

Pain Management- New Discoveries and Treatment Options in Abuse Deterrent Era

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Abstracts

Rescheduling of Hydrocodone combinations from Class III to Class II, clear-cut regulatory guideline for Abuse Deterrent drug formulation NDA & ANDA (solid oral) filing and CDC guideline for Prescribing Opioids for Chronic Pain (2016) are definite steps taken by FDA in last two years for creating “Abuse Deterrent Era” in a short span to stop opioid abuse and reversing opioid epidemic in USA. There were around 18,893 deaths involving prescription of opioids in the United States in 2014 which was up 16% from 2013 as per NCHS (National Center for Health Statistics).

Around +6 plus extended release abuse deterrent formulations with Abuse deterrent (AD) labels are approved in last two years (Xtampza ER, MorphaBond ER, Hysingla ER, Embeda ER, Targiniq ER, Oxaydo) and are expected to provide improvements over existing formulations for abuse deterrent purpose. But they have some limitation for restricting abuse mainly through oral intake- swallowing a number of intact tablets or capsules. Despite, Extended release (ER) Abuse Deterrent Formulations partly control Opioids abuse (through nasal or injection routes), ER opioids has high potential of abuse, its AD formulation add significant value to create “Abuse Deterrent Era” in the coming time.

Around 20 plus Abuse Deterrent Formulations of opioids are in the pipeline and most of them are ER formulations which use different AD tech platform to make its ADF. Amongst these pipeline ADF drugs, 6 are of Hydrocodone, 8 are of Morphine and 6 are of Oxycodone based ADF formulations.

New NCEs targeting Opioids receptor are in pipeline which reduces Opioids abuse by its MoA (slow rate of entry in Brain) and may have potential to deal with reducing opioid abuse through restricting oral intake in coming years.

US Opioids market is of \$8b in size and of which extended release formulations contribute 50%. ADF ER formulations and its generic versions & New NCEs targeting Opioid receptor will drive the growth of opioid market in US and Europe in coming years.

In this report, we have discussed a number of novel delivery technologies employed in the formulating abuse deterrent product, technologies employed in enhancing patient compliances, emerging novel mechanisms and late stage pipeline drugs in the management of pain.

Late stage NCE pipeline drugs (Cebranopadol, Mirogabalin, NKT-181, AVP-923,...) and Novel technologies targeting formulation change in old generic drugs (ORB-201, OX-51, ARX-04, CL-108, once daily Pregabalin..) for pain management has potential to reduce opioids use in future to treat pain. While TRKA receptor antagonist, NAV1.7 sodium channel modulator inhibitor and angiotension II antagonist are few new MoA which has promising drug in clinical development for moderate to severe pain management.

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AbbVie

AcelRx pharma

Acorda Therapeutics

Actavis

Acura Pharma

Acorda Therapeutics

Altus formulations

Alkermes

Algiax Pharmaceuticals

Amorsa Therapeutics

AnGes

AstraZeneca

Balerna

Biogen

BioDelivery Sciences International Inc

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Catalent

Charleston

Celltech

Collegium Pharma

Convergence

Columbia Labs

Convatech

Daiichi Sankyo

Daewoong

Depomed

Direct
Egalet
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Mallinckrodt
Nektar
Novartis
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Recro pharma
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Reckitt Benckiser pharmaceutical
Signature Therapeutics

Spinifex pharma
SPR Therapeutics
Strativa
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