## Corporate Update Presentation: Sumatriptan Alginate Film (KL-00119)

June, 2019

KLARIA

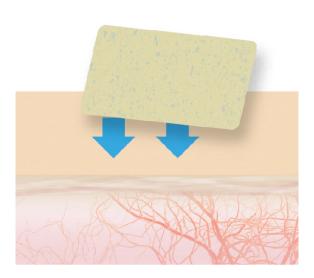
# Agenda

Technology Description

Sumatriptan



#### An Enabling and Transformative Technology



1) The alginate film is attached to the oral mucosa

- 2) Film stays in place for 10 to 30 minutes
- 3) The drug transfers *directly into the bloodstream*

*Film does not melt, is not mixed with saliva and swallowed* like other oral film technologies that claim trans-mucosal delivery but in fact achieve oral delivery

Drugs that are not orally available and have to be injected can be delivered with Klaria's Film Technology

By replacing injections we will both *enable and transform the treatment* in multiple indications



## Features and Benefits of Technology

| Simple and non-invasive            | <ul> <li>Enabling use where injection is not feasible or a poor option</li> <li>Example: Naloxone film vs injection by health care professional</li> <li>Example: Epinephrine vs injection</li> </ul> |
|------------------------------------|---|
| Consistent, low variability        | <ul> <li>Superior to nasal delivery</li> <li>Example: Sumatriptan film vs nasal spray</li> </ul>  |
| Rapid delivery of active substance | <ul> <li>Faster than oral delivery</li> <li>Example: Sumatriptan film vs tablet</li> <li>Example: Cannabinoid film vs oral delivery technologies</li> </ul>   |
| Easy to manufacture                | <ul> <li>Lower COGS than injection systems, nasal spray devices etc.</li> <li>Example: Adrenaline film vs injection</li> </ul>  |
| Easy to store, ship, handle        | <ul> <li>Broader usage than injection devices or injections</li> <li>Example: Adrenaline film vs injection</li> <li>Example: Naloxone film vs injection by health care professional</li> </ul>        |
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# Natural, Uniquely Efficacious, Approved and Patent Protected



- Alginate polymer extracted from the North Sea brown algae (Kelp)
- Extremely muco-adhesive when formulated using our proprietary process
- Approved for food and drug use world wide
- Patent protected world wide



#### Strategy to Create Value

Lower: Risk, Time, Cost

Create Medical Value

Create Commercial Value

Claim Commercial Value and higher approval rates

• Well defined regulatory path with **lower risk**, **lower costs**, **shorter time lines** 

- Create medical value by focusing on projects that address high unmet medical needs and where injection or nasal route is preferred
- Share benefits of lower COGS between stakeholders, allowing for both lower price and high gross margins
- Create pricing power by avoiding pharmacy substitution with tablets
  - Clinical studies (ph II size studies) showing superior efficacy and/or safety
  - Develop doses that are bioequivalent but not identical
  - Establish bioequivalence to non-oral formulations



# Agenda

- Technology Description
- Sumatriptan



#### Migraine is Prevalent, Debilitating and Costly



- Occurs in 12% of population in US and EU
- 85% of Migraine sufferers are women
  - 25% of women suffer 4 or more attacks/month
  - 90% of sufferers are unable to function normally
- > 2.5 million hospital emergency room visits/year in US and EU due to Migraine Attacks
- High societal cost
  - \$70 billion per year in lost productivity in EU and US
  - \$9 billion per year in total treatment costs in EU and US



Migraine Patients are Willing to Try a New Medication - Tablet, Nasal and Injection are Poor Options

# 80%<sup>1,2</sup>

of migraine patients suffer from Nausea

79%

willing to try a new acute medication<sup>2</sup>

# Nasal administration is a poor delivery method

- High variability in uptake results in variable efficacy
- Drug falls through nasal cavity resulting in oral delivery

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# Sub-optimal treatment

# Injections are risky and distressing to patients

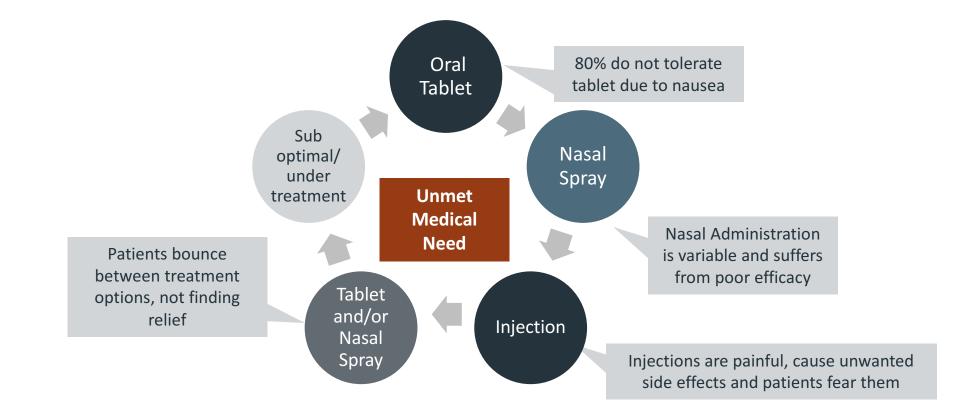
- Fear of injection
- Difficult to administer correctly
  - Potential complications

#### $\rightarrow$

# Under-treated patients



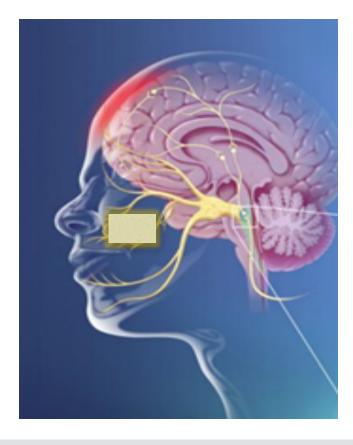
#### Large Pool of Migraine Patients Currently Poorly Served



Sub-optimal treatment and under-treatment causes: - Significant patient suffering<sup>3</sup> -High societal cost due to lost productivity and co-morbidities<sup>3</sup>



# Administration to the Vasculature around the Trigeminal Nerves to Achieve Maximum Efficacy



# Placement of Film and absorption of Sumatriptan is local

on the facial artery which has its terminus in the ophthalmic and maxillary regions of the face where migraines originate<sup>1, 2</sup>

1: Moskowitz, M.A.: The neurobiology of vascular head pain. *Ann Neurol* 1984; 16: 157–168. 2: Goadsby, P.J.: The pharmacology of headache. *Prog Neurobiol* 2000; 62: 509–525.



# Sumatriptan Film is a \$300+ million peak sales opportunity

- The Film will claim significant share of tablet, nasal and injection market
- The oral/tablet market is large and low-priced
- The film will be priced similarly to current US market prices for nasal sprays and injections

