time in my life I have had savings.”
- ▶ “Feels like I’m not on any treatment at all.”

Thank you!

Please feel free to contact me at:

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