Mucodel Pharma Files Citizen Petition Concerning Intransal Naloxone

GREENSBORO, N.C., February 20, 2017 -- Mucodel Pharma LLC ("Mucodel") announced its filing with the United States Food and Drug Administration ("FDA") of a Citizen Petition (FDA-2017-P-0663).

The Mucodel Citizen Petition raises safety concerns relating to intranasal (IN) naloxone. Mucodel asks the FDA to consider the reliability of intranasal naloxone for opioid overdose in actual field use. Mucodel believes that legitimate questions exist concerning the reliability in field use of IN naloxone, and that FDA should therefore consider whether new IN naloxone applications adequately address the potential efficacy disparity of IN naloxone versus intramuscular (IM) naloxone in actual field use.

Potential contraindications to IN naloxone administration may include nasal septal abnormalities, nasal trauma, epistaxis, excessive nasal mucus, concomitant use of vasoconstrictors, and intranasal damage caused by the use of substances such as cocaine.

The Mucodel Citizen Petition, with opportunity to publicly comment, is available at this link:

https://www.regulations.gov/document?D=FDA-2017-P-0663-0001
Mucodel is actively development a buccal naloxone (Exonal).

Joseph Fuisz, Mucodel's head of business development, commented: "It's understandable that the FDA did not look at intranasal reliability issues and potential subpopulation contraindications during the expedited four month review leading to the approval of the reference listed naloxone intranasal spray. However, now that there is an approved intranasal option, we strongly hold the view that FDA should compel future intranasal applicants to address whether an efficacy disparity exists between intranasal and intramuscular treatment options."

Mucodel is actively developing a buccal naloxone product (Exonal™). Mucodel previously announced its successful completion of a pilot clinical study involving Exonal™. The pilot pharmacokinetic study compared Exonal™ buccal naloxone with an approved IM naloxone. The study met its objectives and demonstrated that Exonal™ rapidly delivered the targeted naloxone dose, with comparable Cmax and Tmax to the approved IM reference product.

About Mucodel Pharma:

The mission of Mucodel is to develop improved rescue therapies that are oromucosally administered. Mucodel's proprietary Co-Gel technology allows for oromucosal administration of existing drugs that would not otherwise be amenable to oromucosal delivery. Mucodel's Co-Gel platform enables more convenient

products and offers tangible therapeutic benefits to patients.

Mucodel is a private company based in Greensboro, North Carolina.
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