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Novartis reports new Phase III data showing secukinumab (AIN457) improved moderate-to-severe plaque psoriasis in patients

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- - FEATURE and JUNCTURE data show secukinumab delivered significant skin clearance at week 12(1,2)
- - Patients reported high satisfaction with self-administration of secukinumab pre-filled syringe or autoinjector/pen(3,4)
- - Secukinumab is the first IL-17A inhibitor with Phase III data and the first psoriasis medication to be filed with the FDA targeting the IL-17 pathway

EAST HANOVER, N.J., March 22, 2014 /PRNewswire/ -- Novartis today announced results from the Phase III FEATURE and JUNCTURE studies showing secukinumab (AIN457), a selective interleukin-17A (IL-17A) inhibitor, met both co-primary endpoints at Week 12 based on Psoriasis Area and Severity Index (PASI) 75 and Investigator's Global Assessment modified 2011 (IGA mod 2011) 0/1 response rates compared to placebo. Results from these studies also demonstrated skin clearance at Week 12 based on PASI 90 response rates compared to placebo, usability and acceptability of the secukinumab pre-filled syringe (PFS) and autoinjector pen (AI), and an approximately 50% mean decrease in PASI scores from baseline by Week 3 (300mg) and Week 4 (150mg).(1,2,3,4) These results, along with more than 20 posters were presented for the first time at the 72nd Annual Meeting of the American Academy of Dermatology (AAD) in Denver.

"The results from FEATURE and JUNCTURE offer insights into the potential of secukinumab as a treatment option for moderate-to-severe plaque psoriasis," said Andre Wyss, President, Novartis Pharmaceuticals Corporation, and President, Novartis Corporation. "We are committed to developing innovative therapies that address significant patient unmet needs. We look forward to providing additional information from ongoing secukinumab clinical trials to the dermatology community."

FEATURE results showed the efficacy of secukinumab 300mg and 150mg based on a statistically significant higher proportion of patients who achieved a PASI 75 response at Week 12 compared with placebo patients: 75.9% (300mg) and 69.5% (150mg), versus 0% for placebo (p <.0001). On the co-primary endpoint, the efficacy of secukinumab 300mg and 150mg was shown based on a statistically significant higher proportion of patients who achieved an IGA mod 2011 0/1 response at Week 12 compared with placebo: 69.0% (300mg) and 52.5% (150mg), versus 0% for placebo (p <.0001).(1)

Results from JUNCTURE also showed the efficacy of secukinumab 300mg and 150mg based on a statistically significant higher proportion of patients who achieved a PASI 75 response at Week 12 compared with placebo: 86.7% (300mg) and 71.7% (150mg), versus 3.3% for placebo (p <.0001). On the co-primary endpoint, the efficacy of secukinumab 300mg and 150mg was shown based on a statistically significant higher proportion of patients who achieved an IGA mod 2011 0/1 response at Week 12 compared with placebo: 73.3% (300mg) and 53.3% (150mg), versus 0% placebo (p <.0001).(2)

Additionally, more secukinumab patients in both studies experienced an improvement in PASI of greater than

or equal to 90% (PASI 90) from baseline as compared to placebo,(1,2) which is a higher standard of skin clearance compared to PASI 75. In FEATURE 60.3% (300mg) and 45.8% (150mg) of secukinumab patients achieved a PASI 90 response at Week 12 compared to 0% of placebo patients (p <.0001).(1) In JUNCTURE, 55% (300mg) and 40% (150mg) of secukinumab patients achieved a PASI 90 response at Week 12 compared to 0% of placebo patients (p <.0001).(2)

