NEUROPATHIC PAIN DRUG P2X4 RECEPTOR ANTAGONIST NC-2600 MOVES INTO PHASE 1 CLINICAL TRIAL

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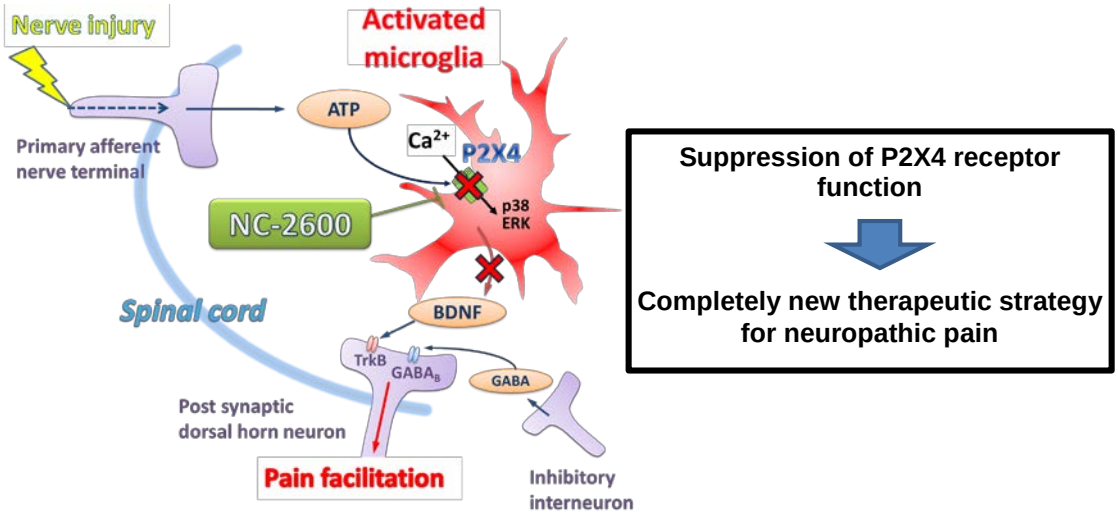
Kyushu University and Nippon Chemiphar Co., Ltd. (hereinafter “Chemiphar”) have started a phase 1 clinical trial of neuropathic pain[1] drug NC-2600 in June 2016. NC-2600 is novel P2X4 receptor[2] antagonist under joint development with the support of the Japan Agency for Medical Research and Development (AMED).

In 2003, the research group of Kazuhide Inoue (Director and Vice President of Kyushu University) found out unusual increased expression of P2X4 receptor in the central nervous system on animal models of neuropathic pain and it enhance neural conduction of pain signals. The abnormal hypersensitivity leads to innocuous stimuli such as the light touch of clothing. Addition to it, they confirmed administration of a selective antagonist for this receptor suppressed the pain powerfully, thus revealing that this action mechanism might lead to development of a new drug for treatment of neuropathic pain.

In 2015, the research group and Chemiphar identified a drug candidate NC-2600, expected to exert efficacy by oral administration. Its nonclinical studies were completed and the phase 1 trial of NC-2600 has now started after submission of the clinical trial protocol to the Pharmaceuticals and Medical Devices Agency (PMDA).

Patients with neuropathic pain suffer from intense pain during their daily lives. Development of a new drug is desired because there are few options of remedies for the disease. NC-2600 is the first-in-class designed to control pain through targeting glial cells[3] and is expected to attenuate neuropathic pain evoked in peripheral and central nervous system.



(Source: ***Nature***, 424, 778-783. 2003; ***Nature***, 438, 1017-1021, 2005)

Outline of phase 1 clinical trial of NC-2600

Target disease	Neuropathic pain induced by peripheral and central nerves injury
Primary endpoints	Safety and tolerability in healthy adult males
Region	Japan

Note:

1. Neuropathic pain

Type of pain arising from injury and abnormal function of nerves caused by various factors and intractable pain persisting chronically even after healing of the underlying disease responsible for nerve injury. It can be classified according to the site of nerve injury into peripheral neuropathic pain and central neuropathic pain. Because of its pathophysiology and onset mechanism are complex and diverse, analgesics such as NSAIDs (nonsteroidal anti-inflammatory drugs) have little efficacy.

2. P2X4 receptor

P2 receptor is a collective term for purine receptors for which ATP serves as a ligand. It can be classified roughly into two type: P2X receptor (ion channel type receptor) and P2Y receptor (G protein-coupled receptor). P2X4 receptor, targeted by NC-2600, is one of the 7 subtypes of P2X receptor and known to be closely involved in the onset of neuropathic pain originating from the central nervous system.

3. Glial cell

The central nervous system is made up of nerve cells and glial cells. Glial cells are characterized by their role of supporting and maintenance the nerve cells that are involved in signal transduction. Three major types of glial cell are known: astrocyte, oligodendrocyte and microglia.

Microglia is playing a role resembling immunocompetent cells in the central nervous system.

If abnormal situations occur in the brain, it immediately migrates to that site; change their form markedly; release cytokines or the like to eliminate foreign bodies such as pathogen and consume dead cells to keep the tissue clean.

About public funding for NC-2600

In collaboration with Kyushu University, Chemiphar is studying P2X4 receptor antagonists for their possible use in the treatment of neuropathic pain. In 2012, we applied to the Japan Science and Technology Agency (JST) for funding under the Adaptable and Seamless Technology Transfer Program (A-STEP) for our study. Although the JST's medical research and development support program was transferred to AMED, which was launched in April 2015, support for this theme is continuing.

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