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Evaluation of efalizumab using safe psoriasis control

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Abstract

Background: Safe Psoriasis Control (SPC) is an important comprehensive measure that is validated for the assessment of benefit:risk of psoriasis treatments, combining efficacy, quality of life, and safety measures. The objective of this analysis was to assess the benefit:risk of efalizumab, a novel biologic agent indicated for the treatment of moderate-to-severe plaque psoriasis, by applying the SPC to data from randomized, placebo-controlled clinical studies of efalizumab.

Methods: SPC was applied to week 12 data from four placebo-controlled, Phase III studies: three retrospective and one prospective, the latter including a cohort of "high-need" patients for whom existing therapies were inadequate or unsuitable.

Results: In the retrospective analysis, 39.4% of patients achieved SPC after 12 weeks of treatment with efalizumab, compared with 10.4% for placebo. In the prospective analysis, 34.3% of patients achieved SPC after 12 weeks of treatment with efalizumab, compared with 7.3% on placebo. Among high-need patients, 33.0% achieved SPC, compared with 3.4% on placebo.

Conclusion: Efalizumab has a favorable benefit:risk profile using the comprehensive outcome measure SPC.

Background

Over the past decade, technological advancements have resulted in a substantial increase in the number of new molecules under investigation for the treatment of psoriasis. At the same time has come the realization that current efficacy measures have significant limitations in assessing the full therapeutic benefit of psoriasis therapies. Despite its shortcomings, the most widely used measure to assess efficacy of new therapies has remained the Psoriasis Area and Severity Index (PASI) [1,2]. However, concerns regarding this endpoint [3] and the lack of use of PASI in current practice by dermatologists have resulted in the development of alternative measures such as the Salford Psoriasis Index (SPI) [4], the Self Administered PASI (SAPASI) [5], the Koo-Menter Psoriasis Instrument [6], and the National Psoriasis Foundation Psoriasis Score (NPF-PS) [7].

To more fully evaluate and interpret the benefit:risk of new therapies for psoriasis requires measures that assess multiple dimensions of the disease in a clinically meaningful way for patients and physicians alike. Safe Psoriasis Control (SPC) [3] is such a measure that is designed to improve relevance and comparability between studies and drugs by focusing on all clinically relevant outcomes so that accurate assessments can be made regarding new therapies for psoriasis [8].