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Ikano Therapeutics Receives Orphan Drug Designation for Epilepsy Drug

SADDLE BROOK, N.J.--([BUSINESS WIRE](#))--Ikano Therapeutics, Inc. (ITI) announced today that it has received Orphan Drug designation for midazolam in the acute treatment of certain forms of epileptic seizure known as cluster seizures or alternatively, as acute repetitive seizures. ITI has a nasally administered form of midazolam called ITI-111 in late stage clinical development that is aimed at the treatment of these specific seizure types in an outpatient setting where other routes of administration can be difficult or inappropriate. Orphan Drug status confers seven years of marketing exclusivity for medicines that meet specific criteria in the treatment of qualifying conditions and patient populations.

Commenting on the announcement, Lawrence J. Hirsch, MD, Associate Clinical Professor of Neurology at Columbia University's Comprehensive Epilepsy Center and an expert clinical advisor to ITI said, "ITI-111 is a product with great potential value for patients with poorly controlled epilepsy of the cluster-type included in this designation. These patients struggle to lead normal lives. With this nasal preparation, patients will be able to function with greater independence and greater confidence that their seizures can be treated successfully when they occur. In addition, this is a much more practical and acceptable dosage form than any currently approved acute treatment of seizure clusters in the outpatient setting. Having a well studied, standardized midazolam formulation that is optimized for intranasal delivery and absorption will be a major advance in the outpatient care of patients with epilepsy. Orphan Drug status is a welcome step towards that goal."

Orphan Drug status is a designation created in 1983 by section 526 of the Federal Food, Drug, and Cosmetic Act intended to encourage private sector investment in medicines for specialized diseases afflicting relatively small patient populations. The marketing exclusivity it provides is based on the first product utilizing a particular molecular entity to enter the market, regardless of the dosage form.

Midazolam belongs to a class of medicines known as benzodiazepines that are a commonly recognized acute treatment for seizure. While the use of nasally administered midazolam to patients having seizures has been extensively documented in the clinical literature, there is no form of the drug currently approved for treatment of epilepsy or seizures. Benzodiazepines have proven difficult to formulate for nasal administration, and ITI-111 employs a proprietary formulation that permits administration of a full dose for the treatment of these seizure types in a single, unit-dose nasal spray.

About ITI

Ikano Therapeutics Inc. (ITI) is a specialty pharmaceutical company focused on developing innovative specialty therapeutics, with an emphasis on drugs in areas for which there is proven, unsatisfied medical and patient need. ITI's goal is to apply formulation and development expertise across selected therapeutic areas to create new and differentiated products that improve safety, efficacy and clinical utility for patients, caregivers and health care professionals. For more information, please visit the ITI web site at <http://www.ikanotherapeutics.com>.

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