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- *All named persons associated with the study*
- *Patient identifiers within text, tables, or figures*
- *By-patient data listings*

Anonymized patient data may be made available subject to an approved research proposal submitted. Information which is considered intellectual property or company confidential was also redacted.

1.0 ABSTRACT

Title

Evaluation of the Effectiveness of Risk Minimization Measures: A survey among pharmacists to assess the impact of the RMP material for patients on promoting the proper use of NINLARO in Japan

Keywords

Ixazomib citrate, RMP, effectiveness evaluation, proper use, web-based survey

Rational and Background

In Japan, ixazomib (NINLARO) in combination with lenalidomide and dexamethasone (IRD therapy) for the indication of relapsed/refractory multiple myeloma (RRMM) was approved on 30 Mar 2017. Since its launch in Japan, Takeda created the RMP material for patients (target material) to instruct the dosing of IRD therapy and disseminated to patients via healthcare professional (HCP)s.

This web survey was planned to assess the effectiveness of the target material in prevention of ixazomib overdose in Japanese clinical practice.

Research Question and Objectives

Primary research question is to investigate whether the target material, which is defined as an additional risk minimization measure (aRMM) in J-RMP, is utilized for the proper use of NINLARO.

Primary Objective:

To assess the frequency of pharmacists who have provided their patients with the contents of the target material

Study Design

This is a web-based cross sectional questionnaire survey, which is intended for pharmacists who have instructed the dosing of IRD therapy to patients with RRMM.

Setting

Participants for this survey were recruited through email delivery to in-hospital pharmacists who were included in the Nikkei Medical Online Panel and were able to receive email. Pharmacists consented and were confirmed to be eligible to participate in this survey and who answered all questions were included in the analysis. Participant recruitment and response collection started on June 1, 2023 and ended on June 9, 2023.

Subjects and Study Size, Including Dropouts

Expected sample size was set as 300 pharmacists.

Variables and Data Sources

Information on

- participating pharmacists
- hospitals where pharmacists are working
- the status of providing patients with the contents of the target material
- recollection of having obtained the target material
- pharmacists' awareness of the proper use of NINLARO, etc.

The survey was a primary data collection among pharmacists who had instructed the NINLARO dosing for IRD therapy to patients.

Results

330 pharmacists who completed all questions were included in the analysis. 307 (93.0%) answered that they explained how to take NINLARO to patients. Of these, 102 (33.2%) answered that they had experience using the target material when explaining how to take NINLARO to patients. Of 120 pharmacists who answered that they obtained the target material and explained how to take NINLARO to patients, 86 (71.7%) answered that they had experience using the target material.

Discussion

It was found that the majority of pharmacists explained how to take NINLARO to patients. On the other hand, the proportion of pharmacists who have experience using the target material at the time of explanation was about 30%. However, among those had obtained the target material and explained how to take NINLARO to patients, approximately 70% answered that they had used the target material, suggesting that the target material is being used.

In conclusion, the contents of the target material were appropriately explained to patients by pharmacists, and the target material was considered to play a role in promoting the proper use of NINLARO.

Marketing Authorization Holder(s)

TAKEDA PHARMACEUTICAL COMPANY LIMITED

1-1, Doshomachi 4-chome Chuo-ku, Osaka 540-8645, JAPAN

Names and Affiliations of Principal Investigators

[redacted]

Director, Global Patient Safety Evaluation Japan, Takeda Development Center Japan

Takeda
C16065
NINLARO, ixazomib citrate
Takeda Pharmaceutical Company Limited

[redacted]

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