# SUPPLEMENTAL DIGITAL CONTENT 1

## Inclusion Criteria

Patients were eligible for the study if they met all of the following criteria:

1. Provided written informed consent
2. Male or female aged 19 to under 80 years old
3. Patients with DPN who had HbA1c <=9.5% and experienced pain for at least six months or patients with PHN who experienced pain for at least three months after the diagnosis of skin rash due to herpes zoster
4. DPRS score ≥ 4 at least three times per week from one month prior to the screening visit
5. Stable concomitant treatment for underlying diseases
6. For women of childbearing potential (WOCBP):
   1. Had negative serum pregnancy test at the screening visit
   2. Willing to use ⴕappropriate contraception during the study

ⴕClinically appropriate contraceptive methods:

* Physical barrier methods used with intrauterine devices, chemical barrier methods, or subdermal contraceptive implant
* Tubal surgery
* Laparoscopic contraception

## Exclusion Criteria

Patients were excluded from participation if they met any of the following criteria:

1. Patients with brittle diabetes mellitus
2. Patients with pain other than DPN or PHN
3. Patients with neuropathy other than DPN or PHN
4. Prior treatment with SR pregabalin
5. Patients who were hypersensitive to pregabalin or a similar class drug, gabapentin
6. Patients who were hypersensitive to acetaminophen
7. Patients with aspirin-induced asthma (asthmatic attacks caused by nonsteroidal anti-inflammatory drugs) or a history of aspirin-induced asthma
8. Patients who received ‡prohibited treatment within seven days before the placebo run-in period
9. Patients with a clinically significant chronic infection (e.g., AIDS, etc.) or a significant medical or psychiatric illness
10. Patients who have been diagnosed with congestive heart failure requiring medication
11. Patients with clinically significant ventricular tachycardia, atrial fibrillation, atrial flutter, or other arrhythmia that were deemed clinically meaningful by their physicians
12. Patients with symptoms of angioedema
13. Patients with acute or chronic illness that can cause tissue hypoxia, such as shock
14. Patients with peptic ulcer
15. Patients with mental defects (e.g., schizophrenia, dementia, etc.) that may interfere with study participation
16. Those who answered “Yes” to one or more of the items in the Columbia-Suicide Severity Rating Scale (C-SSRS)
17. Alanine transaminase (ALT) or aspartate transaminase (AST) level was more than three times the normal upper limit
18. Estimated glomerular filtration rate (eGFR) <60 mL/min/1.73 m2
19. Patients with a history of alcohol or drug abuse within one year from the screening
20. Patients with a history of gastrointestinal disorders, such as dehydration, diarrhea, and vomiting, within six months of the screening
21. Those with a history of malignant tumors. However, those who have been in §complete remission and did not experience a recurrence within a minimum of five years or whose malignant tumor that had developed was only basal cell carcinoma or squamous cell carcinoma of the skin can participate in the study.
22. Patients with hereditary problems of galactose intolerance, lactase deficiency, or glucose-galactose malabsorption
23. Pregnant or lactating women
24. Patients administered with an investigational product within three months prior to the screening of this study
25. Prisoners or involuntary detainees
26. Patients who were compulsorily detained for the treatment of a mental or physical (e.g., infectious disease) illness
27. Patients who were deemed ineligible for study participation by their physicians

‡Prohibited treatment

1. Neuropathic pain medications and analgesics, other than the study medications and rescue medication, were prohibited from the placebo run-in period until the end of the clinical study. However, antipyretics, which were prescribed for purposes other than pain control, were allowed to be taken for three or less consecutive days.
2. Antiepileptics and antidepressants were prohibited from the placebo run-in period until the end of the clinical study. However, it was allowed to use selective serotonin reuptake Inhibitors (SSRI) and tricyclic antidepressants (TCA) as antidepressants in a stable dosing state without changing the type, dose, and regimen from 14 days before the initiation of the placebo run-in period.
3. Exercise therapy, such as physical therapy, acupuncture, moxibustion, and fomentation (or folk remedies) that were considered to affect the results of the study, were prohibited during the study period. In addition, intense exercise, etc., were also prohibited during the study period.
4. Concomitant medications or therapies listed below were prohibited from the placebo run-in period until the end of the clinical study.

* Antiepileptics: pregabalin, gabapentin, carbamazepine, etc.
* Sleeping pills and anxiolytics: all medicines other than triazolam, zopiclone, and zolpidem tartrate were prohibited.
* Analgesics: opioids, tramadol, nefopam, etc.
* N-methyl-D-aspartate (NMDA) receptor antagonist: dextromethorphan, ketamine, memantine, etc.
* Muscle relaxants and topical capsaicin
* Local anesthetics: lidocaine, etc.
* Sodium channel blockers: Mexiletine, etc.
* Central nervous system sympatholytic agents: chronidine, etc.
* Steroids (excluding topical products)
* Cilostazol, prostaglandin, and related medications
* Vitamins B1 and B12 (if prescribed for peripheral neuropathic pain)
* Alpha fatty acids and gamma linolenic acid (evening primrose oil)
* Immunosuppressants (if prescribed for autoimmune disease)
* Medications that may cause irreversible retinal degeneration: phenothiazine, antipsychotics, deferoxamine, ethambutol, voriconazole, etc.
* Other investigational products

§Complete remission was defined as all symptoms and signs of cancer that were recognized before treatment were completely lost when evaluated by physical examination, blood test, radiological examination, etc., and these persisted for at least one month (source: National Cancer Information Center, Korea. Available at: <https://www.cancer.go.kr/>. Accessed Oct 13, 2020).