In FEATURE (n=177), the most common adverse events (AEs) in any treatment group including placebo were diarrhea, nasopharyngitis and headache. There were a total of four serious adverse events in the study – three (5.1%) in the 300mg secukinumab arm and one (1.7%) in the placebo arm. Two patients (one in secukinumab 300mg arm, one in placebo arm) discontinued due to AEs.(1) In JUNCTURE (n=182), the most common AEs in any treatment group including placebo were nasopharyngitis, headache, pruritus and hypertension.(2) There were a total of five serious adverse events in the study – one (1.7%) in the 300mg secukinumab arm, three (4.9%) in the 150mg secukinumab arm and one (1.6%) in the placebo arm. One patient in the placebo arm discontinued due to adverse event.(2) There were no deaths reported during either study.(1,2)

Patient satisfaction and usability data related to self-injection also presented at AAD
A secondary endpoint of both FEATURE and JUNCTURE measured patient satisfaction and usability with self-injection of secukinumab via PFS and AI, respectively. Satisfaction was assessed in both studies using a self-administered Self-Injection Assessment Questionnaire (SIAQ) which measures overall subject experience with subcutaneous self-injection before the first self-injection and after dosing on the domains of feelings about injections, self-confidence, satisfaction with self-injection, injection-site reactions, ease of use, and self-image. Overall, patient-reported acceptability of both the PFS and AI were high at baseline across both studies and remained high during the study. These studies were presented in separate posters at AAD.(3,4)

"Treating psoriasis can be challenging as not all treatments are appropriate or effective in every patient," said Dr. Andrew Blauvelt, President of the Oregon Medical Research Center and an investigator in the secukinumab clinical trial program. "The clinical data we have seen with secukinumab suggest it may offer a new therapeutic approach for patients living with moderate-to-severe plaque psoriasis."

Studies presented at AAD are part of a clinical program reporting results in moderate-to-severe plaque psoriasis with more than 3,000 patients in over 35 countries.

About FEATURE
FEATURE (First study of sEcukinumAb in prefilled syringes in subjecTs with chronic plaqUe-type psoriasis REsponse) was a randomized double-blind, placebo-controlled, multicenter, Phase III study involving 177 subjects with moderate-to-severe plaque psoriasis. In this study, prefilled syringes (PFS) were introduced into the secukinumab clinical program.(1)

The co-primary endpoints were assessed at Week 12 and compared secukinumab efficacy versus placebo according to PASI 75 and Investigator's Global Assessment modified 2011 (IGA mod 2011) 0/1 response. Secondary endpoints included PASI 90 response up to Week 12 and patient satisfaction with self-injection of secukinumab via PFS determined by a self-administered Self-Injection Assessment Questionnaire (SIAQ). The trial is ongoing.(1)

About JUNCTURE
JUNCTURE (Judging the efficacy of secUkinumab in patients with psoriasis using autoiNjector: a Clinical Trial evalUating treatment REsults) was a double-blind, placebo-controlled, multicenter, Phase III study involving 182 subjects with moderate-to-severe plaque psoriasis. In this study, the autoinjector/pen (AI) was introduced into the secukinumab clinical program.(2)

The co-primary endpoints were PASI 75 and Investigator's Global Assessment modified 2011 (IGA mod 2011) 0/1 response for secukinumab vs placebo at Week 12. Secondary endpoints included PASI 90 response up to Week 12 and patient satisfaction with self-injection of secukinumab via the AI device determined by a self-administered Self-Injection Assessment Questionnaire (SIAQ). The trial is ongoing.(2)

About secukinumab (AIN457) and interleukin-17A (IL-17A)
Secukinumab (AIN457), an investigational agent, is a fully human monoclonal antibody (mAb) that selectively targets interleukin IL-17A.(5) Secukinumab has been shown to selectively bind to and neutralize IL-17A, inhibiting its pro-inflammatory effects.(6,7)

IL-17A is a key cytokine (messenger protein) involved in the development of plaque psoriasis, and is found in high concentrations in psoriasis skin plaques.(8) Research shows that IL-17A plays an important role in driving the body's immune response in disorders such as moderate-to-severe plaque psoriasis and may represent a new target for investigational therapies.(9,10)

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