Novartis to reveal landmark Phase III data for AIN457 (secukinumab) in psoriatic arthritis and ankylosing spondylitis at ACR 2014

- Detailed results of 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

- Data will include study results from FUTURE 1 and FUTURE 2 in PsA and MEASURE 1 and MEASURE 2 in AS; data to be presented include joint structural damage progression in PsA and symptoms, quality of life/physical function in PsA and AS

- PsA and AS are part of a family of long-term diseases impacting joints, known as spondyloarthritis (SpA); high unmet treatment need exists for patients living with SpA

Basel, 10 November 2014 – Novartis announced today that four oral presentations and four posters for AIN457 (secukinumab) will be presented at the American College of Rheumatology (ACR) Congress, 14-19 November, in Boston, Massachusetts, USA. The secukinumab abstracts include 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). All studies met primary endpoints. Global regulatory applications of secukinumab in PsA and AS will be submitted in 2015.

Secukinumab is the first selective IL-17A inhibitor with positive results in PsA and AS which are common conditions of spondyloarthritis (SpA). SpA is a family 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. Specifically, many people with PsA do not respond to or tolerate anti-TNF (tumor-necrosis-factor) medicines, the current standard of care, with approximately 45% of people dissatisfied with current treatments. Additionally, people with AS have very few therapeutic options available to them. In case of non-response to non-steroidal anti-inflammatory drugs (NSAIDs), anti-TNF medicines are the only currently available biologic treatment alternative but are not effective for all patients.

“There remains a significant unmet need for new Psoriatic Arthritis and Ankylosing Spondylitis therapies as many patients have an inadequate or no response to available treatments,” said Vasant Narasimhan, Global Head of Development, Novartis Pharmaceuticals. “At Novartis, we are committed to providing new treatment options for patients suffering from these debilitating joint diseases that can significantly impact a patient’s quality of life. We’re excited about the Phase III data we’re presenting at ACR 2014 and what these results could mean for patients.”
Novartis rheumatology highlights at ACR 2014 include:

Oral presentations:
- FUTURE 1: Secukinumab, a Human Anti–Interleukin-17A Monoclonal Antibody, Improves Active Psoriatic Arthritis and Inhibits Radiographic Progression: Efficacy and Safety Data from a Phase 3 Randomized, Multicenter, Double-Blind, Placebo-Controlled Study (abstract 953; 16 November, 4:45 PM – 5:00 PM EST)
- FUTURE 1: Secukinumab, A Monoclonal Antibody to Interleukin-17A, Provides Significant and Sustained Inhibition of Joint Structural Damage in Active Psoriatic Arthritis Regardless of Prior TNF Inhibitors or Concomitant Methotrexate: a Phase 3 Randomized, Double-Blind, Placebo-Controlled Study (abstract 954; 16 November, 5:00 PM – 5:15 PM EST)
- MEASURE 1: Secukinumab, a Monoclonal Antibody to Interleukin-17A, Significantly Improves Signs and Symptoms of Active Ankylosing Spondylitis: Results of a 52-Week Phase 3 Randomized Placebo-Controlled Trial with Intravenous Loading and Subcutaneous Maintenance Dosing (abstract 819; 16 November 12:15 PM – 12:30 PM EST)
- FUTURE 2: Secukinumab, a Human Anti-Interleukin-17A Monoclonal Antibody, Improves Active Psoriatic Arthritis: 24-Week Efficacy and Safety Data from a Phase 3 Randomized, Multicenter, Double-Blind, Placebo-Controlled Study Using Subcutaneous Dosing (Late-breaking abstracts session; 18 November 2:30 PM – 2:45 PM EST)

Posters available throughout the congress:
- FUTURE 1: Secukinumab, An Anti–Interleukin-17A Monoclonal Antibody, Improves Physical Function, Quality of Life and Work Productivity in Patients with Active Psoriatic Arthritis: Results from a Phase 3, Randomized, Controlled Trial (abstract 550, 16 November 8:30 AM – 4:00 PM EST)
- FUTURE 1: Secukinumab, A Human Anti–Interleukin-17A Monoclonal Antibody, Significantly Reduces Psoriasis Burden in Patients with Psoriatic Arthritis: Results from a Phase 3 Randomized Controlled Trial (abstract 537, 16 November 8:30 AM – 4:00 PM EST)
- MEASURE 1: Secukinumab, a Monoclonal Antibody to Interleukin-17A, Significantly Improves 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 (abstract 538, 16 November 8:30 AM – 4:00 PM EST)
- MEASURE 2: Secukinumab, a Monoclonal Antibody to Interleukin-17A, Significantly Improves Signs and Symptoms of Active Ankylosing Spondylitis: Results of a Phase 3, Randomized, Placebo-Controlled Trial with Subcutaneous Loading and Maintenance Dosing (abstract 536, 16 November 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). Global regulatory applications for secukinumab in AS and PsA are planned for 2015. This follows the secukinumab global regulatory applications for moderate-to-severe plaque psoriasis which were filed in October 2013 with approvals anticipated in late 2014 or 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 family 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 reveal,” “to be presented,” “will,” “committed,” “could,” “planned,” “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 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 133,000 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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