Novartis AIN457 (secukinumab) is the first ever IL-17A inhibitor to meet primary endpoint in two Phase III studies in psoriatic arthritis

- **Secukinumab met primary and key secondary endpoints in two pivotal Phase III studies showing superiority to placebo in patients with adult onset psoriatic arthritis (PsA)**

- **PsA is a debilitating, long-lasting condition that causes inflammation of joints and skin and affects up to 30% of people with psoriasis globally**[^1]**[^2]

- **Many people with PsA do not respond to current standard of care, with approximately 45% of people dissatisfied with current treatments**[^3]

- **Secukinumab is the first interleukin-17A (IL-17A) inhibitor with positive Phase III results in PsA and regulatory submissions are planned for 2015**

**Basel, September 25, 2014** – Novartis today announced that two pivotal Phase III studies (FUTURE 1 and FUTURE 2) of AIN457 (secukinumab) in psoriatic arthritis (PsA) met primary and key secondary endpoints. Endpoints included improving signs and symptoms of psoriatic arthritis (PsA), including improving peripheral joint disease and preventing joint damage versus placebo, while delivering clear or almost clear skin (PASI 90). Secukinumab is an investigational medicine that works by stopping the action of interleukin-17A (IL-17A)[^4], a protein that is central to the development of inflammatory diseases[^5]. FUTURE 1 and FUTURE 2 enrolled a combined total of more than 1,000 patients. Detailed results of the studies will be presented at an upcoming medical congress.

PsA is a long-lasting, complex condition involving joint inflammation (arthritis), and usually occurs in combination with psoriasis[^1]. There are many different features of PsA that affect the skin, joints and tendons, resulting in irreversible joint damage in many patients[^1]. It is linked with significant disability, poor quality of life, reduced life expectancy[^1] and major economic burden for the society[^6].[^8]. Although TNF (tumor-necrosis-factor) inhibitors, the current standard of care for PsA[^10].[^11], can improve clinical symptoms[^11].[^16], responses may diminish over time. Furthermore, many patients with PsA do not respond to or tolerate these agents[^4], leaving an unmet need.

“Building on the positive data previously reported in psoriasis, we are excited to present the first Phase III results of secukinumab in PsA. These positive results are planned to form the basis of a filing application to regulatory authorities in this indication,” said Vasant Narasimhan, Global Head of Development, Novartis Pharmaceuticals. “Effective new therapies are urgently needed for newly PsA diagnosed patients and for nearly half of PsA patients who are dissatisfied with or not responding to their current treatments.”

Global regulatory applications for secukinumab in 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.

FUTURE 1 and FUTURE 2 are randomized, placebo-controlled, multicenter studies designed to demonstrate efficacy of secukinumab in PsA compared to placebo and to assess safety and tolerability. The American College of Rheumatology response criteria (ACR20) was the primary endpoint in the studies. Secukinumab was well tolerated in both studies. The observed safety
profile was consistent with previously reported results from the large psoriasis clinical trial program involving nearly 4,000 patients\textsuperscript{17}.

**About psoriatic arthritis (PsA)**

Psoriatic arthritis (PsA) is closely associated with psoriasis; approximately 30\% of patients with psoriasis have psoriatic arthritis\textsuperscript{2}. It is a debilitating, long-lasting inflammatory disease linked with significant disability, poor quality of life and reduced life expectancy\textsuperscript{1}. PsA causes joint pain and stiffness, skin and nail psoriasis, swollen toes and fingers, persistent painful tendonitis, and irreversible joint damage\textsuperscript{1}. 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\textsuperscript{2,5}.

**About AIN457 (secukinumab) and interleukin-17A (IL-17A)**

AIN457 (secukinumab) is a fully human monoclonal antibody that selectively stops the action of IL-17A\textsuperscript{4}. Secukinumab is the first medicine selectively targeting IL-17A with positive Phase III results for the treatment of PsA. IL-17A, a protein that stimulates inflammatory disease, is central to the development of psoriasis and other inflammatory arthritic diseases, including PsA\textsuperscript{3}.

In addition to PsA, secukinumab is also in clinical trials for the treatment of ankylosing spondylitis (AS) and rheumatoid arthritis (RA). Following the presentation of the first moderate-to-severe plaque psoriasis Phase III results of secukinumab in October 2013, EU and US regulatory filings were submitted at the end of 2013.

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The foregoing release contains forward-looking statements that can be identified by words such as “planned,” “investigational,” “will,” “upcoming,” “may,” “excited,” “anticipated,” or similar terms, or by express or implied discussions regarding potential additional marketing authorizations for secukinumab (AIN457), potential new indications or labeling 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, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that AIN457 will be approved for sale in any market where it has been submitted, or that it will be submitted or approved for sale in any additional markets, or at any particular time. Neither can there be any guarantee that AIN457 will be submitted or approved for any additional indications or labeling in any market, 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, unexpected regulatory actions or delays or government regulation generally; the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; 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.

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employ approximately 136,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

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