ZISTDARU DANESH Co.
Tehran - Iran

Tehran University of Medical Sciences

European Charcot Foundation

Post-marketing experience

of safety profile of interferon beta 1 b biosimilar product in relapsing remitting multiple sclerosis: 7 years' follow-up

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Introduction

Interferon (INF) beta 1b was the first disease modifying drug (DMD) approved by FDA for the treatment of relapsing-remitting multiple sclerosis (RRMS) in 1998. Regarding potentially long- term use of established DMDs in MS treatment, data evaluation of safety profile on a large group of people for an appropriate duration is recommended.

Objectives

The goal of this study is evaluation of long term safety outcomes of biosimilar product of INF beta 1b (Ziferon®; 300 mcg vial) produced by Zistdaru Danesh biopharmaceutical company in Iranian patients with relapsing-remitting MS over 7 years.

Method

A non-interventional cohort study was conducted on 5311 patients from Aug 2011 to March 2019. The patients had a confirmed and documented diagnosis of RRMS as defined by the Revised McDonald Criteria (2010), were ambulatory with a Kurtzke Expanded Disability Status Scale score of 0 to 5.5, and their treatment by Ziferon 300 mcg subcutaneously every other day was just started. Safety profile including adverse drug reactions (ADRs), and its severity and related-laboratory tests were monitored over 7 years.

Results

The most common reported adverse drug reactions during period of the time were injection site reaction (69.38%), flu-like symptoms (21.99%), central nervous system (3.5%), musculoskeletal system (2.03%), and gastrointestinal (1.96%) which all were mild to moderate and rarely caused treatment discontinuation (Fig 1, 2). Injection site reactions was the most common reason for drug discontinuation (Fig 3).

Conclusion

The present post-marketing study confirms long term tolerability and safety outcomes of biosimilar product of INF beta 1 b (Ziferon®) in Iranian RRMS patients was acceptable and no new alarming signal was detected during the study period.

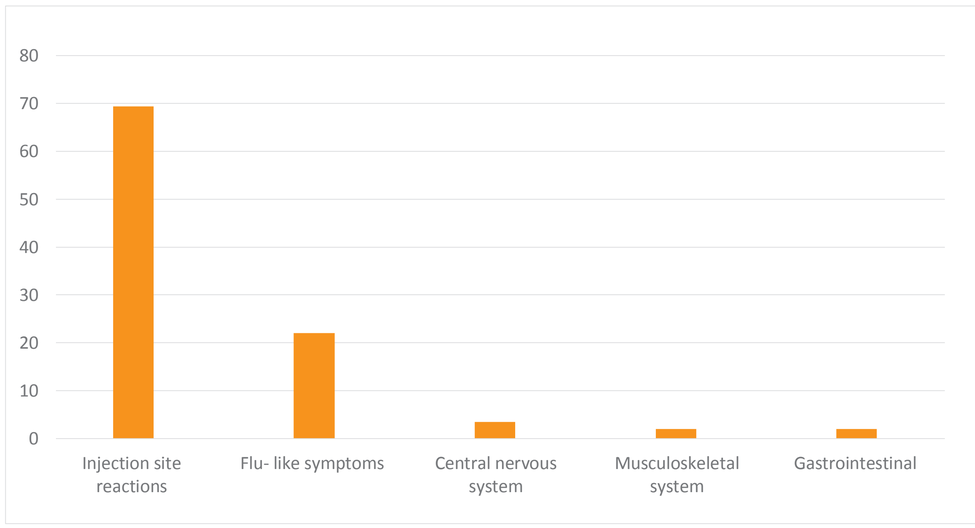

Figure 1 : **Adverse effect categories**

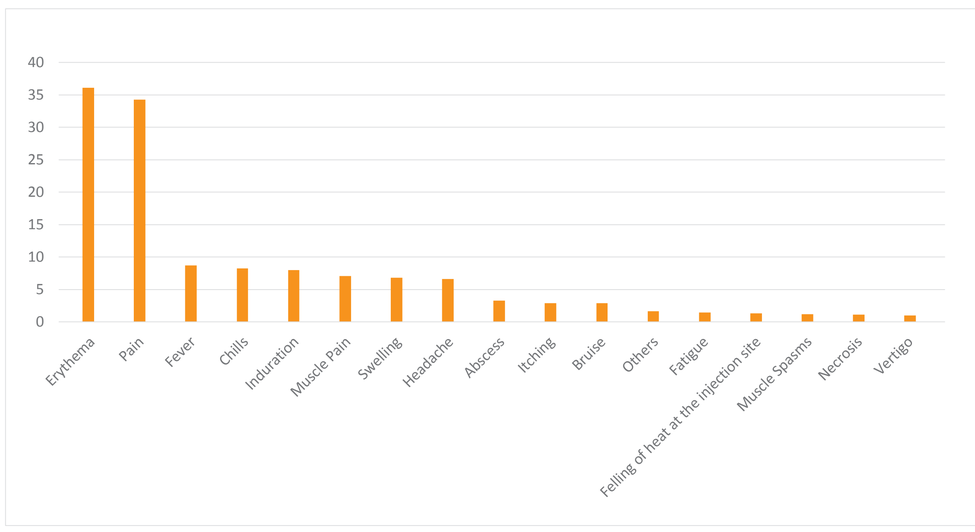

Figure 2 : **Subcategories of adverse effect**

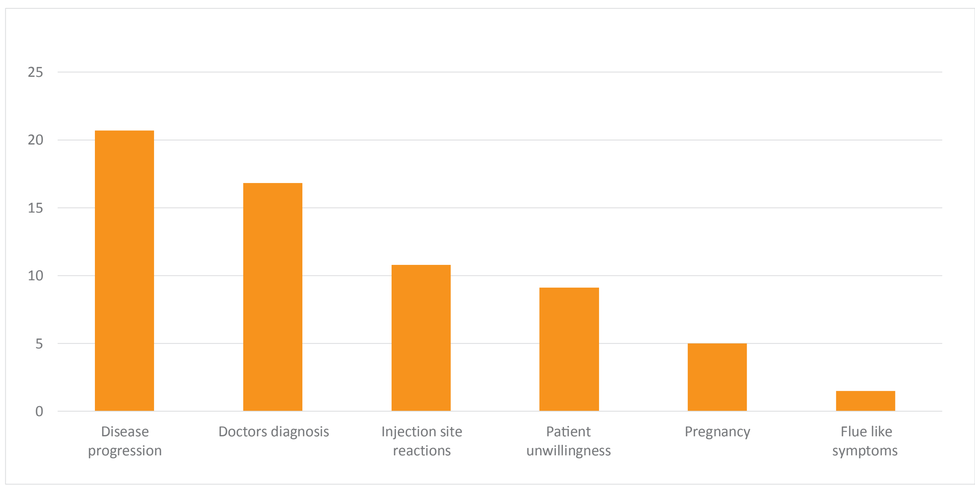

Figure 3 : **Subcategories of drug discontinuation causes**

Literature

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