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Novartis to present first IL-17A Phase III data for AIN457 (secukinumab) in psoriatic arthritis and ankylosing spondylitis at ACR 2014

Nov 10, 2014

- - Four pivotal Phase III studies of secukinumab in psoriatic arthritis (PsA) and ankylosing spondylitis (AS) to be presented for the first time at ACR 2014
- - Secukinumab is the first selective interleukin-17A (IL-17A) inhibitor with Phase III data to demonstrate efficacy and improve symptoms in patients with PsA and AS
- - Results from FUTURE 1 and FUTURE 2 in PsA and MEASURE 1 and MEASURE 2 in AS to be presented including joint structural damage progression in PsA and symptoms, quality of life/physical function in PsA and AS
- - PsA and AS are part of a spectrum of long-term diseases impacting joints, known as spondyloarthritis (SpA); high unmet treatment need exists for patients living with SpA

EAST HANOVER, N.J., Nov. 10, 2014 /PRNewswire/ -- Novartis announced today that data from two pivotal Phase III studies (FUTURE 1 and FUTURE 2) in psoriatic arthritis (PsA) patients and two pivotal Phase III studies (MEASURE 1 and MEASURE 2) in patients with ankylosing spondylitis (AS) will be presented at the American College of Rheumatology (ACR) Congress, November 14-19, in Boston. The four oral presentations and four posters measure efficacy and symptom improvement in PsA and AS patients treated with AIN457 (secukinumab). US regulatory applications of secukinumab in PsA and AS are planned to be submitted in 2015.

Secukinumab is the first selective IL-17A inhibitor with positive Phase III results in PsA and AS which are common conditions of spondyloarthritis (SpA). These conditions represent a spectrum of long-term debilitating diseases impacting joints (inflammatory diseases), which can lead to irreversible damage. There is a high unmet need for new treatment options for both PsA and AS. Approximately 45% of people with PsA are dissatisfied with their treatment. Additionally, for AS patients who do not respond to non-steroidal anti-inflammatory drugs (NSAIDs), there are very few therapeutic options available and they may not be effective for all patients.

Novartis rheumatology highlights at ACR 2014 include:

Oral presentations:

- FUTURE 1: Efficacy and Safety Data from a Phase 3 Randomized, Multicenter, Double-Blind, Placebo-Controlled Study of Secukinumab in Psoriatic Arthritis (abstract 953; November 16, 4:45 PM – 5:00 PM EST)
- FUTURE 1: Joint Structural Damage in Active Psoriatic Arthritis: a Phase 3 Randomized, Double-Blind, Placebo-Controlled Study of Secukinumab (abstract 954; November 16, 5:00 PM – 5:15 PM EST)
- MEASURE 1: Results of a 52-Week Phase 3 Randomized Placebo-Controlled Trial in Ankylosing Spondylitis with Intravenous Loading and Subcutaneous Maintenance Dosing of Secukinumab (abstract 819; November 16, 12:15 PM – 12:30 PM EST)
- FUTURE 2: 24-Week Efficacy and Safety Data from a Phase 3 Randomized, Multicenter, Double-Blind,

Placebo-Controlled Study using Subcutaneous Dosing of Secukinumab in Psoriatic Arthritis (abstract L1, Late-breaking abstracts session; November 18, 2:30 PM – 2:45 PM EST)

Posters available throughout the congress:

- FUTURE 1: Physical Function, Quality of Life and Work Productivity in Patients with Active Psoriatic Arthritis: Results from a Phase 3, Randomized, Controlled Trial of Secukinumab (abstract 550; November 16, 8:30 AM – 4:00 PM EST)
- FUTURE 1: Psoriasis Burden in Patients with Psoriatic Arthritis: Results from a Phase 3 Randomized Controlled Trial of Secukinumab (abstract 537; November 16, 8:30 AM – 4:00 PM EST)
- MEASURE 1: Physical Function and Quality of Life in Subjects with Active Ankylosing Spondylitis: Results of a Phase 3 Randomized, Placebo-Controlled Trial with Intravenous Loading and Subcutaneous Maintenance Dosing of Secukinumab (abstract 538; November 16, 8:30 AM – 4:00 PM EST)
- MEASURE 2: Signs and Symptoms of Active Ankylosing Spondylitis: Results of a Phase 3, Randomized, Placebo-Controlled Trial with Subcutaneous Loading and Maintenance Dosing of Secukinumab (abstract 536; November 16, 8:30 AM – 4:00 PM EST)

About secukinumab (AIN457)
Secukinumab (AIN457) is a human monoclonal antibody (mAb) that selectively binds to and neutralizes IL-17A. Secukinumab is the first IL-17A inhibitor with positive Phase III results for the treatment of PsA and AS. Research shows that IL-17A plays an important role in driving the body's immune response in psoriasis and certain inflammatory arthritic diseases, such as PsA and AS.

In addition to PsA and AS, secukinumab is also in clinical trials for the treatment of rheumatoid arthritis (RA). US regulatory applications for secukinumab in AS and PsA are planned for 2015. This follows the secukinumab US regulatory application for moderate-to-severe plaque psoriasis which was filed in October 2013 with approval anticipated in early 2015.

About psoriatic arthritis (PsA)
Psoriatic arthritis (PsA) is a debilitating, long-lasting inflammatory disease linked with significant disability, poor quality of life and reduced life expectancy. PsA is associated with joint pain and stiffness, skin and nail psoriasis, swollen toes and fingers, persistent painful tendonitis, and irreversible joint damage. Between 0.3% and 1% of the general population may be affected by PsA and as many as one in four people with psoriasis may have undiagnosed PsA.

About ankylosing spondylitis (AS)
Ankylosing spondylitis (AS) is a common type of spondyloarthritis (SpA), a spectrum of long-term diseases of joints (inflammatory disease). Up to 70% of patients with severe AS can develop spinal fusion (bones grow together), significantly reducing mobility and quality of life. AS occurs in up to 1% of the general population and typically affects young men and women aged 25 or older. Certain genetic factors may increase a person's risk of developing AS by more than 50%.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as "to present," "to be presented," "will," "planned," "can," "may," "anticipated," or similar terms, or by express or implied discussions regarding potential marketing authorizations for AIN457, or regarding potential future revenues from AIN457. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially

from those set forth in the forward-looking statements. There can be no guarantee that AIN457 will be submitted in AS or PsA in any market, or approved for any indication, or at any particular time. Nor can there be any guarantee that AIN457 will be commercially successful in the future. In particular, management's expectations regarding AIN457 could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected manufacturing issues, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis
Novartis Pharmaceuticals Corporation researches, develops, manufactures and markets innovative medicines aimed at improving patients' lives. We offer a broad range of medicines for cancer, cardiovascular disease, endocrine disease, inflammatory disease, infectious disease, neurological disease, organ transplantation, psychiatric disease, respiratory disease and skin conditions. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2013, the Group achieved net sales of USD 57.9 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 135,000 full-time-equivalent associates and sell products in more than 150 countries around the world. For more information, please visit http://www.novartis.com.

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