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Acceptable Clinical Trial Differences vs Placebo in Plaque Psoriasis

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Introduction & Objectives: In plaque psoriasis (PsO) dermatologists have a substantial number of advanced systemics in their armamentarium. Each biologic option increases the efficacy threshold resulting in a saturated biologic market. As such, the pipeline for psoriasis product is primarily comprised of oral options in a variety of mechanism of actions. This research sought to understand what dermatologists consider to be minimally acceptable and a significant advance for PASI-75 and PASI-90 among in-line and pipeline oral options in the US and EU5.

Materials & Methods: An independent market analytics firm collaborated with US & EU5 dermatologists (n=372) to conduct analysis of the PsO market. Data were collected via an online survey fielding at various time points from October 25, 2023, through February 26, 2024, including physician demographics, product usage, and attitudinal survey responses.

Results: With an expanding armamentarium, dermatologists across the US and EU5 report PsO has one of the lowest unmet needs for new treatment options compared to other dermatology conditions with most physicians reporting a low to moderate need. Despite having access to oral options such as apremilast and deucravacitinib, the desire for a highly efficacious, yet safe oral option is reported across geographies.

When reviewing placebo-controlled clinical trials for oral options in PsO, US dermatologists consider the minimally acceptable improvement (delta between study results vs placebo) for PASI-75 to be 38% and 32% for PASI-90. EU5 dermatologists report similar figures for PASI-75, though they report a higher delta for PASI-90 (39%). When compared to various clinical trial results for apremilast, deucravacitinib, JNJ-2113, orismilast, and ME3183, all molecules are at or nearly meeting dermatologists' minimally acceptable range, apart from apremilast.

When identifying what would be considered a significant advance over the standard of care, US dermatologists consider a delta of 62% for PASI-75 and 56% for PASI-90 as a significant advance. EU5 dermatologists report a similar delta of 63% for PASI-75 and report a higher delta of 61% for PASI-90. The deltas from various clinical trial results for apremilast, deucravacitinib, JNJ-2113, orismilast, and ME3183, suggest only JNJ-2113 at the 100mg dose meets physician's expectations.

Regarding perceptions of JNJ-2113, dermatologists across geographies are more interested in having the oral IL-23 inhibitor approved and a greater percentage of physicians anticipate prescribing the asset within the first three months of being available compared to other oral assets.

Conclusion: With a substantial armamentarium for biologics in psoriasis,** physicians express a need for efficacious and safe oral options for PsO. Current late-stage assets and deucravacitinib meet dermatologists' minimum threshold for improvement, however, only JNJ-2113 100mg meets the delta considered to be a significant advance over the standard of care. Data suggests JNJ-2113 would fill an unmet need if approved.