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Moderate to Severe Pain: Novel Abuse Deterrent Formulation Technologies and Emergence of Novel Mechanisms in the Management of Pain

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Abstracts

Pain is the leading cause of disability in the US, affecting more than cancer, diabetes and heart disease combined. Current analgesics for persistent pain are relatively ineffective, are associated with significant adverse effects or abuse liability, and do not reduce pain in all treated individuals. Opioids (e.g., morphine, codeine, oxycodone) are currently one of the most potent groups of analgesics used clinically, with prescriptions increasing by 50% over the past 10 years for chronic, non-cancer pain. However, there is clear evidence that as opioid prescription rate rise, there is a corresponding increase in opioid overdose deaths, misuse and addiction. These adverse effects are attributed to the opioid agonist effects on central opioid receptors—causing dependence, tolerance, sedation, and respiratory depression.

Non-steroidal and steroidal anti-inflammatory drugs have serious side effects such as gastric erosions, ulcer formation, bleeding, hypersensitivity reactions, cardiovascular toxicity, renal toxicity, and hepatotoxicity. In addition, they are also not peripherally selective thereby causing a range of central adverse effects. Over the past 20 years, most analgesic development activities have been limited to the reformulation of opioids, production of new cyclooxygenase (COX) inhibitors, amine reuptake inhibitors and anticonvulsants, and introduction of topical local anesthetics—all of these act on well-established targets. A significant unmet need exists in the emergence of novel mechanism which will avoid the current NSAIDS side effects with improved efficacy. Several newer mechanisms currently being explored will have the ability to replace opioids in the treatment of acute and chronic moderate to severe pain.

Globally, pain is one of the important therapy areas with a market size of over $50b in 2013, and is expected to grow at 10%. The recent patent expiry of Cymbalta and Lyrica

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(2018) will have significant impact on the overall pain market size in the near future. However, several pipeline molecules are emerging to fill this gap.

The importance of abuse deterrent labeling in the formulations can be better understood from FDA’s non-approval of oxycontin generics in 2013. The revised labeling with abuse deterrence has protected Purdue’s oxycontin revenue slide from its generization.

In the wake of abusive potential of opioids drugs reported all across the US, FDA recently drafted guidance for evaluation and labeling of opioids formulations based on their ability to reduce its abusive potential (tier 1 to 4). Despite the process being in nascent stage, several specialty companies have already ventured into the development of abuse deterrent formulations to reap benefits in the near future.

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COMPANIES MENTIONED:

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Acura Pharma
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Amorsa Therapeutics
AstraZeneca
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Cara Therapeutics
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